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THE EFFECT OF URINARY INCONTINENCE ON THE QUALITY OF LIFE FOLLOWING RADICAL PROSTATECTOMY

By

Katherine N. Moore 

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfilment of the requirements for the degree of Doctor of Philosphy

Faculty of Nursing

University of Alberta
Edmonton, Alberta, Canada
Fall 1997

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled *The Effect of Urinary Incontinence on Quality of Life Post Radical Prostatectomy* submitted by Katherine Nancy Moore in partial fulfilment of the requirements for the degree of Doctor of Philosophy.

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ABSTRACT

Urinary incontinence after radical surgery for cancer of the prostate has historically been a significant postoperative complication even with the refined surgical techniques currently available. This study was designed to assess the impact of quantified levels of incontinence on postoperative quality of life and evaluate the use of pelvic muscle exercise (PME) with or without electrical stimulation (ES) compared to a control group of patients given only verbal instructions. Sixty-three men with incontinence 4 weeks post surgery were randomized to 1 of 3 groups: (1) a control group-standard treatment of verbal instruction only, (2) PME's twice a week for 30 minutes plus home exercises 3 times a day, and (3) PME plus ES. Assessment of the 3 groups was done at 12, 16, and 24 weeks post enrollment using 24 hour pad tests and quality of life (EORTC QLQ, version 2, C30) and incontinence impact (IIQ-7) questionnaires. Major observations of the study included: a rapid, initial improvement in bladder control up to 12 weeks postoperatively; a lack of treatment efficacy with pelvic muscle exercises and/or electrical stimulation in the early phases of recovery; an understanding that the consequences of incontinence after radical prostatectomy, based on subjective descriptions, include worry, embarrassment, curtailment of activities, and disappointment; a realization of the severe impact of incontinence on quality of life in the early weeks after radical prostatectomy; an increased sensitivity to the notion that quality of life may be enhanced by communication and specific patient education information; and a conclusion that the Incontinence Impact Questionnaire (IIQ-7) has the potential to be a reliable and valid instrument for assessing the impact of incontinence in men after radical prostatectomy.

ACKNOWLEDGEMENTS

At the end of a dissertation, it is the student who receives all the accolades. Yet, without a host of material and human supporters, no student would reach that end point. I would first like to acknowledge the Doctoral Fellowship from the Kidney Foundation of Canada which enabled me to dedicate myself fully to my studies and research. The research project itself was funded generously by a Dr. Dorothy Keregin Scholarship from the Canadian Nurses' Foundation, as well as by Caritas Health Group, Edmonton, Edna Marie Minton Endowment Fund, Internal Allocation Fund-- Faculty of Nursing University of Alberta, Oncology Nurses Society (USA), and the Alberta Physiotherapy Association.

I am indebted to Anna Hughton, Physiotherapist at North Town Physio who dedicated hours of extra clinic time to treating the men randomized to therapy. Anna is a *therapist* in the true sense of the word and the men who were fortunate to meet her benefitted tremendously from her sensitive and caring approach. I, in turn, was moved by the generosity of the men who participated in this study. Their commitment to improving the post operative path for other men affected by incontinence after radical prostatectomy was remarkable.

My urological career has been nurtured and directed by many wonderful nurses, urologists, patients, and by my husband, Rick Bowers. Mikel Gray, RN, PhD, University of Virginia, Charlottesville, Virginia deserves particular mention as a mentor and friend who challenged my thinking and always believed that what I had to contribute as an academic could make a difference.

One of the joys of being a student is the close ties with one's classmates. Our computer room support meetings and pot luck dinners carried us through

what we thought were "tough" times but will be remembered by me as the best four years of my life. Thank you for being my life-long friends.

Thanks to the data entry and statistical advice of Wayne Day and Zack Florence, the study was completed in a timely fashion. Their support, laced with humour and encouragement, was greatly appreciated

Finally, I thank my dissertation committee members: Louise Jensen, Derek Griffiths, and Malcolm McPhee challenged and encouraged me in their own ways and I thank them sincerely. I was honoured to have Mickey Dougherty, University of North Carolina, Chapel Hill, North Carolina join the committee as the external examiner. My advisor, Marion Allen, has been a role model, friend, and companion over the course of my academic growth for both my graduate degrees. It was a privilege to be her student.

TABLE OF CONTENTS

APPENDICES

TABLES

FIGURES

CHAPTER I
INTRODUCTION

Prostate cancer is the most common male cancer in Canada, comprising 28% of all predicted male cancers in 1997 (NCIC, 1997). There has been a progressive increase in the number of radical prostatectomies as the primary treatment of localized prostate cancer, a trend which has seen a fourfold rise in surgery at some American centres in the past decade (Litwiller, Djavan, Klopukh, Richier, & Roehrborn, 1995). This increase in radical prostatectomy is related to several factors: (1) improvements in surgical technique, (2) early detection of prostatic cancer with combined digital rectal exam, transrectal ultrasound, and prostate specific antigen (PSA), (3) evidence that a number of patients will have a positive biopsy after curative radiation therapy, and (4) a rising incidence with an estimated 19,800 new cases in Canada in 1997 (NCIC,1997). Despite improved techniques and a corresponding decrease in morbidity, urinary incontinence remains a significant post surgical problem. Moreover, the psychosocial aspects of prostate cancer and radical prostatectomy have received little attention perhaps because men have, traditionally, been reluctant to express emotional needs (Cassileth et al., 1992). Thus little is known about the effect of urinary incontinence on quality of life post radical prostatectomy. While the negative effects of urinary incontinence on women's social, psychological, physical, and emotional functioning are well documented (Grimby, Milsom, Molander, Wiklund, & Ekelund, 1993; Hunskaar & Vinsnes, 1991; Wyman et al., 1987), similar issues relating to men have not been considered systematically.

Yet incontinence after radical prostatectomy is significant, ranging from 0-88% (Appendix 1), and has been documented as a problem since radical prostatectomy was first described by Hugh Hampton Young in 1905. A recent

mailout survey by a mid-sized Eastern U.S. hospital revealed that incontinence is perceived as a major problem, which up to 70% of patients report for as long as 4 years after radical prostatectomy (Constan-Armstrong, 1993).

Treatment of post radical prostatectomy incontinence with various conservative methods has been reported as moderately successful in non-randomized, uncontrolled trials. Pelvic muscle exercises continue to be the mainstay therapy and improvement has been reported in men who follow an intensive exercise regimen in nurse-run clinics (Meaglia, Joseph, Chang, & Schmidt, 1990) or physiotherapy clinics. On the basis of the results of non-randomized uncontrolled studies (Hirakawa, Hassouna, Deleon, & Elhilali, 1993; Krauss & Lilien, 1981; Salinas et al., 1996; Sotiropoulos, Yeaw, & Lattimer, 1976), practitioners have suggested that continence is regained more rapidly when pelvic muscle exercises are augmented with electrical stimulation in men post radical prostatectomy. Electrical stimulation is believed to enhance the proprioceptive awareness of levator ani and pubococcygeus muscle contractions, thereby resulting in optimum pelvic muscle contraction more efficiently than with pelvic muscle exercises alone. Treatment with electrical stimulation of post radical prostatectomy incontinence appears successful but in published reports, groups are heterogeneous, non-treatment control groups are not included, sample sizes are small, and long-term follow up has not been done. Moreover, the efficacy of electrical stimulation as a means to enhance pelvic muscle contractions has not been well studied, nor have researchers compared pelvic muscle exercises augmented with electrical stimulation in randomized, controlled trials. Furthermore, studies examining quality of life in relationship to post radical prostatectomy sequelae and treatment efficacy are lacking.

The number of men who have early stage prostate cancer will continue

to rise in Canada and the United States. As a consequence, the number of radical prostatectomies will also rise. Recovery from radical prostatectomy has traditionally been measured by five year survival and disease-free status. However, there are aspects of recovery which are not captured by these measures. A common sequela of radical prostatectomy, urinary incontinence, may influence the quality of life in these men. Health care professionals are committed to holistic health care, yet without an appreciation of the subjective impact of incontinence, it may be impossible to provide complete care. It was proposed that urinary incontinence has a negative impact on quality of life for men post radical prostatectomy, that effective treatment of incontinence would result in higher reported quality of life, and that treatment would hasten the return to continence.

Purpose of The Study

The overall objectives of this study were to: (1) compare the standard therapy for post radical prostatectomy incontinence with two intensive physiotherapies: pelvic muscle exercises (PME's) and PME's plus electrical stimulation (PME+ES); (2) examine risk factors for urinary incontinence after radical prostatectomy; and (3) explore influencing factors on reported quality of life in men with urinary incontinence post radical prostatectomy.

The following research hypotheses were addressed:

(1) Men with urinary incontinence post radical prostatectomy who participate in a 12 week intensive physiotherapy programme for treatment of incontinence will have less total urine loss immediately after therapy than men post radical prostatectomy who, during the same period, do not participate in a 12 week intensive physiotherapy programme (standard therapy).

(2) Men with urinary incontinence post radical prostatectomy who participate in a 12 week PME + ES physiotherapy programme for treatment of urinary

incontinence will have less total urine loss immediately after therapy than men post radical prostatectomy who participate in a 12 week PME physiotherapy programme without electrical stimulation (ES).

(3) Men with urinary incontinence post radical prostatectomy who participate in a 12 week physiotherapy programme for treatment of urinary incontinence will report lower Incontinence Impact scores immediately after therapy than men post radical prostatectomy, 12 weeks from baseline, who do not participate in a physiotherapy programme (standard therapy).

(4) Men with urinary incontinence post radical prostatectomy who participate in a 12 week physiotherapy programme for treatment of incontinence will report higher EORTC quality of life scores immediately after therapy than men post radical prostatectomy, 12 weeks from baseline, who do not participate in a physiotherapy programme.

Definition Of Terms

Urinary Incontinence: Urine loss is a weight gain of 2 or more grams in 1 or more pads during a 24-hour pad test. The total increase in weight of all the pads, the number of wet pads, and the maximum weight of urine in the wettest pad will indicate the severity of incontinence (Griffiths, McCracken, & Harrison, 1991). (1 gm weight equals 1 ml urinary leakage).

24 Hour Pad Test: Twenty-four hour monitoring is a standardized test of 2 hourly preweighed pad change using a Mettler PJ 4000 balance (Mettler Instrument Corp., Hightstown, N.J.), post-change weighing, and a frequency/volume chart. The pad test is capable of detecting a 1 gm urine loss if the pads are weighed within 36 hours of their placement in a sealed plastic bag (Jønler, Madsen, Rhodes, Sall, Messing, & Bruskewitz, 1996).

Quality of Life (QOL): QOL is a multidimensional concept which incorporates physical symptoms, and psychological, social, economic, and time impact of a

radical prostatectomy (Table 2.3). It was measured by the quality of life instrument developed for cancer patients by the European Organization for the Research and Treatment of Cancer (EORTC-C30, version 2.0) plus a module developed by the EORTC specifically for prostate cancer patients, the Prostate Cancer Module.

Impact of incontinence: The Incontinence Impact Questionnaire (IIQ-7) was used to measure the impact of urinary incontinence on one's life. It is a single, summary scale of seven items with a score ranging from 0 to 100 where 0 means *No Impact* and 100 means *Significant Impact* of incontinence (Uebersax, Wyman, Shumaker, McClish, Fantl, et al., 1995).

Standard Treatment: Group I subjects received the standard post prostatectomy pelvic muscle exercise teaching at the preadmission clinic which included written and brief verbal instruction on pelvic muscle exercises. The contents of the exercise sheet were reviewed verbally and subjects told by both the nurses in the preadmission clinic and the urologist, as part of standard practice, that repeating strength exercises at home might help in the achievement of continence. Group I was seen again by the researcher at 12 weeks from initial contact.

Intensive Pelvic Muscle Exercises: Subjects randomly assigned to the pelvic muscle instruction group (Group II) received the initial instructions (above) plus the protocol listed below for pelvic muscle exercises. Each session was 30 minutes twice a week in the office of one physiotherapist.

Position

Supine with knees bent, feet and knees apart approximately 25 cm, on an examining table with physiotherapist seated at the right side of the subject with a view of the subject's face as well as a view of the perineum and rectum.

Muscle Function

Four components of muscle function were worked on: strength, endurance, speed, and control.

Strength. Exercises focused on recruiting as many muscle fibres as possible and maintaining the contraction at an optimum hold for 5 to 10 seconds while, at the same time, keeping the abdominal, gluteal, and quadriceps muscles relaxed. Initial contractions were 5 to 10 seconds with a 10 to 20 second rest with 12 to 20 repetitions. Subjects were requested to repeat strength exercises at home on non-treatment days.

Endurance. Exercise focused on maintaining a muscle contraction at 50-60% of maximum strength. Hold time was 20 to 30 seconds with equal rest time, with 6 to 8 repetitions.

Speed. The focus was on quick repetitive contractions in a 10 second time span. Quick recruitment of muscle fibres was taught with an equally quick release of fibres. A set of 5 to 10 contractions were done in 10 seconds with a 20 second rest period.

Control. Gradual recruitment of muscle fibres to a maximal contraction was taught. Contractions occurred in three stages with 5 second hold at each stage and a slow release, with rest period of 5 seconds.

Other. The subject was instructed to do a penile lift by contracting the bulbocavernous muscle and to watch for a visible dip at the angle at the base of the penis. As well, subjects were instructed to palpate for a contraction of the bulbocavernous muscle at the perineum. The subject was requested to repeat the strength, endurance, speed, control, and penile lift exercises three times a day at home on non-treatment days. Subjects were also provided with a check list exercise reminder attached to the pelvic muscle exercise sheet.

Electrical stimulation: The International Continence Society (1990) defines electrical stimulation as the application of electrical current to stimulate the pelvic viscera or their nerve supply. The aim of electrical stimulation may be to directly induce a therapeutic response or to modulate lower urinary tract, bowel or sexual function (Andersen, Blaivas, Cardozo, Thüoff, 1990). For this study, access was with a surface electrode anal plug (InCare™), using intermittent, temporary stimulation of the peripheral nerves. Stimulation parameters were:

(1) frequency 50 Hz (the quantity of cycles or phases per second reported in Hertz),

(2) biphasic pulse shape with 1 second bursts,

(3) 1 second pulse width (duration of an electrical phase reported in msec),

(4) 1 second pulse trains.

Electrical Stimulation and Intensive Pelvic Muscle Exercises: Subjects randomized to Group III also met with the physiotherapist twice a week. Each session was 30 minutes and alternated between electrical stimulation and voluntary pelvic muscle exercises as per Group II (above). Intensity of the stimulation was adequate to induce visual lifting of levator ani and pubococcygeus muscle, considering level of comfort of the subject (Hahn, Sommer, & Fall, 1991).

Position.

Supine with knees bent, feet and knees apart approximately 25 cm, on an examining table with physiotherapist seated at the right side of the subject with a view of the subject's face as well as able to hold the rectal probe.

Therapy

The two phases of therapy involved stimulation and reinforcement. Therapy began with 5 minutes of stimulation to increase awareness of levator

ani and pubococcygeus muscle contractions. Muscle contraction was determined by the physiotherapist by visual observation of rectal contraction and penile lift. Contractions produced by stimulation were then reinforced with 10 minutes of practice by digital rectal exam and consisted of fast contractions, slow maximal contractions, and progressive build up of endurance. The reinforcement focused on relaxation of abdominal and gluteal muscles while concentrating on perineal contractions. Five minutes of stimulation and ten minutes of biofeedback were alternated for a maximum of 30 minutes (or less if subject was fatigued).

Significance of the Study

Urinary incontinence after radical prostatectomy may contribute to social and psychological problems which may severely affect quality of life (Roberts, Jacobsen, Rhodes, Girman, Guess, & Lieber, 1997). Pelvic muscle exercises combined with electrical stimulation has been hypothesized as an effective treatment for urinary incontinence. If physiotherapy improves the debilitating problem of urinary incontinence, and if there is a correlation between lack of bladder control and poor quality of life, then men's quality of life may be improved with effective treatment.

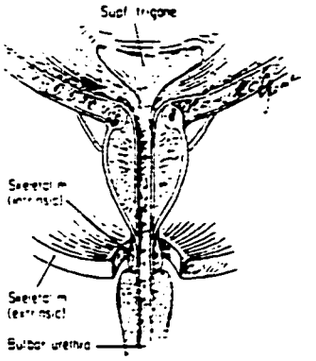
CHAPTER II

LITERATURE REVIEW

Since 1905, when Dr. Hugh Young first reported in The Bulletin of The Johns Hopkins Hospital that a radical prostatectomy could cure prostate cancer, urinary incontinence has been reported as a significant post surgical problem. Postprostatectomy incontinence is complex and a discussion of anatomy of the male continence mechanism is first presented. This is followed by a discussion of the current theories of risk factors and aetiology, recent research addressing treatment of incontinence, and considerations of quality of life with urinary incontinence.

Anatomy of the Male Continence Mechanism

Urinary continence is the result of a complex interaction of smooth and striated muscle fibres blended together to form the continence mechanism (Figure 2.1).



Male Continence Mechanism
From Walsh, Gittes, & Perlmutter (eds): *Campbell's Urology* (1986), p 2658
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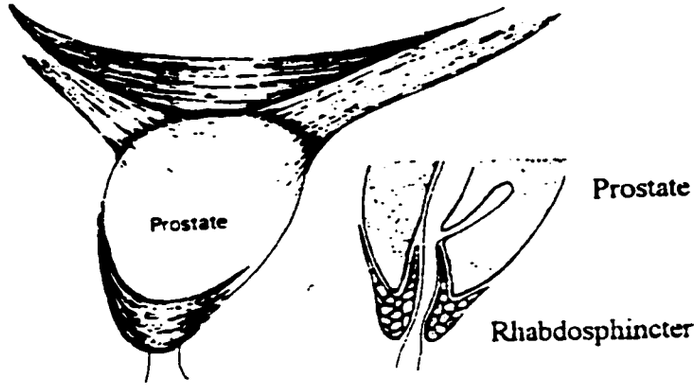
Figure 2.1. Male Continence Mechanism

Landmark research on the male sphincter was conducted in the late 1970's by Gosling and colleagues and their seminal work has been key to the understanding of male continence (Dixon & Gosling, 1994; Gosling, 1979; Gosling, Dixon, Critchley, & Thompson, 1981). Until only recently, and based on the work of Gosling and others, the prevailing opinion has been that males have an internal or proximal and an external or distal sphincter. More recently, however, histochemical analysis not available twenty years ago, has modified the approach somewhat. Elbadawi (1995) has led thinking away from such terms such as internal or external sphincter describing instead a continence mechanism which is a continuous muscular structure consisting of the bladder base, the bladder neck, and the subvesical urethra supplemented by the rhabdosphincter. The main difference between current thought and that of Gosling and colleagues is that the mechanism is continuous, rather than being divided. This may have, as yet not articulated, implications for continence after radical prostatectomy.

The rhabdosphincter is meshed with the subvesical urethra and the prostatic capsule. Structurally, the rhabdosphincter consists of striated muscle with both slow-twitch (Type I) and fast-twitch (Type II) fibres. Fast twitch fibres may be voluntarily activated on sudden, increased stress such as coughing, laughing, or sneezing. Such a combination of slow and fast twitch fibres allows an integrated voiding response not only critical to involuntary bladder control but also to voluntary termination of micturition. It is the ability to do voluntary contractions which are capitalized on during exercise therapy for post prostatectomy incontinence. Morphometric analysis of the rhabdosphincter has shown that the proportion of striated muscle cells decreases with advancing age, from approximately 79% in an infant to 35% in

an 83 year old man (Strasser, Steinlechner, & Bartsch, 1997). Such decreases have been proposed as one reason why post prostatectomy incontinence may occur in older rather than younger men although the significance for practice of this finding is not known.

During radical prostatectomy, the bladder neck, subvesical urethra, and prostatic apex, may all be removed so that continence may depend only on the rhabdosphincter (Harrison & Abrams, 1994). Figure 2.2 shows the caudal extension of the rhabdosphincter into the prostate and illustrates its vulnerable position with respect to injury during surgical dissection.



Complex Association Between Urethral Rhabdosphincter & Prostate
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Figure 2.2. Caudal Extension of Rhabdosphincter (Reproduced with permission)

Yet, of all men who have similar surgical excision of the prostate for early stage cancer, only 30% will have marked incontinence at 8 weeks postoperatively. Thus, although injury to the rhabdosphincter and surgical

excision of the bladder neck and subvesical urethra clearly contribute to post prostatectomy incontinence, because of a lack of understanding of function of the normal lower urinary tract (Mundy & Thomas, 1994), the specific aetiology is difficult to define and not well understood (O'Donnell, Finan, Barnett, & Brookover, 1990). Wein (1989) warns against seeking a specific "cause and effect", rather, he suggests, that the problem of incontinence after transurethral resection for benign disease or radical prostatectomy for cancer is multifactorial.

Risk Factors Associated With Post Prostatectomy Incontinence

Two risk factors have been repeatedly identified for post radical prostatectomy incontinence: (1) abnormalities of detrusor contractility (Leach, 1995) and (2) age (Diokno, 1997). Other related factors include preoperative radiotherapy (Rainwater & Zincke, 1988), trauma, spinal cord lesion, new obstruction such as unresected adenoma, bladder neck contracture, or urethral stricture (Litwiller, McIntire, Schnitzer, & Roehrborn, 1997), Parkinson's disease (Staskin, Vardi, & Siroky, 1988), dementia, and medications (Khan, Mieza, Starer, & Singh, 1991; Yalla et al., 1982). Surgical expertise (Eastham et al., 1996) and having surgery in a hospital which performs fewer than 20 radical prostatectomies a year have also been implicated (Albertsen, Lu-Yao, & Warren, 1997).

Abnormalities of Detrusor Contractility

In the few studies which have included preprostatectomy urodynamics, the risk of incontinence with preoperative detrusor dysfunction is clearly identified. Aboseif, Konety, Schmidt, Goldfien, Tanagho, and Narayan (1994) reported on 92 men who had urodynamics pre radical prostatectomy and then were followed at 1 year post operatively by telephone interview (incontinence was defined as the use of 1 or more pads per day).

Preoperatively, 64 men had normal urodynamics and 28 had abnormal findings which included detrusor instability, mean urethral closure pressure of less than 50cm H_2O at rest or less than 100cm with voluntary contraction, or combined detrusor and sphincter instability. Postoperatively, only 2 men in the normal group reported incontinence versus 11 men in the abnormal group (39%). The authors suggested that preoperative urodynamics may indicate those men at risk of incontinence postoperatively. Although the authors' telephone follow up of subjects does not provide information on the aetiology of incontinence in those men who had incontinence, it does provide a warning sign that men who have instability preoperatively may be at higher risk than those who do not.

Age

The other known risk factor for incontinence in the general population is age. In 1986, Diokno, Brock, Brown, and Herzog conducted a survey of Michigan state residents and found a 19% prevalence of incontinence among men 60 years or older. In a survey of people over 65 in the Boston area, the prevalence was 24% in men and 31% in women (Wetle et al., 1995) and in a randomly selected cohort of Maine men aged 40 to 84, the prevalence was 13.3% (Roberts, Jacobsen, Rhodes, Girman, Guess, & Lieber, 1997). Detrusor instability is more common in the elderly (Abrams, 1980; Abrams, 1985; Eastham et al., 1996; Gormley et al., 1993; Griffiths et al., 1992; Haab, Yamaguchi, & Leach, 1996; Speakman, Sethia, Fellows, & Smith, 1987), as is decreased detrusor contractility. Thus, if men over 65 who have radical prostatectomies follow the general population trend, one might expect a similar incidence, recognizing that concomitant medical conditions influence the incidence of incontinence. An increased rate of post radical prostatectomy incontinence in men over 75 was reported by Kerr and Zincke (1994). In a

retrospective review evaluating survival in younger (less than 55) versus older (more than 75) men undergoing radical prostatectomy between 1966 to 1988, 16% of the elderly but only 3% of the younger men had incontinence 1 year postoperatively. Survival was equal in both groups.

Factors which have not been identified as risk factors include prostate size, clinical stage, pathologic stage, operative time, or number of transfusions (Gray & Theodorescu, 1997; O'Donnell, Finan, Barnett & Brookover, 1990), although in one review of 229 patients, blood loss more than 1000 ml, transfusion, positive margins, and clinical stage more than T2a were found to be significant risk factors for postoperative incontinence (Litwiller, McIntire, Schnitzer, & Roehrborn, 1997). Finally, while most authors (Lindner, deKernion, Smith, & Katske, 1983; Ramon, Rossignol, Leandri, & Gautier, 1994) have not found a correlation between prior transurethral resection of the prostate (TURP), Eastham, Kattan, Rogers, Goad, Ohori, Boone, and Scardino (1996) did report TURP as a contributing factor to post radical prostatectomy incontinence.

Post Prostatectomy Incontinence: Benign Disease

Incontinence after transurethral resection of the prostate (TURP) for benign obstructive disease is less than 5% (Foote, Yun, & Leach, 1991). Although bladder neck damage after TURP may play a role, urodynamics have shown that abnormalities in bladder function, such as poor compliance or detrusor instability, are also significant (Golobuff, Chang, Olsson, & Kaplan, 1995). The complexity of the problem is clearly illustrated by Danish urodynamic experts Andersen and Nordling (1978). Thirty-four men were evaluated by urodynamics after open prostatectomy for benign disease (m= 2.5 years; range=1 week-10 years). Half of the subjects had two or three disorders contributing to their incontinence, including sphincter injury with or

without detrusor instability, urethral stricture, acontractile or reduced contractility bladder, detrusor instability, or poor compliance. Thus men who have incontinence after transurethral resection for benign disease may be more likely to have bladder dysfunction than sphincter incompetence. Therapy may include pelvic muscle exercises but should also incorporate behavioural strategies such as urge suppression (Burgio, Stutzman, & Engel, 1989).

Post Prostatectomy Incontinence: Prostate Cancer

The actual incidence of incontinence after radical prostatectomy is difficult to pin point. Limitations to quantifying incidence include definitions of incontinence, retrospective reports, inconsistent follow up, and outcomes based on subjective report rather than objective measurement. Moreover, men who have undergone a radical prostatectomy are distinctly different from those with benign disease and neither the mechanism underlying postoperative incontinence nor the innervation of the distal urethral sphincter are well understood (Elbadawi, 1995; O'Donnell, Finan, Barnett, & Brookover, 1990). Most would agree, however, that incontinence is less than 20% by one year post surgery. Appendix 1 illustrates the disparity among researchers in the quantification of incontinence.

The most frequently considered etiologies of incontinence following radical prostatectomy focus on one of four factors: neourethral or functional urethral length, destruction of the bladder neck, destruction of the neurovascular bundles, and *de novo* instability. It is likely that all four factors singly or combined, as well as others not so clearly defined, play a role.

Neourethral Length Or Functional Urethra Length

Presti, Schmidt, Narayan, Carroll, and Tanagho (1990) reported that functional neourethral length, maximum urethral pressure, and maximum urethral pressure during voluntary contraction were all significantly lower in

incontinent men post radical prostatectomy when compared with continent counterparts. Others have challenged such findings, stating that there is a poor correlation between continence, urethral pressure, and functional urethral length (Foote, Yun, & Leach, 1991; Gudziak, McGuire, & Gormley, 1996). Two studies evaluating men with pre and postoperative urodynamics support the belief that urethral pressure and functional urethral length are poorly correlated with urinary continence (Rudy, Woodside, & Crawford, 1984; Hellström, Lukkarinen, & Kontturi, 1989).

Destruction Of The Bladder Neck

Recent support is noted for preservation of the bladder neck and prostatic urethra to improve continence without compromising cancer control (Braslis, Petsch, Lim, Civantos, & Soloway, 1995; Gaker, Gaker, Stewart, & Gillenwater, 1996). In contrast, Licht, Klein, Tuason, and Levin (1994) concluded that preservation of the bladder neck during radical prostatectomy did not, in itself, impact on continence but that the rate of bladder neck contracture was lower when the bladder neck was preserved. In a prospective study of 206 consecutive men who underwent a modified surgical technique which preserving periurethral musculature and urethral length and incorporating posterior periurethral fascia into the vesicourethral anastomosis, the only predictors of incontinence were age and bladder neck contracture. The bladder neck was preserved in 57% of men.

Removal of the Neurovascular Bundles

Although most would argue that nerve-sparing surgery is important in regaining continence (Eastham et al., 1996; Foote, Yun, & Leach, 1991; O'Donnell & Finan, 1989), Walsh, Quinlan, Morton, and Steiner (1990) down-play the role of nerve sparing surgery in favour of preservation of the striated urethral sphincter. In a retrospective review of 547 consecutive cases,

incontinence ranged from 6 to 20% even in men whose neurovascular bundles were not preserved. The authors reported that they had systematically identified the striated urethral sphincter and then incorporated it into the anastomosis, resulting in a rapid regaining of continence. The following year, the group proposed that preservation of the striated sphincter is probably more important in achieving continence than preservation of the neurovascular bundles (Steiner, Morton, & Walsh, 1991).

De Novo Instability

Leach (1995) suggests that, after prostatectomy, a significant number of men have *de novo* instability, findings supported by others (Abrams, 1985; Fitzpatrick, Gardiner, & Worth, 1979). Goluboff and colleagues (1995), for example, reported on the urodynamic studies of 56 men. Thirty-one were post transurethral resection (TUR) and 25, post radical retro pubic prostatectomy (RP). Detrusor instability (DI) was present in 61% and only 5% had demonstrated genuine stress incontinence. Goluboff warns the reader to avoid the false assumption that most men have sphincteric damage and stress incontinence (SUI). Table 2.1 summarizes the findings.

Table 2.1
Post Prostatectomy Urinary Incontinence: Mean 37 months post op (range=11 months to 14 years)

Trans Urethral Resection of the Prostate	Detrusor Instability (DI)	Stress Urinary Incontinence (SUI)	DI+SUI
N=31	24 (77%)	1	6
RRP*			
N=25	10 (40%)	2	13 (4 with ↓compliance)

RRP=Radical retro pubic prostatectomy

On the other hand, others argue convincingly that despite the presence of instability which could affect treatment outcomes if overlooked, intrinsic sphincter deficiency remains the primary aetiology (Aboseif, O'Connell, Usui, & McGuire, 1996; Chao & Mayo, 1995; Gudziak, McGuire, & Gormley, 1996; Presti, Schmidt, Narayan, Carroll, & Tanagho, 1990; Winters, Rackley, Fralick, Simich, & Appell, 1997). Presti et al. (1990) for example, compared incontinent men post radical prostatectomy with continent counterparts and found an equal incidence of detrusor instability in both groups (25%), suggesting that instability does not necessarily correlate with incontinence.

The Role Of History And Physical Exam In Determining Aetiology

In practice, it is not realistic to evaluate all men by urodynamics but diagnosis based on presenting symptoms alone may not correlate well with the more objective urodynamic findings. Leach, Yip, and Donovan (1987), for example, report on 38 patients post prostatectomy. Only 15 of 38 patients had sphincteric insufficiency alone. Table 2.2 summarizes their findings.

Prospective Reports

One of the problems in determining aetiology, particularly with respect to detrusor instability, is that preoperative urodynamic information on bladder stability is rarely available. Some papers, however, included preoperative urodynamic reports. In an early paper by Rudy, Woodside, and Crawford (1984), 16 consecutive men were evaluated pre radical prostatectomy and most at 6, 12, and 24 weeks postoperatively. The only significant difference between pre and post urodynamics at 6 months was functional urethral length, but this finding did not correlate with maximal urethral closure pressure. In another prospective study, Sasaki et al. (1995) presented findings at the 1995 International Continence Society meeting. The authors noted that bladder capacity was reduced by approximately 100 ml H_20 from the pre to

postoperative period (although capacity was recovered by 6 months) but that compliance changed and remained significantly lower for up to a year after surgery, a finding also reported by others (Foote, Yun, & Leach, 1991; Hellström, Lukkarinen, & Kontturi,1989). Although mean urethral closure pressure regained preoperative (continent) measures by 3 months postoperatively, at 12 months, 22% of subjects were still incontinent (not defined). These findings are of interest and add support to the belief of Gudziak, McGuire, and Gormley (1996) and Foote, Yun, and Leach (1991), that urethral pressure profile may not be a good indicator of continence.

Table 2.2
Correlation Between Presenting Symptoms And Urodynamic Findings

PRESENTING SYMPTOMS		**URODYNAMIC DIAGNOSIS**		
Post Radical Prostatectomy N=24		**Stress Urinary Incontinence (SUI)**	**SUI + Bladder Dysfunction**	**Bladder Dysfunction**
	SUI = 12	4	5	3
	Urge +SUI =12	4	7	1
	Urge=1			1
Post Transurethral Resection of the Prostate N=13				
	SUI = 10	6	4	0
	Urge + SUI = 2	1	0	1
	Urge = 1	0	0	1

Summary Of Aetiology

In addition to the detrusor or sphincteric factors and age, peripheral

neuropathies and subclinical neurological deficits may jeopardize the return to continence (Yalla et al., 1982). Mostwin (1990) suggests other causes of sphincteric injury during prostatectomy, including ischaemia, scar tissue causing immobilization of the sphincter, and pudendal nerve injury. Finally, Narayan, Tewari, and Kamerer (1997) propose that anatomical descent of the bladder neck to the membraneous urethra contributes significantly to incontinence after radical prostatectomy.

The preceding review of aetiology, however, should be interpreted with some caution. Urodynamics, for example, are not consistently done and vary from supine only (Abrams, 1980; Presti, Schmidt, Narayan, Carroll, & Tanagho, 1990), sitting only (Goluboff, Chang, Olsson, & Kaplan, 1995; Winters, Rackley, Fralick, Simich, & Appell, 1997), supine and standing (Aboseif, Konety, Schmidt, Goldfien, Tanagho, & Narayan, 1994; Yalla, et al., 1982), all three positions (Leach, Yip, & Donovan, 1987), or not stated (Chao & Mayo, 1995; Foote, Yun, & Leach, 1991; Sasaki et al., 1995). As well, many reports are retrospective, or sample sizes are too small in the prospective studies to permit generalization of the findings.

Without doubt, sphincteric injury plays a major role in urinary incontinence in the early postoperative phase. However, the assumption that all men with incontinence have pure intrinsic sphincter deficiency may be incorrect, particularly in cases of long standing incontinence. Implications for treatment, then, include not only pelvic muscle strengthening, but also behavioural strategies, such as bladder retraining, decreased caffeine, adequate fluid intake, anticholinergic or musculotropic medications, and effective containment products. Urodynamics play an important role in correctly diagnosing the aetiology of post prostatectomy incontinence. However, doing preoperative urodynamics for all men is not cost effective. Finally, history

alone may be a poor predictor of detrusor dysfunction unless patients are directly asked about the four cardinal indicators of unstable bladder contractions: precipitous urge to urinate, inability to delay urge, diurnal and nocturnal frequency (Gray & Marx, 1997). Physicians and nurses may need to pay more attention to the subtle symptoms which patients will only admit on direct questioning and counsel them appropriately concerning their risk of incontinence.

Principles of Conservative Treatment for Post Radical Prostatectomy Incontinence

Young, Davis, and Johnson (1926) were one of the first urologists to recommend exercising the "sphincter muscles by cutting off the flow of urine and retaining urine as long as possible" (p. 495) for men with post prostatectomy incontinence. To date, treatment of post radical prostatectomy incontinence continues to focus on exercising the pubococcygeus and levator ani muscles (Meaglia, Joseph, Chang, & Schmidt, 1990; Jackson, Emerson, Johnston, Wilson, & Morales, 1996; Joseph & Chang, 1989), with varying reports of success.

Treatment of post radical prostatectomy incontinence is directed at increasing urethral closure by direct and reflex contraction of the periurethral striated, levator ani, and pubococcygeus muscles. Both slow twitch muscle fibres, which involuntarily maintain the resting tone of the urethra, and the fast twitch fibres of the distal sphincter which prevent a drop in urethral closure during stress events such as coughing or sneezing, may be exercised artificially by electrical stimulation or by voluntary contraction (taught as *pelvic muscle exercises*). Pelvic muscle exercises represent an ordinary muscular contraction, whereas electrical stimulation is an artificial nerve stimulation with direct and reflex responses of the urethral and periurethral striated

muscles (Hahn, Sommar, & Fall, 1991; Wise, Khullar, & Cardozo, 1992). The artificial stimulation heightens the patient's proprioceptive awareness of a muscle contraction which in turn teaches the patient to independently contract the pelvic muscles. Wise and colleagues demonstrated by ultrasound, that both voluntary pelvic contractions and electrical stimulation result in similar elevation of the pelvic muscles in women. The treatment of post prostatectomy incontinence--both radical and transurethral prostatectomy--has incorporated these principles and current conservative management consists of pelvic muscle exercises often augmented with external electrical stimulation. It is unclear, however, whether the theoretical basis of pelvic muscle exercises in women can be directly applied to men. The normal male continence mechanism differs from the female, notwithstanding the impairment which occurs after radical prostatectomy. Nevertheless, few alternates present themselves and pelvic muscle exercises remain the mainstay of treatment for post prostatectomy incontinence.

Treatment of Urinary Incontinence: Pelvic Muscle Exercises

Pelvic muscle exercises (PME) are defined as "repetitive selective volitional contractions and relaxations of specific pelvic floor muscles. This necessitates muscle awareness in order to be sure that the correct muscles are being utilized and to avoid unwanted contractions of adjacent muscle groups" (International Continence Society, 1992). The purpose of PME's is to increase the strength of the pubovisceral muscle of the levator ani and compressor urethrae, thereby increasing the closing pressure of the urethra (Palmer, 1997). A fundamental assumption of PME is that training will hypertrophy muscle and increase muscular aerobic and anaerobic capacity (Griffin, Dougherty, & Yarandi, 1994). Pelvic muscle training consists of endurance exercises conducted at moderate intensity and muscle bulking

exercises which are achieved using strong, repetitive muscle contractions (Palmer, 1997).

Pelvic muscle exercises for women with stress urinary incontinence have been prescribed by gynaecologists and nurses for many years. As early as 1922, E.L.Young wrote that incontinence in elderly women might be prevented if instructions to exercise the perineal muscles were given after childbirth. However, it was the work of Dr. Arnold Kegel (1948, 1951) which has influenced practice to the present day. Using theories of pelvic muscle physiology and rehabilitation, Kegel described systematic exercises for women with urinary incontinence. Since the 1950's, many health care professionals have prescribed exercises based on Kegel's recommendation of 20 minute sessions three times a day, or a total of 300 contractions a day. Kegel was emphatic that instructions for exercises included instruction with vaginal examination, stating that isolated contraction of the pubococcygeus muscle was difficult and that, unless the patient had thorough instruction and weekly follow up, the exercises might be of no benefit. He also believed that instruction was best reinforced with visual reinforcement and he used a perineometre which he invented for the purpose.

It is interesting that Kegel's (1951) work was not confirmed with randomized, controlled trials and the outcomes were essentially based on non-objective measures such as self-reported change in urine loss or pad usage. The number, frequency, intensity, or patient acceptance of the exercises was not challenged for the next two decades. Unfortunately, the instructions for pelvic muscle exercises became gradually diluted and modified over the years and Kegel's meticulous work and emphasis on exacting patient education was overlooked. Bump, Hurt, Fantl, and Wyman (1991) found that at least 30% of women who were given only written or verbal instructions were unable to

perform a pelvic muscle contraction. In the last decade, considerable attention has been repaid to the importance of appropriate patient teaching and follow up. Appendix 2 summarizes the research-supported pelvic muscle regimens and Appendix 3 shows recent clinical reports suggesting a variety of non research-based regimens.

Research: Pelvic Muscle Exercises

Urinary incontinence is, perhaps, one of the best examples where the research of health professionals such as nursing, physiotherapy, and behavioural therapists, builds on itself and changes patient care. Molly Dougherty at the University of Florida was one of the first in either nursing or physiotherapy to directly apply the principles of exercise physiology to pelvic muscle exercises and consider objective measures of successful treatment (pad test, 24 hour diary, and intra vaginal pressure measurement) rather than subjective report. The multidisciplinary team approach differed from that of Kegel (1948; 1951) by providing thrice weekly exercises for a total of 48 sessions over 16 weeks (Dougherty, Bishop, Mooney, Gimotty,& Williams,1993). Perhaps the most interesting departure from pelvic muscle exercise tradition was the "three times a week" regimen, rather than 20 minutes three times a day. The regimen of alternate days was based on standard skeletal muscle training programmes of repeated, regular activity, and endurance development. As well, the authors believed that patients would be more likely to adhere to a less demanding programme. To contribute to consistency of home exercises, the programme included an audio tape of pelvic muscle exercises. The authors found an 80% compliance rate with their recommended regimen, a figure which has seldom been factored into the success of a patient directed programme. Their work deserves full attention and further research is required to compare the three times a week regimen to

the more traditional approaches of pelvic muscle exercises several times a day.

In contrast to the above regimen, Burns, Pranikoff, Nochasjki, Hadley, Levy, and Ory (1993) randomized older community dwelling women to a daily home therapy of 200 contractions augmented with weekly biofeedback plus pelvic muscle exercises or pelvic muscle exercises alone. Both treatment groups were seen once a week for eight weeks, with follow up at 12 and 24 weeks (Appendix 2 provides details of the method). Urine loss, as recorded in a subject diary, was reduced by approximately 54% in both treatment groups and was significantly different from the control group improvement of 6%. Adherence to the exercise programme was helped by weekly telephone calls from the researcher and appointment cards.

Leading work in pelvic muscle exercises has also been done by physiotherapists, particularly the work of Scandinavian physiotherapist Kari Bø and colleagues (1990a, 1990b, 1990c). Again, using exercise theory as the rationale for the regimen, the authors suggested that hypertrophy of the pelvic muscles would increase the maximal urethral closure pressure in females with genuine stress incontinence. The authors hypothesized that the pelvic floor muscles stabilize the proximal urethra in the intra abdominal position and that the levator ani muscle contraction shifts the vesical neck anteriorly to compress against the precervical arch. Bø, Hagen, Kvarstein, Jørgensen, and Larsen (1990c) randomized 52 female subjects with urodynamically proven stress incontinence to one of two pelvic exercise regimens: a home regimen of 8 to 12 maximal contractions three times a day for six months or an intensive programme of daily exercises plus a weekly session with a physiotherapist (see Appendix 2). Sixty percent of women in the intensive regimen group showed a mean urine loss reduction on one hour pad test from 27.1 grams to 7.1 grams. No significant change in urine loss occurred in the home therapy group. The

authors concluded that positive results of pelvic muscle exercises are dependent on the degree and duration of treatment and frequent supervision by the therapist. However, it is difficult to know whether it was the weekly meeting with the therapist or the addition of the three or four rapid contractions which resulted in the positive outcome.

The theory behind continence achievement with pelvic muscle exercises remains poorly understood. While Bø, Kvarstin, Hagan, and Larsen (1990A) suggest that exercises increase the maximal urethral pressure, others would argue that not only is urethral pressure at rest or with voluntary contraction a poor indicator of pelvic muscle strength but also that the results are difficult to reproduce (Burns et al., 1993; Foote, Yun, & Leach, 1991; McGuire,1990). Burgio, Stutzman, and Engel (1989) noted that men who failed biofeedback therapy still had good sphincter control and could stop and start their stream voluntarily. Such findings suggest that achievement of continence is not straightforward and involves more than increasing the bulk and strength of the periurethral striated muscle. Finally, the success rates of pelvic muscle exercises reported in the literature show a great variation ranging from 50 to 90% cure or improvement (Appendix 2; Appendix 3). This may be explained, in part, by the different durations of exercise ranging from six weeks to several months, the amount of therapist involvement, and the grams of urine loss at baseline. In addition, objective measures are lacking for both urine loss and pelvic muscle strength, the exercise regimen is often poorly described and thus difficult to replicate, and few studies have control groups.

Biofeedback-Assisted Pelvic Muscle Exercises

Biofeedback assisted pelvic muscle exercises has been used for men with post prostatectomy incontinence. In a clinical study with subjects as their own controls, Burgio, Stutzman, and Engel (1989) treated 20 men post

prostatectomy with urinary incontinence more than 6 months in duration (TURP in 13; radical prostatectomy in 5; open prostatectomy in 2). A baseline evaluation consisted of 2 weeks of bladder diaries followed by 2 weeks of two hourly voiding. The baseline interventions resulted in a 28% decrease in stress incontinence and a 33% increase in urge incontinence, underscoring the importance of pretreatment conservative interventions. Baseline evaluation was followed by one to five sessions of biofeedback (interval not stated), conducted with the bladder filled with 400 ml sterile water and a rectal probe with sensor balloons at the internal and external anal sphincter as well as within the rectum to measure intra abdominal pressure. Biofeedback combined with home practice of 51 sphincter exercises three times a day sitting, standing, and lying resulted in a 78% decrease in frequency of incontinence for men with symptoms of stress incontinence. The exercise protocol combined with urge suppression strategies for men with urge or mixed incontinence resulted in an 80% decrease in urine loss from baseline. Mean frequency of incontinence by bladder diary was 13.8 per week for men with stress incontinence and 27.4 episodes per week for those with urge or mixed incontinence (by history). Eight of the nine subjects with continuous leakage (more than 56 episodes per week) did not improve. The authors suggest that biofeedback is not an effective strategy for men with severe incontinence and advocate the use of pretreatment diary as one method of separating those men who will succeed in therapy.

Similar success rates were reported for 28 men, a median of 7 months post radical prostatectomy (Jackson, Emerson, Johnston, Wilson, & Morales, 1996). Using a rectal probe (Incare ™) subjects were taught pelvic muscle exercises in 10 weekly 15 minute sessions. The authors do not state whether home exercises or behavioural strategies were included. Success was evaluated

by patient diary and 74% of subjects were cured or improved.

Preoperative biofeedback or pelvic muscle exercise instruction has been proposed as one method to reduce postoperative urinary incontinence. Mathewson-Chapman (1995) randomized 53 men to preoperative pelvic muscle exercises taught with biofeedback or non-exercise control. Both groups improved at similar rates and by 12 weeks postoperatively, the majority had regained continence. The challenge in preoperative interventions is sample size because of the natural course of healing. At 12 weeks post radical prostatectomy, one can expect that over 60% of men will be continent or nearly continent even without intervention (Donnellan, Duncan, MacGregor, & Russell, 1996).

Electrical Stimulation

Electrical stimulation is another noninvasive method to treat incontinence. The use of electrical stimulation for female urinary incontinence by external electrodes is not new and was a frequently suggested therapy by urologists in the 1920's and 1930's (Dean 1933; Furniss, 1924; Kahn, 1927; Lewis, 1936; Lowsley & Kirwin, 1926). As well, the efficacy of implanted electrodes in select male and female patients has been reported (Brindley, 1993; Caldwell, Cook, Flack, & James, 1968; Carlsson & Fall, 1984; Kaplan & Richards, 1988; Li et al., 1992; & Madersbacher, 1990). However, the inconvenience, invasive nature, and expense of these treatments has meant that the use has been limited in clinical practice. The principles of treatment from the implanted electrodes may be extended to those designed for intermittent use.

Intermittent treatment of urinary incontinence is delivered by vaginal or rectal electrodes. Electrical stimulation produces a reflex contraction of the pelvic floor musculature by way of the pudendal nerve and its branches. It is

believed that the reflex muscular contraction trains the neuromuscular junctions and enhances the patient's proprioceptive awareness of the levator ani muscle group. The aim is for the patient to eventually perform adequate muscular contractions on her/his own. A recent randomized controlled trial in 52 women with urodynamically proven stress urinary incontinence comparing sham stimulation or electrical stimulation (ES) showed that the ES group improved significantly. All subjects used stimulation 15-30 minutes daily at home for 12 weeks, were seen in an office follow up every 2 weeks, and had telephone follow up on non-office visit weeks. One hour pad testing showed that incontinence was reduced by at least 50% in the treated group and by only 19% in the placebo group (Sand, Richardson, Staskin, Swift, Appell, Whitmore, & Osterfard, 1995).

Electrical Stimulation: Male Incontinence

Electrical stimulation has received recent attention for men with post prostatectomy urinary incontinence. Hirakawa, Hassouna, Deleon, and Elhilali (1993) reported positive results in a clinical study involving 13 men post transurethral prostatectomy (TURP) patients and 9 post radical prostatectomy. Weeks post surgery are not stated. All patients received stimulation plus biofeedback twice a week for 3 weeks and weekly for 9 weeks, each session dedicating 20 minutes to stimulation and 10 minutes to biofeedback reinforcement. Home exercise consisted of 10 minutes daily of pelvic muscle exercises. Incontinence was reported as improved in 82%, measured by subjective report and number of pads used, although long-term results showed a tapering off to only 50% of subjects improved. The authors do not report whether subjects continued home exercises after the cessation of therapy. Sotiropoulos, Yeaw, and Lattimer (1976) treated incontinence with continuous stimulation using an intra anal plug. Of the 40 subjects, 3 were

post radical prostatectomy. After continuous stimulation, which last from a "few sessions" to 3 months, 2 of the 3 were dry, based on subject report. One man was 4 months postoperatively and the other was 11 years post surgery. The third subject, incontinent for 6 years, was dry during stimulation but not when stimulation was removed. In all 40 subjects, the urethral pressure was increased during stimulation but the rise in urethral pressure did not predict the final outcome.

A randomized, blinded, sham control study of electrical stimulation in men post prostatectomy is currently underway at Emory University and Shepherd Spinal Center in Atlanta (Bennett, Foote, Green, Killorin, & Martin, 1997). To date (June 1997), 39 men have been randomized to either treatment or sham stimulation for 15 minutes daily for twelve weeks at home with a portable home unit. Thirty two of the subjects have improved, including those with the sham device, suggesting that stimulation may not play a significant role in continence recovery.

A modification of direct anal stimulation is transcutaneous electrical stimulation (TENS) applied to the perianal area. Krauss and Lilien (1981) reported improvement in 6 of 8 post transurethral prostatectomy patients ranging from 5 months to 17 years postoperatively, all with urodynamically demonstrated stress incontinence. The patients had not responded to pelvic muscle exercises alone. After 6 to 21 days of continuous stimulation with two perianal patch electrodes at 3 and 9 o'clock, 3 of the 8 patients were completely dry (2 of whom were less than 6 months post surgery) and three were much improved. No change occurred in the man who was 17 years post surgery. The authors suggest that the stimulation may simply have worked as a reminder to the patients to contract their perineal muscles and that this effect alone may be significant in patients achieving continence. The authors

noted that even with TENS running during urodynamic testing, the urethral pressure did not change.

Summary Of Treatment Of Post Prostatectomy Incontinence

Within 3 months after radical prostatectomy, the majority of men will regain continence or require only 1 or 2 small pads a day even without treatment. Currently, conservative management involves strategies to improve the pelvic muscle strength such as biofeedback, electrical stimulation, or pelvic muscle exercises, intended to hypertrophy the rhabdosphincter and increase endurance. It remains to be determined whether the present conservative therapies are the most effective strategy for treating post prostatectomy incontinence. Moreover, the severity and frequency of urinary incontinence after radical prostatectomy may seriously impact quality of life. Such an issue has not been systematically investigated in either men or or their spouses. Roberts, Jacobsen, Rhodes, Griman, Guess, and Lieber (1997) reported that men with moderate or severe incontinence were ten times more likely than non-incontinent counterparts to feel dissatisfied, unhappy, or terrible about spending the rest of their lives with lack of bladder control. The negative impact of incontinence after radical prostatectomy on quality of life has been corroborated by others (Gray et al., 1997; Herr, 1994; Litwin et al., 1995).

Quality of Life

Quality of life as it relates to health is an elusive term which has been variously conceptualized as satisfaction (Calman, 1987; Campbell, Converse, & Rogers, 1976; Cella & Cherin, 1988; Ferrans, 1990; Ferrans & Powers, 1985; Meeberg, 1993; Rieker, Clark, & Fogelberg, 1992), well-being (Moinpour & Hayden, 1990; Padilla & Grant, 1985; Padilla, Ferrell, Grant, & Rhiner, 1990; Padilla, Presant, Grant, Metter, Lipsett, & Heide, 1983), functional ability (Karnofsky & Burchenal, 1949), and multidimensional

factors including physical, role, emotional, cognitive, and social functioning and symptoms (Aaronson et al., 1987; Schipper, Clinch, McMurray, & Levitt, 1984). The many instruments developed to measure quality of life reflect the variety of perspectives of the researchers working in the field. Debate surrounds the question of whether a generic or disease-specific quality of life instrument would most accurately reflect health-related quality of life issues. Widely used generic health related instruments with established reliability and validity include, for example, the Nottingham Health Profile (Hunt, McEwan, & McKenna, 1985), Sickness Impact Profile (Bergner, Bobbitt, Carter, & Gilson, 1981) and the Spitzer Quality of Life Index. Generic instruments, however, have not been validated for cancer populations.

Varricchio (1990) summarizes the criteria which may guide selection of a quality of life instrument. It should be disease-specific, subject administered, short and easy to understand, sensitive to changes over time or in condition, as well as include a measure of functional status, have a global construct of quality of life, be clinically relevant, and have adequate validity and reliability. Instruments which meet the above criteria in oncology include the Functional Living Index or FLIC (Schipper, Clinch, McMurray, & Levitt, 1984), Selby's LASA (Selby, Chapman, Etazadi-Amoli, Dalley, & Boyd, 1984), and the European Organization for Research and Treatment of Cancer (EORTC) quality of life instrument, QLQ-C30.

Quality of Life: Urinary Incontinence

Surgical techniques have improved since the pioneer surgery of Dr. Young, but urinary incontinence post radical prostatectomy is still a debilitating complication which approximately 10% of patients experience. Roberts et al. (1997) found that men with incontinence reported depression, lack vitality, or lower reported health-related quality of life. In a recent

informal survey of men attending a monthly prostate cancer support group meeting (Moore, 1996), participants with iatrogenic incontinence were asked does "urine leakage affect your quality of life?" The gentlemen described the impact vividly: "devastating, awful, depressing, lousy, life is restricted, learned to adjust but not happily, resigned, discouraged."

Clearly, incontinence after prostatectomy causes significant distress. The potential impact of urinary incontinence on quality of life has been recognized by many social scientists and recent publications reflect attempts to quantify the concept. Simons (1983) used the Rosenberg Self-Esteem scale to determine if women with urinary incontinence reported lower self-esteem than their continent counterparts. In the small group of women who volunteered, the author found no correlation between incontinence and reported self-esteem. Hunskaar and Vinsnes (1991), using the Sickness Impact Profile (SIP) for community dwelling elderly women with incontinence, found that urge symptoms were associated with more impairment of quality of life (sleep, rest, and visiting) than those women with symptoms of stress urinary incontinence. Similar results were found by Grimby, Milsom, Molander, Wiklund, and Ekelundl (1993) when they compared community dwelling, elderly Swedish women with urinary incontinence to an age matched continent sample. Quality of life was assessed using the general health related instrument, the Nottingham Health Profile (NHP). Because both the SIP and the NHP are designed to measure overall functioning rather than the impact of a particular problem, the instruments may lack the sensitivity necessary to detect the unique aspects of incontinence. Only two instruments were found with established reliability and validity which specifically address the day-to-day impact of incontinence. The York Incontinence Perceptions Scale (YIPS) was developed by psychology and nursing at Sunnybrook Hospital in Toronto

(Lee, Reid, Saltmarche, & Linton, 1995). Content validity was established by expert professionals and individuals with incontinence by open-ended question in face-to-face interviews. The key domains identified were control, coping, and acceptance. Reliability and validity were established by testing on 118 community dwelling individuals (101 females and 17 males) who were randomly assigned to a behavioural management treatment group or control group. Positive adjustment was found to correlate with a reduction in urinary incontinence. The other instrument, the Incontinence Impact Questionnaire (IIQ-7), is intended to address the severity of symptoms associated with urinary incontinence in women. Seven questions assess the impact of incontinence on relationships, distress, and activity. The IIQ-7 differs from the YIPS in that the emphasis is on one's abilities to engage in activities rather than on knowledge, adjustment, coping, or personal acceptance of incontinence. The IIQ-7 long form (Shumaker, Wyman, Uebersax, McClish, & Fantl, 1994) was used by Fleshner and Herschorn (1995) from Toronto with two groups of post radical prostatectomy men who were essentially continent of urine. Thirty men in Group I who had had an artificial urinary sphincter (AUS) implanted because of post prostatectomy incontinence were compared with 31 men in Group II who did not require treatment for incontinence (length of time following surgery is not stated for either group). Both groups indicated that voiding symptoms did not significantly impact on day to day activities. However, AUS men were not interviewed pre sphincter implant (when they were incontinent) so that there is no comparison group. Haab, Trockman, Zimmern, and Leach (1997) administered the IIQ-7 short form (Uebersax, Wyman, Shumaker, McClish, & Fantl, et al., 1995) to men post AUS and found a significant correlation ($r=0.75$; $p<0.001$) between self-reported pad use and impact of incontinence in incontinent men post radical

prostatectomy awaiting AUS implant and the treated comparison group. Both studies suggest that the IIQ has face validity in men with continence. However, the instrument has not been validated on men and it is possible that the questions are not sensitive enough to detect the impact of incontinence or impotence on this group, given the marked difference in onset of symptoms between women with longstanding urinary incontinence and men who were continent until surgery.

Quality of Life: Post Radical Prostatectomy

In studies on quality of life of prostate cancer patients, the Functional Living Index-Cancer (FLIC) (Braslis, Santa-Cruz, Brickman, & Soloway, 1995; Cassileth et al., 1992) and the EORTC-QLQ (Fosså et al., 1989; Hjermstad, Fosså, Bjordal, & Kaasa, 1995; Herr, Kornblith, & Ofman, 1993) have been utilized and determined to be valid in a prostate cancer group even though both are general instruments intended for use with any cancer group. The QLQ-C30 has the added advantage of having a disease-specific module which asks questions specifically related to prostate cancer. As well, the QLQ-C30 has had international field testing in 13 countries and has been translated into 11 languages.

To date, most publications presenting information on the quality of life post radical prostatectomy base the presence or absence of symptoms of disease progression as a marker of quality of life rather than patient report of the impact of symptoms. For example, using continence, potency, and disease control as the measures of quality of life, Leandri, Rossignol, Gautier, and Ramon (1992) present a 10 year retrospective review of 620 consecutive patients. At one year, 95% of patients were continent and 71% were potent. The authors concluded that quality of life is not affected by radical prostatectomy. Similarly, in another 10 year retrospective review, Walsh,

Partin, and Epstein (1994) state that quality of life will be best for men who have organ-confined disease and who will live long enough to benefit from surgery. Those most likely to be potent and continent had both neurovascular bundles preserved, a surgical cure, and were less than 60 years of age. However, improved quality of life is an assumption made by the authors which is not confirmed by patient report.

Others have attempted to quantify quality of life in the post radical prostatectomy population. Pedersen, Carlsson, Rahmquist, and Varenhorst (1993) assessed 131 of 182 eligible patients using a modified version of the York University (UK) quality of life measure. Modifications to the questionnaire were made on disease-specific side-effects deemed important by senior urologists. The results showed no difference in pre and postoperative anxiety, no distress related to urinary incontinence at 18 months postoperatively (does not state how many were continent/incontinent). Notably, at 18 months, over half of those surveyed reported major or severe distress due to erectile dysfunction. However, the cumulative distress score was better 18 months after surgery than before (but patients had recently been diagnosed when the baseline questionnaire was administered) despite erectile dysfunction. The conclusions, based on a summary score, result in a down-playing of the impact of the erectile dysfunction.

Braslis, Santa-Cruz, Brickman, and Soloway (1995) presented data on 79 select patients, 28 of whom were booked for surgery and 51 who were 12 months or more post-operative. All subjects were given the FLIC, the Profile of Mood States (McNair, Lorr, & Droppleman, 1971, and a symptom score evaluating bladder and sexual function. The authors report a significant relationship between incontinence and increased confusion, depression, and anger. There was an inverse correlation between patient incontinence and

perceived physical and psychological well-being. Sexual function correlated positively with vigour and negatively with age. Although 5 of 51 post surgical patients stated they would not have surgery again, the authors suggest that the radical prostatectomy has minimal overall impact upon patient quality of life and despite the erectile dysfunction in 26 patients, 21 of these said they would have surgery again. The authors point out that one consistent comment on the questionnaire was that patients felt that the risk of erectile dysfunction had been understated. Because of the outcomes, the authors have modified their preoperative teaching programme, placing more emphasis on the potential incontinence and loss of potency. The findings that incontinence and lack of well-being were associated may give support to the belief that quality of life is comprised, in part, of well-being.

Herr (1994) also tried to measure quality of life of incontinent men post radical prostatectomy using a questionnaire designed for the project. Of the 14 questions, the last four asked (1) how upset the person was with the symptoms of incontinence, (2) whether the individual believed they were cured of prostate cancer, (3) whether they would undergo the procedure again, and (4) whether understanding incontinence would enhance coping with incontinence. None of the questions asked about the individual's perception of his quality of life. Fifty men participated, all of whom were classified as moderately or severely incontinent and all requiring pads. The authors found 13 of the 50 patients reported significant restrictions in physical activity. There was no correlation between the reported distress with incontinence and the amount of self-reported urinary incontinence or erectile dysfunction. The two patients reporting the most distress also reported using only 1 incontinence pad a day suggesting that one's ability to cope with incontinence is dependent on factors other than leakage alone. Both Herr (1994) and Jønler,

Messing, Rhodes, and Bruskewitz (1994) questioned incontinent patients about their decision to have surgery rather than radiotherapy and whether they would choose surgery again, considering urinary incontinence was an outcome. Herr reported that acceptance of surgery seemed to change over time. Of the patients less than 3 years post surgery, 83% would have chosen radical prostatectomy again, despite incontinence and impotence, whereas only 47% more than 3 years post surgery would choose it again.

Jønler and colleagues (1994) also found that 88% of patients between 12-48 months postoperatively stated they would undergo surgery again. Ninety-three consecutive patients 12 to 48 months post radical prostatectomy were sent questionnaires asking specific questions about incontinence, erectile dysfunction, and satisfaction with surgery. Response rate was 92%, with 59% of the respondents reporting urine leakage and most requiring a pad. Of the patients who had erectile function preoperatively, 51% were unable to achieve an erection postoperatively. Although both studies highlight rates of incontinence and erectile dysfunction, the results are somewhat subsumed by the response that most patients were satisfied with their decision to have surgery. Herr (1994) suggests that continued education, support, and regular "functional" assessment may improve coping abilities of patients. Both Herr and Jønler et al. included questions which assessed the presence or absence of incontinence and satisfaction but no questions asked specifically how the subject rated his quality of life. Jønler et al. conclude "more work is needed to understand the influence of these sequelae [urinary incontinence and erectile dysfunction] on the quality of patients' lives" (p. 357).

Several cancer-specific instruments are available but the majority have not had sufficient testing, thus limiting their use at present. While researchers have yet to reach a consensus on the key dimensions of quality of life, there

appears to be agreement that a quality of life instrument should be multidimensional and include at least four categories: physical complaints, psychological distress, social interaction, and functional status (Aaronson, Bullinger, & Ahmedzai, 1988). Which variables indeed define quality of life is a topic of continuing debate. Moreover, individual characteristics may affect one's perception of quality of life. These include age, religion, perceived health status, education, community living arrangements, perceived social support, marital status, income, and employment (Molzahn, 1989). To this, Wood-Dauphinée and Küchler (1992) would add the importance of *time* in one's life. Cohen and Mount (1992) argue convincingly that spirituality strongly affects one's interpretation of quality of life. Because there is no consistent definition or conceptualization which determines quality of life, researchers may be misguided in thinking they are, indeed, measuring the concept. "Since there are no widely accepted measures of quality of life and no gold standards for measurement of the concept, estimations of reliability and validity will remain crude attempts to measure what has not as yet been adequately defined" (Molzahn, 1989, p. 218).

The factors or variables which were believed to influence a personal evaluation of life's quality with urinary incontinence and erectile dysfunction and which were considered in this study, are summarized in Table 2.3.

Summary

To date, the impact of urinary incontinence after radical prostatectomy on men's quality of life has not been well explored. Subjective responses suggest that incontinence is a prevalent problem which affects men's social and psychological well being, ranging from mild interference to severe limitations. None of the current researchers linked treatment of incontinence in men with improved quality of life. Pelvic muscle exercises (PME's) have been the

mainstay of incontinence therapy in women and the effectiveness has been demonstrated by randomized controlled trials. In men, the results of conservative management of incontinence after radical prostatectomy are not as clear. Clinical reports suggest efficacy of pelvic muscle exercises or electrical stimulation, but no randomized controlled trials have confirmed this belief. The small, heterogeneous samples without urodynamic confirmation of detrusor or sphincter dysfunction combined with subjective rather than objective outcome measures, leave gaps for evidence-based practice. Moreover, the positive results attributed to uncontrolled studies may be credited to therapy when, in fact, change over time has been significant. Several authors have noted a marked reduction over time without treatment of post radical prostatectomy incontinence (Foote, Yun, & Leach, 1991; Jønler, Madsen, Rhodes, Sall, Messing, & Bruskewitz, 1996; O'Donnell, Finan, Barnett, & Brookover, 1990; Rudy, Woodside, & Crawford, 1984; see Appendix 1). Indeed, if many men with incontinence post surgery have *de novo* detrusor instability (Golubuff, Chang, Olsson, & Kaplan, 1995; Leach, 1995), then pelvic muscle exercises may not be appropriate treatment and may explain in part the varying success rates reported in the literature. Questions which need to be addressed by practitioners include: Will early intervention speed up the recovery of continence? When is the optimum time to begin conservative treatment? Is electrical stimulation plus pelvic muscle exercises more effective than pelvic muscle exercises alone? What is the role of biofeedback? How many and how often should pelvic muscle exercises be performed? Does preoperative instruction improve continence rates postoperatively? Finally, can the principles of therapy for female incontinence be applied directly to post prostatectomy incontinence? None of the above questions can be answered without systematic investigation and the current

literature, while providing some promising results in clinical studies, does not provide these answers. To be economically and ethically sound, practice for incontinence must be based on objective outcomes of therapy.

Table 2.3
A Conceptualization Of Factors Impacting Quality Of Life For Men Post-radical Prostatectomy Based On The Published Literature

Symptom: Urinary Incontinence (UI)				
Physical Impact	**Psychological Impact**	**Social Impact**	**Economic Impact**	**Time Impact**
(in 24 hrs) # of Pads used Grams of urine lost # voids/volume Wet underwear or clothing Physical activity	Satisfaction Well being/Health Expectations Self-esteem Sexuality	Relationships Intimacy Socialization (in & out of the home) Role Travel	Employment Supplies for incontinence Use of health care d/t UI or erectile dysfunction Physiotherapy cost + travel for treatment	Past experience with UI & Erectile dysfunction, present situation, and future expectations; Change from baseline to post therapy for UI
Quality of life post radical prostatectomy measured by QLQ-C30, version 2; IIQ-7; Urinary Symptom Inventory				

It was proposed that the first step in evaluating the current treatment in men with incontinence after radical prostatectomy would be to conduct a randomized controlled trial evaluating the current practice of recommending pelvic muscle exercises postoperatively. As electrical stimulation was believed to enhance the ability to do efficient pelvic muscle exercises and has been reported as efficacious in non-controlled studies, the pelvic muscle exercises were also augmented with electrical stimulation. If subjects randomized to PME's plus electrical stimulation achieved continence more rapidly than with pelvic muscle exercises alone, there may have been a significant impact on patient adherence to and satisfaction with the treatment programme as well as being more cost effective. In turn, if urinary incontinence after radical

prostatectomy is related to a reduced quality of life, then effective treatment could result in an improved quality of life.

CHAPTER III

METHOD

The objectives of this study were to test the efficacy of two intensive physiotherapy regimens and to assess the impact and relationship of incontinence on quality of life. A total of 63 men with urinary incontinence post radical prostatectomy (RP) were randomized to control or to one of two treatment groups: pelvic muscle exercises (PME's), or PME's plus electrical stimulation (InCare™). Subjects were seen twice weekly for a maximum of 12 weeks. The control group received written instructions on PME's as part of the standard practice but no intervention during the first 12 weeks. Outcome measures were: 24 hour pad tests, a quality of life questionnaire (EORTC quality of life questionnaire, version 2.0), an impact questionnaire (Incontinence Impact Questionnaire -IIQ-7), and a urinary incontinence symptom inventory.

Research Design

This was a randomized, controlled, experimental design in which the effect of treatment on and the emotional impact of urinary incontinence post radical prostatectomy was explored. Men post radical prostatectomy were recruited. Self-report and objective data were collected at baseline, immediately after treatment for incontinence, and 4 and 8 weeks after completion of treatment. Table 3.1 outlines the study design.

Sample

Men who had urinary incontinence after radical prostatectomy for early stage prostate cancer were candidates for the study. Names of potential subjects were obtained from the offices of the 8 urologists who performed radical prostatectomies in the city of Edmonton between December 1, 1995 to March 31, 1997. A total of 180 surgeries were performed, approximately 10

per month.

Table 3.1
Study Design: Randomized Control

Subjects	Baseline (Time 1)	Active Treatment	Time 2 (@ 12 wks)	Time 3 (@ 16 wks)	Time 4 (@ 24 wks)
Group I Standard treatment (ST)	X		X	X	X
Group II (ST + PME)	X	O	X	X	X
Group III (ST + PME + ES)	X	O	X	X	X

Measures: IIQ-7, QLQ-C30, 24 Hour pad test, 24 Hour pad test, and Urinary symptom questionnaire.
Standard treatment: verbal instruction and typewritten sheet describing pelvic muscle exercises
Time 2: Immediately after completion of therapy (maximum of 24 sessions 2x/week or earlier at the subject's request)
Time 3: 16 weeks from baseline (four weeks after completion of therapy)
Time 4: 24 weeks from baseline (eight weeks after completion of therapy)

Inclusion criteria were:

- urinary incontinence with the onset attributed to radical prostatectomy,
- ability to speak and read English,
- reside within driving distance of Edmonton,
- self-reported preoperative urinary continence,
- ability to attend therapy twice a week for 12 weeks if randomized to treatment groups.

Exclusion criteria were:

- a past history of radiotherapy or pelvic trauma,
- presence of neurological deficit which might affect the potential for

continence, including multiple sclerosis, Parkinson's disease, diabetes (non-insulin or insulin dependent), history of alcohol abuse, or spinal cord injury,

- prior treatment for post radical prostatectomy urinary incontinence

Setting alpha at 0.05, effect size at 0.35, and power at 0.88, sample size required was 20 per group (Cohen,1988, p. 321). Effect size was set at 0.35 because of a known change over time without therapy (Donnellan, Duncan, MacGregor, & Russell, 1997; Jønler et al., 1996) and because of a known placebo effect of up to 20% in women treated for urinary incontinence (Laycock & Jerwood, 1993; Sand et al.,1995).

Setting

Subjects had surgery at two large acute care hospitals in Edmonton, Alberta, Canada affiliated with the University of Alberta: Royal Alexandra Hospital and University of Alberta Hospital. All treatment was delivered by one physiotherapist in her private clinic in north Edmonton.

Instruments

Quality of Life Questionnaire (QLQ-C30)

The European Organization for the Research and Treatment of Cancer (EORTC) quality of life instrument, QLQ-C30, version 2 (Appendix 4) was utilized to answer the question whether active therapy for urinary incontinence enhances the reported health related quality of life. The instrument is designed to record "quality of life factors" which may assess the impact of cancer and its treatment on physical, psychological, and social functioning of the patient (Aaronson et al., 1993). The purpose of developing the EORTC questionnaire was to have an integrated assessment of quality of life for clinical trials. The QLQ-C30 is designed to be used as one method of evaluating quality of life of patients participating in international clinical trials and

consists of a generic health-related set of questions plus disease-specific modules. The questionnaire has been tested on 305 patients with nonresectable lung cancer, in 13 countries. Reliability of items is reported as $\geq$.70 (.52-.89) for all items except role functioning. Test/retest reliability was conducted on 270 oncology patients with a variety of diagnoses in a Norwegian outpatient clinic. Pearson's correlation coefficient and Spearman's rank correlation were high, ranging from .82 for cognitive and role function to .91 for physical function (Hjermstad, Fosså, Bjordal, & Kaasa, 1995). Multi trait scaling techniques were employed to test for item-discriminant validity. Scaling successes were observed in 96% of cases. The majority of the subscales were able to discriminate between patient subgroups on the basis of clinical criteria. Using known group comparisons, statistically significant changes ($p < .001$) were observed in the expected direction in physical and role functioning, fatigue, nausea and vomiting, and global health related quality of life. As well, reliability and validity were consistent across three language and cultural groups (English-speaking countries, Northern Europe, and Southern Europe) (Aaronson et al., 1993).

The generic questionnaire contains 28 items designed to evaluate overall quality of life, fatigue, pain, other physical symptoms (hot flashes, appetite, nausea and vomiting, sleep), cognitive abilities and emotional distress, and interference with family or social life. The answers to individual questions were scored on a four-point Likert Scale ("Not at all", "A little", "Quite a bit", "Very Much"). Two separate questions asked about health and global quality of life. Subjects were asked to rate these two questions on a seven-point scale with "1" being "Very Poor" and "7" being "Excellent" (Anderson, Aaronson, & Wilkin, 1993). Although the EORTC instrument has been shown to exhibit high levels of reliability and validity, the authors point out that further

developmental work is necessary. To be a generic instrument, a wider range of diagnostic groups must be tested. As well, although tested internationally, small sample sizes in some countries such as Japan limits the cross-cultural generalizability of the instrument. Further research is also required for disease-specific modules such as the one for prostate cancer (Anderson, Aaronson, & Wilkin, 1993; Fosså, 1996).

EORTC Prostate Cancer Module

At present, there is no reliable and valid instrument for evaluating symptoms of urinary function after radical prostatectomy. Under investigation by the EORTC study group are several disease specific modules intended to be administered along with the EORTC generic instrument, including one for prostate cancer. For this study, the 11 disease-specific questions for prostate cancer were added as part of the quality of life assessment (Appendix 5). The disease-specific module does not have established reliability and validity but preliminary work by Herr, Kornblith, and Ofman (1993) and Fosså, Aaronson, and de Voogt (1990) suggests that the questions capture the symptoms which may affect quality of life in men with late stage prostate cancer. The module has not been tested on men with early stage prostate cancer. The time frame is the past week. The individual questions are formatted on a "yes/no" response or by a four-point Likert scale ("Not at all", "A little", "Moderately", "Very much"). Average time to complete the questionnaire is approximately 11 minutes.

The present research study has contributed to the on-going EORTC validation of the prostate-specific module questions as well as providing further testing of the generic core instrument. Permission was received from the authors to utilize the generic instrument and the prostate-specific module for this study.

Incontinence Impact Questionnaire (IIQ-7)

The IIQ-7 (Appendix 6) has been developed by nursing and medicine through the Continence Program for Women Research Group in Richmond, Virginia to address the severity of symptoms associated with urinary incontinence and lower urinary tract dysfunction in community dwelling women. Factor and cluster analysis resulted in four subscales: physical activity, travel, social/relationships, and emotional health. Internal consistency for the subscales ranged between .87-.90. The scale correlates positively (.46) with change in incontinent episodes (Shumaker, Wyman, Uebersax, McClish, & Fantl, 1994). Refinement of the IIQ resulted in a short form of seven items -- IIQ-7. The results on the IIQ-7 are consistent with those on the longer former scale (Uebersax, Wyman, Shumaker, McClish, Fantl, et al., 1995). The IIQ-7 consists of seven questions assessing the impact of incontinence on relationships, distress, and activity. Question 1 may reflect more female activities if "household chores" are interpreted to mean cooking, house cleaning, or laundry. Face validity for Questions 2 to 7 suggested that the questions may be appropriate for men and thus, for purposes of this study, the IIQ-7 was one of the instruments used for data collection on the impact of urinary incontinence post radical prostatectomy.

Frequency/Volume Record

A chart was drawn with 2 hourly sections in which the subject was asked to record the amount of fluid consumed (in ml) and the amount of each void (in ml)(Appendix 7). Subjects were provided with a urine measuring cup which fit under the toilet lid (Sage 2500) and which was marked in 50 ml increments. Frequency volume records are reliable tools to assess urinary symptoms, even without detailed instruction from the health care provider (Robinson, McClish, Wyman, Bump, & Fantl, 1996). Subjects were able to

complete the Frequency/Volume Record without difficulty.

24 Hour Pad Test

Subjects were instructed to change the pre-weighed pads every 2 hours wet or not. To change the pad, the written instructions were: remove the used pad, place it in the empty ziploc bag it is supplied in, zip bag tightly shut, write "**Off at _____ hours**" on the bag, remove new pad from next ziploc bag, place new pad on, write "**On at ____ hours**" on the bag. A sticky paper label was placed over the seal of the ziploc bag so that the researcher would know that the bag had been opened and the pad used (Appendix 8).

Pelvic Muscle Exercise Instruction Sheet

The pelvic muscle instruction sheet (Appendix 9) was constructed by the researcher, in consultation with a physiotherapist expert in incontinence treatment, a patient education expert, and men with post prostatectomy incontinence. The reading level of the sheet is grade five, according to RIGHT WRITER (Rightsoft Inc., 1987). Grade five reading level was chosen as it has been found that patients have difficulty comprehending health information written at a greater than a grade five level (Estey, Kemp, Allison, & Lamb, 1992).

Check List Reminder

To have a general measure of subject's adherence to the three times-a-day home pelvic muscle exercise regimen, a check list was used. Subjects were asked to place a ✓ mark when they completed their exercise (Appendix 10).

Urinary Symptom Inventory

An inventory was constructed to evaluate symptoms of urinary incontinence; type, number of, and occasions for pad usage (Appendix 11). One question asks about practising postoperative exercises to enhance urinary control. The last five questions ask about the effect of incontinence and

erectile dysfunction on one's life, whether it would bother the subject to spend his life with bladder control or erections the way they are now, and finally, whether he would choose radical prostatectomy again. Each section of the inventory has between 4 to 8 questions numerically coded 1 to 8. Scores for questions A to I are derived by summing responses, with a minimum score of 9 reflecting few urinary symptoms and a maximum score of 34 indicating severe problems with urinary incontinence. The patient's perception of when leakage occurs and the number of pads required was also evaluated.

Demographic Information

Demographic variables were collected which others (Molzahn, 1989) have suggested could influence the outcome of quality of life responses. These were age, length of time postoperatively, perceived health status, education, reported social support, marital status, income, employment, race, community standard of living, and religion (Appendix 12).

Data Collection Protocol

Subjects were informed of the study by their urologist and permission was requested by the urologist to release their names to the researcher. None of the men declined the initial telephone contact. Once a month, the names of all subjects who agreed to be contacted were provided to the researcher. Potential subjects were contacted approximately 5 weeks after surgery (range= 2 to 12 weeks). The call was an introductory one by the researcher with an explanation of how the potential subject's name was obtained, who the researcher was, and the purpose of the call. At the initial call the researcher only talked to the potential subject on general postoperative concerns rather than the specifics of the research study. Subjects had many concerns which are discussed later. At the close of the call, which usually lasted 15 to 20 minutes, the potential subject was asked if the researcher could telephone

again in about 4 weeks. Men were unanimous in answering "yes" to this question. They were also given the telephone number of the researcher to call if they had any questions. Table 3.2 shows the data collection protocol.

Protocol Per Group

Outcome measures for all three groups were: IIQ-7, QLQ-C30 (version 2), urinary symptom inventory, and 24 hour Pad Test with a frequency/volume chart. These were done at baseline, 12 weeks from baseline (post therapy for Groups II and III), 16 and 24 weeks from baseline to determine the durability of exercise results as well as to follow the improvement over time. For purposes of this study, the pivotal work of Bø et al. (1990a, 1990b, 1990c) on pelvic muscle exercises was followed for two main reasons: (1) the strategies employed closely followed those of the standardized recommendations of the ICS (1990), and (2) the regimens closely follow those currently implemented by the associated physiotherapist. To standardize the pelvic muscle instructions provided at the preadmission clinics and acute care units at the University of Alberta Hospital and the Royal Alexandra Hospital, all patient information sheets on pelvic muscle exercises were replaced with the one designed for the study.

Group I: (Standard Treatment). Group I subjects received the standard post prostatectomy pelvic muscle exercise teaching at the preadmission clinic which included written and brief verbal instruction on pelvic muscle exercises. The contents of the exercise sheet were reviewed verbally and subjects told by both the nurses in the preadmission clinic and the urologist, as part of standard practice, that repeating strength exercises at home might help in the achievement of continence. Group I was seen again by the researcher at 12 weeks from initial contact.

Group II: (Intensive Pelvic Muscle Exercises). Subjects randomly

assigned to the pelvic muscle instruction group (Group II) received the initial instructions (above) plus the protocol listed below for pelvic muscle exercises. Each session was 30 minutes twice a week in the office of one physiotherapist. Subjects were supine with knees bent, feet and knees apart approximately 25 cm, on an examining table with the physiotherapist seated at the subject's right side with a view of the subject's face as well as a view of the perineum and rectum. Four components of muscle function were worked on: strength, endurance, speed, and control.

Strength: Exercises focused on recruiting as many muscle fibres as possible and maintaining the contraction at an optimum hold for 5 to 10 seconds while, at the same time, keeping the abdominal, gluteal, and quadriceps muscles relaxed. Initial contractions were 5 to 10 seconds with a 10 to 20 second rest with 12 to 20 repetitions. Subjects were requested to repeat strength exercises at home on non-treatment days.

Endurance: Exercise focused on maintaining a muscle contraction at 50-60% of maximum strength. Hold time was 20 to 30 seconds with equal rest time, with 6 to 8 repetitions.

Speed: The focus was on quick repetitive contractions in a 10 second time span. Quick recruitment of muscle fibres was taught with an equally quick release of fibres. A set of 5 to 10 contractions were done in 10 seconds with a 20 second rest period.

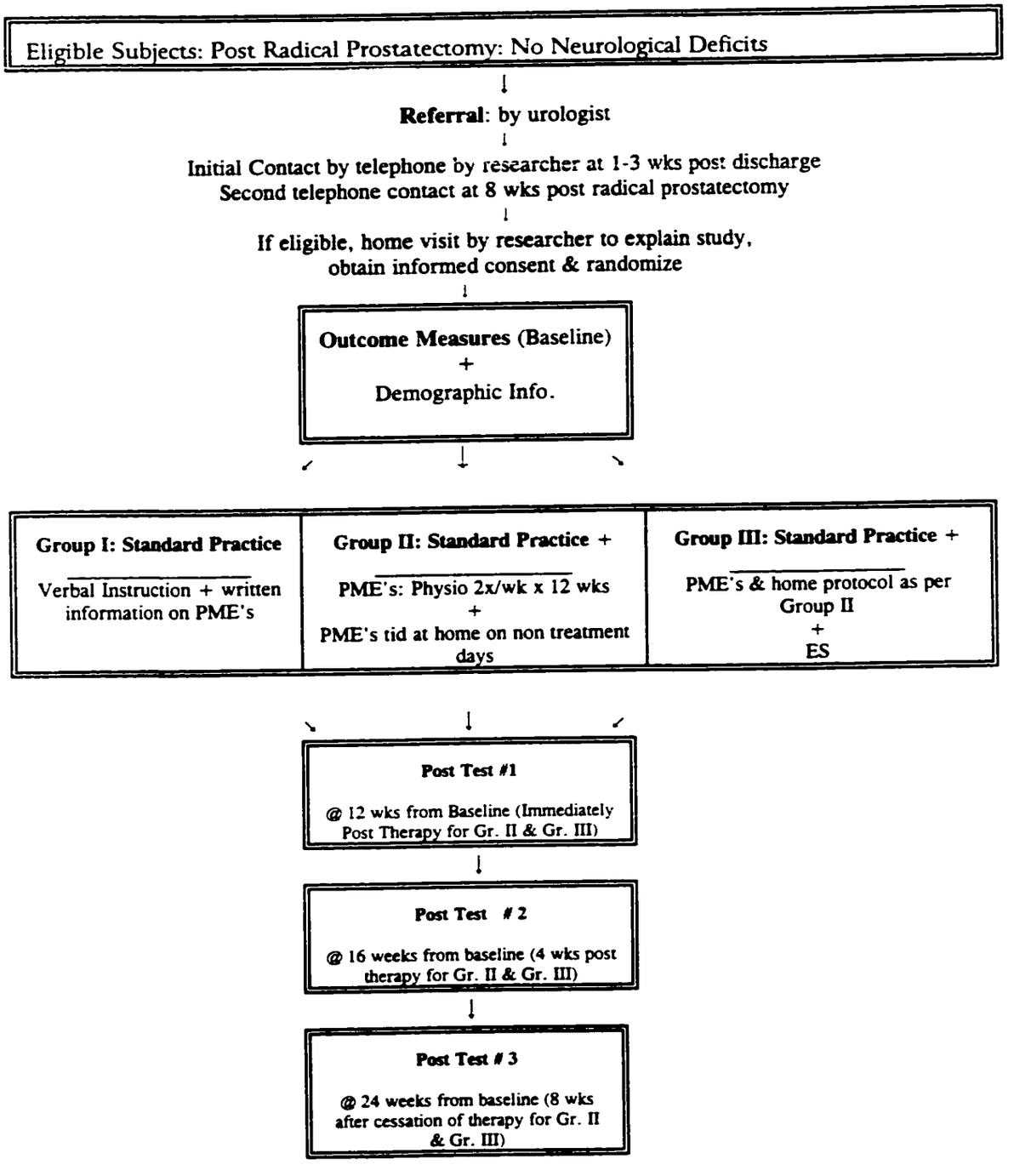
Control: Gradual recruitment of muscle fibres to a maximal contraction was taught. Contractions occurred in three stages with 5 second hold at each stage and a slow release, with rest period of 5 seconds.

Other: The subject was instructed to do a penile lift by contracting the bulbocavernous muscle and to watch for a visible dip at the angle at the base of the penis. As well, subjects were instructed to palpate for a contraction of

the bulbocavernous muscle at the perineum. The subject was requested to repeat the strength, endurance, speed, control, and penile lift exercises three times a day at home on non-treatment days. Subjects were also provided with a check list exercise reminder attached to the pelvic muscle exercise sheet (Appendix 10).

Group III: (Electrical Stimulation and Intensive Pelvic Muscle Exercises). Subjects randomized to Group III also met with the physiotherapist twice a week. Each session was 30 minutes and alternated between electrical stimulation and voluntary pelvic muscle exercises as per Group II (above). Intensity of the stimulation was adequate to induce visual lifting of levator ani and pubococcygeus muscle, considering level of comfort of the subject (Hahn, Sommer, & Fall, 1991). Subjects received therapy in the same position as those in the PME group (Group II). The two phases of therapy involved stimulation and reinforcement. Therapy began with 5 minutes of stimulation to increase awareness of levator ani and pubococcygeus muscle contractions. Muscle contraction was determined by the physiotherapist by visual observation of rectal contraction and penile lift. Contractions produced by stimulation were then reinforced with 10 minutes of reinforcement by digital rectal exam and consisted of fast contractions, slow maximal contractions, with progressive build up of endurance. The reinforcement focused on relaxation of abdominal and gluteal muscles while concentrating on perineal contractions. Five minutes of stimulation and ten minutes of biofeedback were alternated for a maximum of 30 minutes (or less if subject was fatigued).

Table 3.2
Data Collection Protocol



Data Analysis

Data were entered into SPSS version 7.5 files. Descriptive statistics, frequencies, and t-tests were used to compare differences between non-treated and treated groups at Time 2 (12 weeks). One way repeated measures ANOVA using a general linear model was chosen to explore the difference between and within groups as well as the change over time at 12, 16, and 24 weeks from baseline. MANCOVA was used to explore the effect of weeks post radical prostatectomy and age of subjects on urinary continence.

Ethical Considerations

This research was subject to review by the Faculty of Nursing, University of Alberta and the Capital Health Region (University of Alberta Hospital and Royal Alexandra Hospital) as well as by Caritas Health Group (Misericordia Hospital). Data were kept confidential by replacing names on the questionnaires with a code number. The linkage between the code number and the subject was known only to the researcher. Questionnaires were stored in a locked cabinet to which only the researcher had access. Any reference or description which could identify the subject was excluded in all reports, any published or presented papers, and secondary analysis of the data. Subjects were informed that the information provided to the researcher was completely confidential between the subject and researcher only.

There were some inconveniences from being in this study: two subjects found the questionnaires tedious or invasive of privacy. Some subjects, particularly farmers who lived more than 100 km from the physiotherapy centre, found attending physiotherapy twice a week for a minimum of four weeks to be time consuming and inconvenient. Electrical stimulation with an anal probe had the potential to be uncomfortable or embarrassing for some subjects although none complained of this on direct questioning. The

frequency/volume record was felt to be very inconvenient, mainly because many of the subjects had returned to work after the initial assessment. None found the 24 hour pad test problematic. Subjects were free to withdraw from the study at any time. Physiotherapy expenses were covered by the researcher.

The subject was informed about the consent procedures before any data collection and given an information sheet to read (Appendix 13). The purpose of the study and the time commitments were stated verbally to the subject before asking for his consent to participate (Appendix 14).

CHAPTER IV

RESULTS

The purpose of the study was (1) to evaluate the effectiveness of intensive physiotherapy for urinary incontinence in men post radical prostatectomy, and (2) to compare quality of life and urinary incontinence impact scores with grams of urine lost. Men post radical prostatectomy were randomized to control, PME, or PME+ES. The two treatment groups received physiotherapy twice a week for 30 minutes for a maximum of 12 weeks. Subjective and objective data were obtained on 4 occasions, at baseline, and at 12, 16, and 24 weeks from baseline. Throughout the discussion which follows, these data collection times are called Time 1, Time 2, Time 3, and Time 4.

Characteristics of the Subjects

During the data gathering period from December 1, 1995 to March 31, 1997, 63 men met the sample eligibility criteria out of a total of 180 men undergoing a radical prostatectomy. No subjects who were eligible refused to participate. During the study, 3 subjects were dropped because of bladder neck contractures, 1 because of rectal pain when he did the exercises, and 1 because he went on holidays for 4 months and could not continue therapy. Data are available for 58 subjects, 48 of whom completed all four data collections and 58 of whom completed 3 of the 4 data collections. The reasons for incomplete data were lack of interest in the study, holidays, or return to work.

Mean Age, Living Arrangements, Employment Status, Income

Table 4.1 summarizes the demographic characteristics of the sample. The mean age of the subjects was 66.8 years with a range from 49 to 77 years. All of the men were Caucasian, married (95%), or living alone (5%). Income ranged from less than $20,000 (21.4%) to more than $50,000 (17.9%).

Table 4.1
Demographic Characteristics of Subjects in the Study

Variables	Control n=20	PME n=20	PME + ES n=20	N	%
Age, mean years	66.8	67.4	65.7	58	
Race: white	21	18	19	58	
Relationship Status					
Living with spouse or partner	20	18	17	55	95%
Single, living alone		1		1	2%
Divorced, living alone	1		1	2	3%
Annual household income					
<$20,000 $20,000-40,000 $40,000-50,000 >$50,000	6 9 4 2	3 9 2 5	2 12 3 1	11 30 9 8	19% 52 15 14
Education					
<Grade 8	11	2	2	15	26%
Grade 8-12	2	4	7	13	22
Grade 12	5	5	4	14	24
College	2	3	3	8	14
University	1	5	2	8	14
Employment					
Employed full-time	3	4	2	9	16%
Employed part-time	1	1	4	6	10
Not Employed (retired)	17	14	12	43	74
Description of current health					
Very healthy	5	6	5	16	28%
Mainly healthy	14	8	10	32	56

Variables	Control n=21	PME n=18	PME+ES n=19	N	%
Somewhat healthy	1	5	2	8	14
Mainly unhealthy	0	0	1	1	2
Living Accommodations					
House	17	16	17	50	88%
Apartment	3	3	1	7	12
Rent	2	2	1	5	9%
Own	19	17	18	54	91
Religious Affiliation					
Do not follow a prescribed faith	9	5	6	20	36%
Follow a prescribed faith	5	10	5	20	36
Attend church or temple regulariy	6	3	7	16	28
Main source of support					
Spouse	20	18	17	55	94%
Children	1			1	2%
Friends		1		1	2
Other		1		1	2
Satisfaction with support					
Very satisfied	20	17	16	53	91%
Moderately satisfied	1	2	0	3	5%
A little satisfied	0	0	1	1	2
Not at all satisfied	0	0	1	1	2

Twenty-six percent were from rural areas and had farmed all their lives. Sixteen (27.6%) had less than grade 8 education and 20.7% had less than grade 12 education, for a total of 48% with less than a grade 12 education. The remainder varied from completing Grade 12 (24%), to completing college

(14%) or university (14%). Most were retired (76%), but 24% were involved with full time or part time employment which had implications for the ability to attend physiotherapy on a regular, twice weekly basis. At the baseline interview, 84% of the men responded that they were *very* or *mostly healthy*, 14% *somewhat healthy*, and 2% *mainly unhealthy*.

Chronic Medical Conditions

Several subjects had chronic medical conditions. Cardiovascular conditions, including hypertension and arrhythmias were reported by 22 subjects (35.5%). Five men (8.1%) stated they were depressed; 4 had been treated for the problem prior to the diagnosis of prostate cancer. The remaining gentleman stated he was taking Prozac because of his urinary incontinence. Musculoskeletal conditions such as arthritis and back pain were reported by 5 (8.1%) and gastrointestinal problems requiring medications by 4 (6.5%). One subject had epilepsy controlled with Dilantin and 2 had chronic chest conditions. One subject reported a previous MI in 1993. Two subjects had non insulin controlled diabetes mellitus, 1 of whom took Diabeta daily. Because of difficulty recruiting subjects, the overall good preoperative health and denial of any preoperative voiding problems of these 2 subjects, they were included in the sample.

Bladder disorders were infrequent. One man reported long standing frequency preoperatively, one had been treated for bladder cancer 6 years ago. None had a history of urinary tract infection and all denied urinary incontinence prior to surgery.

Surgical Procedures

A variety of surgical procedures had been experienced by the subjects prior to having their radical prostatectomy, including coronary artery bypass surgery (CABG) (n=4; 6.6%), urological surgery included transurethral

resection of the prostate (n=4) or transurethral resection of bladder tumour (n=1), or unrelated surgery (n=4; 6.6%). None of the men had had back or pelvic surgery. Figure 4.1 shows the proportion of men having surgical procedures compared with those who had not had any surgery preradical prostatectomy.

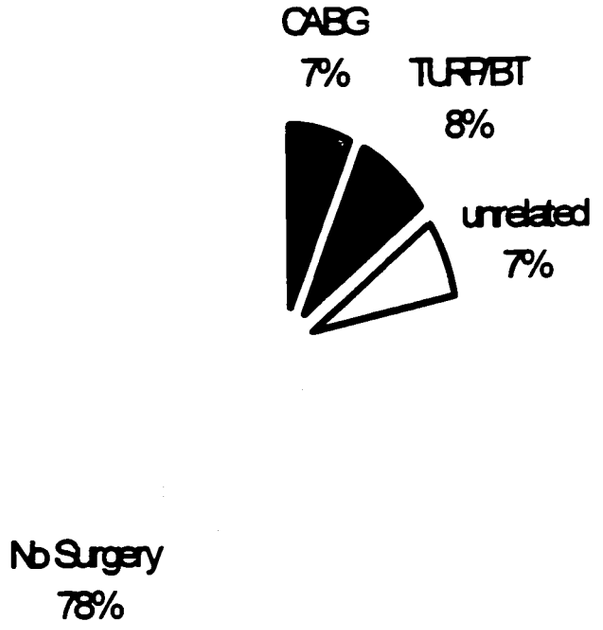


Figure 4.1. Pie Chart: Proportion of Surgical Procedures of Total Sample

Diagnosis of Prostate Cancer

Although nearly half the subjects had some urological symptoms, only the 4 men with retention sought help directly related to their urological problems. All the other subjects had abnormal digital rectal exam (DRE) or raised PSA after seeing the physician for an unrelated complaint or a routine check up. Six men had a family history of prostate cancer and had been followed with annual PSA and DRE. A rise in PSA resulted in a urological

followed with annual PSA and DRE. A rise in PSA resulted in a urological consult.

Preadmission Clinic

All patients were seen in a preoperative assessment clinic, called *preadmission clinic*, for complete physical and anaesthetic evaluation approximately 1 month prior to surgery and were admitted on the day of surgery. In addition to the physical examination, patients received information ranging from bowel preparation and enema the day before surgery to erectile dysfunction postoperatively. The preadmission clinic was described by several men as being overwhelming with too much information provided. Few could recall many specifics, particularly with respect to bladder control and incontinence products. For 2 subjects, the time between preadmission clinic and surgery was more than 3 months. Others found the clinic very worthwhile: "I felt the preoperative clinic held at the hospital was most informative and covered all aspects of the post-operative problems one might encounter, as did my surgeon".

Postoperative Course

Mean Length of Stay in Hospital

The mean length of hospital stay was 5 days with a range from 4 to 21 days. Subjects had positive experiences with nursing care in the hospitals although several found the nurses and physicians very busy. For this reason, they did not want to bother the staff with questions about caring for their catheter or incision after discharge.

Mean Weeks Post Radical Prostatectomy At Study Enrollment

The mean weeks post surgery of the total sample was 18.9 weeks (range=4 to 241 weeks; median=8.0). Four subjects were more than 2 years post radical prostatectomy. Table 4.2 shows the mean weeks post surgery at

the study entry and Appendix 15 shows the mean weeks post operatively at all 4 data collection points. The 3 groups were not homogeneous with respect to number of weeks post surgery ((Cochrans C (18,3)=0.89, p=.000; Bartlett-Box (F (2,67)=43.40, p=.000)). Nonparametric analysis among groups using Kruskal-Wallis also indicated non-homogeneity of groups. This demonstrated the influence of the extreme values in weeks postoperatively of the 4 subjects. The outlier subjects were in the PME (1) and PME+ES (3) groups. ANOVA was rerun with the outliers removed and group homogeneity was accepted ((Cochrane C (17,3) 0.53, p=0.07; Bartlett-Box F(2,58), p=0.08)).

Table 4.2
Summary of Number of Weeks Postop by Treatment Group

Time Postop to begin treatment (weeks)	Treatment group			Total	Percent
	CONTROL	PME	PME+ES		
0 - 4	5	2	2	9	15.0
5 - 16	15	16	13	44	73.3
17 - 36	1	0	2	3	5.0
37+	0	1	3	4	6.7
Total	21	19	20	60	
Percent	35.0	31.7	33.3		100.0

Medications

Medications may affect bladder control. Thus all postoperative medications were recorded and classified (Table 4.3). The most frequently used were cardiovascular. Thirty-six percent of subjects took them on an on-going basis. One man took antihistamines for chronic allergies and one used

Entex LA prior to beginning therapy.

Table 4.3
Medication Use of Men Post Radical Prostatectomy. (N =58)

Medication	# of subjects using	% of subjects using	# of subjects not using	% of subjects not using	Total
Analgesic	15	25%	45	75%	100%
Antiandrogen post operatively	2	3.3%	58	96.7%	100%
Anticholinergic, antihistamine	5	8.2%	55	88.9%	100%
Anticonvulsants	1	1.6%	58	98.4	100%
Antihypertensive, antiarrhythmic, anticholesterol	22	36.1%	38	63.9%	100%
GI medications	3	4.9%	57	95.1%	100%
Hypoglycaemic	1	1.6%	58	98.4%	100%
Smokes	5	8.2%	55	91.8%	100%
Stool softener	5	8.2%	55	91.8%	100%
Vitamins	6	9.8%	54	90.2%	100%

Weeks to Complete the Protocol

The study was designed so that by 12 weeks from baseline entry, treatment group subjects would have completed 24 twice weekly therapy sessions. Mean weeks to complete therapy was 13.0 $\pm$ 3.2 weeks (range=6-23 weeks). Table 4.4 shows the weeks from baseline to Time 2 for the 3 groups (Appendix 15 shows the weeks postoperatively at baseline and at Times 2, 3, and 4). Some men lived long distances from Edmonton which affected their ability to attend the sessions twice weekly during the unpredictable Northern Alberta winter weather, some missed sessions because of vacation, and, the

therapist was on holidays for 4 weeks in December. Men were motivated to receive therapy, however, and to the best of their ability attended all their appointments. Subjects who did not complete all appointments stopped because they were dry, or because they felt they knew how to do the exercises and did not need further intervention.

Table 4.4
Weeks to Time 2 (Second pad test) by Group

Control		PME		PME + ES	
Mean (WKS)	13	Mean	13	Mean	13
Minimum	9	Minimum	6	Minimum	8
Maximum	19	Maximum	20	Maximum	23
SD	3	SD	4	SD	4

Urine Loss

At 12 weeks (Time 2) from the baseline measurements (Time 1), total mean grams of urine loss had dropped from 463 gm (range=5-1539 gm) to 115 gm (range=1 to 702 gm) and 20 (34%) of the sample had less than 10 gm of total urine loss in 24 hours (7 Control, 6 PME's, and 7 PME + ES). There was a marked decrease in urine loss in all three groups at 12 weeks and a continuous decrease up to the end point of the study, 24 weeks from baseline which, on average, was approximately 36 weeks postoperatively. By Time 4 (the fourth pad test) at approximately 24 weeks from baseline, 27 (47%) of the sample had less than 10 gm of urine loss (11 Control, 8 PME's, and 8 PME + ES). Mean total urine loss at 24 weeks was 72 gm (Control=54 gm; PME=70 gm; PME+ES=98 gm). Table 4.5 summarizes the results of the total urine loss as measured by 24 hour pad tests at Time 1 (baseline), Time 2 (12 weeks), Time 3 (16 weeks), and Time 4 (24 weeks). Results by individual

subject are presented in Appendix 16. Of note is the variation between mean and median as well as the large standard deviation.

Table 4.5
Mean Grams Of Urine Lost In 24 Hours By Group Over Time

Group	*Time 1* Baseline	*Time 2* 12 Weeks	*Time 3* 16 Weeks	*Time 4* 24 Weeks
Control				
Mean	385.9	103.8	67.3	54.1
Median	395.5	23.8	11.5	6.9
SD	256.9	176.3	137.4	103.1
Minimum	6.3	1.0	2.0	1.0
Maximum	921.5	702.4	530.3	277.3
N=	21	21	20	16
PME				
Mean	565.6	86.9	73.5	69.9
Median	513.9	32.50	10.35	8.7
SD	403.3	123.0	131.4	113.5
Minimum	21.5	2.2	1.0	1.0
Maximum	1538.6	385.9	494.6	362.8
N=	18	17	16	17
PME+ES				
Mean	452.5	155.5	202.2	98.2
Median	492.1	87.5	85.7	8.95
SD	385.1	168.1	242.23	132.1
Minimum	5.3	1.0	1.0	1.0
Maximum	1344.8	509.3	753.4	424.2
N=	19	19	19	16
Total				
Mean	463.5	115.5	114.2	72.5
Median	419.8	27.2	14.1	7.5
SD	352.2	158.7	185.6	115.7
Minimum	5.3	1.0	1.0	1.0
Maximum	1538.6	702.4	595.7	424.2
N=	58	58	57	48

Figure 4.2A shows the pattern of urine loss over time at baseline, 12, 16, and 24 weeks of all subjects and Figure 4.2B is a graph of the total urine loss at Times 1 to 4 with a profile line showing the decrease over time.

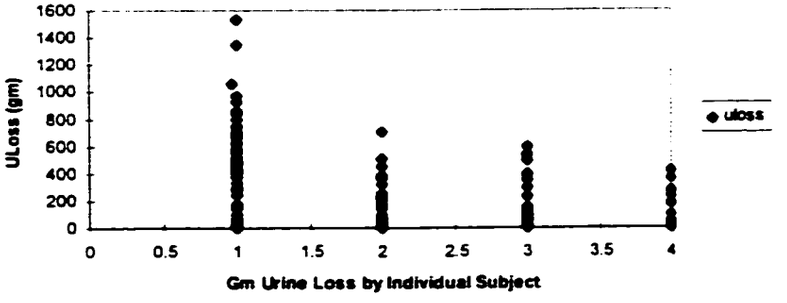
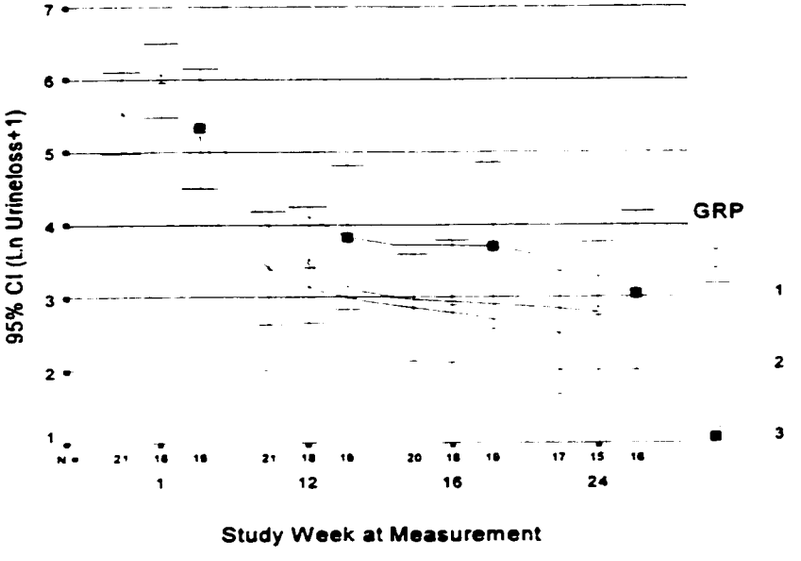


Figure 4.2A. Urine Loss at Time 1, Time 2, Time 3, and Time 4 by Individual Subject.



Group 1=Control; Group 2=PME; Group 3=PME+ES

Figure 4.2B. Urine Loss at Times 1, 2, 3, & 4 with Profile Lines

24 hour Frequency Volume Record

All subjects were able to complete the fluid volume charts without difficulty and the information provided was a good baseline guide to fluid intake and voiding patterns. In the follow up visits, however, after approximately 20 subjects had completed fluid volume charts, the researcher realized that the data obtained did not provide any further information that assisted with the research project. At baseline, fluid intake was influenced by how well the subject was feeling after surgery. A surprisingly high number of men needed encouragement to drink adequate fluids. They had cut down on intake with the belief that fluid reduction would improve bladder control. However, as bladder control improved, fluid intake also improved. Most importantly, by the second pad test, all subjects were active, feeling more energetic, and drinking sufficient fluids. As several had returned to work, the frequency volume record became inconvenient. Thus, to encourage subject adherence to the protocol, it was decided to drop the voided volume section of the records at the follow up visits. At the baseline record, fluid intake varied from 720 ml to 2500 ml in 24 hours. It was suggested to some subjects that fluid intake be varied or increased. One man drank 650 ml between midnight and 06:00 and advice was given on the timing of fluids. Two men drank large amounts of coffee and suggestions were made to try reducing caffeine and increasing water, however, such fluid adjustments, according to subjective report, did not change the amount of urine loss.

Tests Of Assumptions Required For Parametric Tests

Before using parametric statistics to test the null hypothesis that there was no difference between treatment and control groups, tests were run on the baseline data to ensure that the required assumptions for repeated measures analysis were met, namely (1) normal distribution, (2) homogeneity of

variance, and (3) compound symmetry (Munro & Page, 1993).

Normal distribution

Normal distribution of the dependent variable, urine loss, was confirmed using the Shapiro-Wilks test (p=0.09). The test calculates the expected values and compares the fit with predicted values. If deviations are wide, the data cannot be considered normally distributed. In this study, Shapiro-Wilks was not significant and data were accepted as normally distributed. Graphical analysis using Q-Q plots confirmed the normal distribution.

Homogeneity

Homogeneity of dispersion matrices was tested with Box's M (p=0.034). The level of significance meant that the variances within the raw data were not equal and univariate tests would not be appropriate. Data were transformed to natural log and Box's M was not rejected with the data in this format (p=0.69). Graphic analysis with Q-Q plot confirmed the distribution.

Compound Symmetry

Compound symmetry implies that the variance and covariance structures remain equal and consistent over time within each subject and among the groups. Correlations across the measurements (within subject serial correlations) and the variances were calculated with Mauchly sphericity test (w=0.0001; Huynh-Feldt Epsilon = 0.47097). Although Box's M (above) of the natural log transformed data suggested homogeneity, the Mauchly sphericity test was significant (p=0.001) and compound symmetry could not be assumed. When cases occur where normality is met but other validity is in question, there are several approaches to analysing repeated measures data. Looney and Stanley (1989) recommend that the multivariate repeated measure model be chosen when Epsilon is less than .75. Thus, for the

MANOVA tests which follow, multivariate techniques with natural log transformed data were used.

Missing values

There were no estimates for missing values. Data analysis is done on the 58 subjects who have complete data at 3 or 4 data collection points.

Urine Loss

To test the first hypothesis that men who participated in a treatment programme would have fewer grams of urine loss after 12 weeks of therapy than their non-treated counterparts, an independent two-tailed t-test was used with *treatment* as one group and *control* as the other. The t-test revealed that at 12 weeks from baseline, the mean total urine loss of subjects in the treatment group (112.3 gm) was not significantly different from that of subjects in the control group (103.7 gm), (t=-.20, p=0.84).

Next, the 3 groups were considered separately. To test for treatment effects between PME or PME+ES groups, compared to the Control, a repeated measures MANOVA on the natural log transformed data was done on urine loss at baseline, 12, 16, and 24 weeks after baseline (Times 1, 2, 3 and 4).

There was no apparent overall effect of treatment on urine loss between the 2 treatment groups when compared to the control group (F=0.23, p=0.80). As well, although grams of urine loss was reduced over time in all 3 groups, there was again, no statistically significant difference between the treatment and control groups with respect to regaining continence over the 6 months of the study (F=1.90, p=0.09). Figure 4.3 illustrates the changes in urine loss from Time 1 to Time 4.

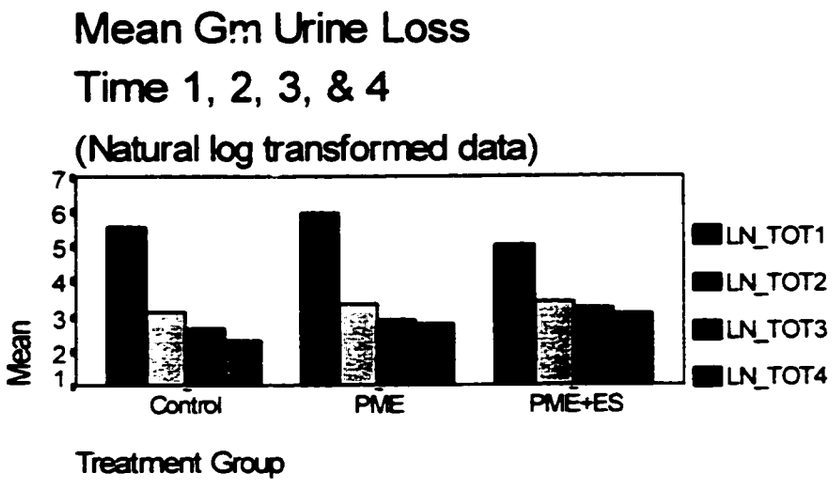


Figure 4.3. Urine Loss Over Time For All Groups

The change in urine loss over time among subjects, regardless of group assignment was statistically significant (F=85.23, p=0.001). Thus, while the treatment did not demonstrate an effect on the return to continence, time did (Table 4.6).

Table 4.6
MANOVA Summary Table for Group by Time by Mean Grams of Urine Loss

Source of Variance	SS	DF	MS	F	p
Among Treatment Groups	4.10	2	2.05	0.227	0.80
Among Treatment Groups Error	398.04	44	9.05		
Within Subjects					
Time	239.19	3	79.73	85.23	0.001
Group x Time	10.61	6	1.78	1.89	0.09
Within Subjects Error	123.48	132	0.94		

Because of the reduction in grams of urine loss in the early weeks after surgery regardless of group assignment, analysis was done with repeated

measures ANCOVA holding number of weeks postoperatively as a covariate to control for the influence of time. The analysis showed that time was still significant ($F=2.9$, $p=0.04$) at all 4 data collection points.

Finally, to try to reduce the effect of time and look for differences between groups in subjects for whom the time variation was smaller, a subset was selected. Subjects were chosen who were 12 weeks or more after surgery at baseline because their condition appeared to have plateaued by this point. Thirteen subjects met the criteria: 3 control, 2 PME, and 8 PME+ES. Although the sample is too small to make any inferences and is under represented in the Control and PME groups, some trends are of interest. Although the influence of time was expected to be less important for these selected subjects, improvement continued. The bar graph (Figure 4.4) suggests a continuing response to time in all three groups.

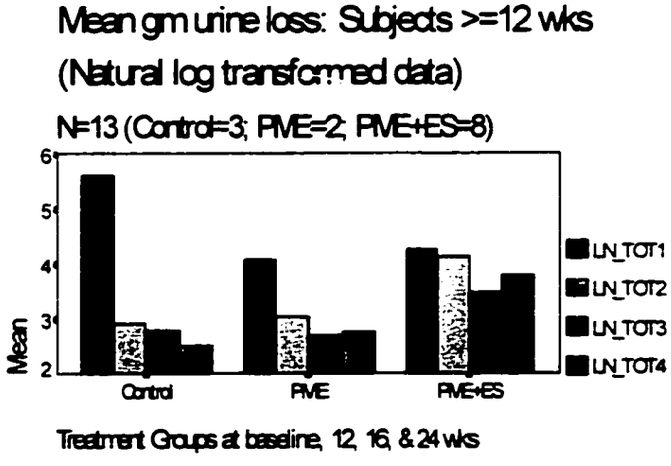


Figure 4.4. Bar Graph Selected Subjects x Group over Time

Impact of Risk Factors On Urinary Incontinence

To assess the impact of age, detrusor dysfunction, and previous urologic surgery on postoperative urinary incontinence after radical prostatectomy, t-tests and descriptive statistics were used.

Age. Sixteen men were over 70 years, 43 were less than 70 years of age. There were no differences between the two age groups in total urine loss at Time 1 (t=-1.32, p =0.09) nor at Time 4 (t =0.61, p= 0.27). Differences were also non significant when age was split to more than 65 years (n=49) or less than 65 years (n=10) at Time 1 (t=.50, p=0.31) or at Time 4 (t=-0.92, p=0.18).

Detrusor Dysfunction. In this study, urodynamics were not performed, thus it was not possible to obtain a definitive diagnosis of detrusor dysfunction (instability, poor compliance, reduced contractility) apart from the history at the baseline interview. At Time 1 (baseline), on direct questioning, 54% (30/56) of subjects stated they had had preoperative symptoms (preoperative symptom information is missing on 2 subjects). Of these 30 subjects, 14 had nocturia alone, 12 had urgency, frequency, and nocturia, and 4 had preoperative retention. Twenty six stated they had no presenting symptoms. At Time 4, of the men with nocturia alone, 79% (11/14) had less than 10 gm urine loss in 24 hours, whereas only 33% (4/12) of men with frequency, urgency, and nocturia, and 25% (1/4) with retention had less than 10 gm. These percentages are compared those of the 26 men who stated they had no presenting symptoms: 64% (16/25) had urine loss less than 10 gm at Time 4 (2 cases are missing). Figure 4.5 shows the proportion of men at Time 4 with and without urine loss greater than 10 gm. Because those with nocturia had a low incidence of incontinence at Time 4, they are placed in the group with no symptoms.

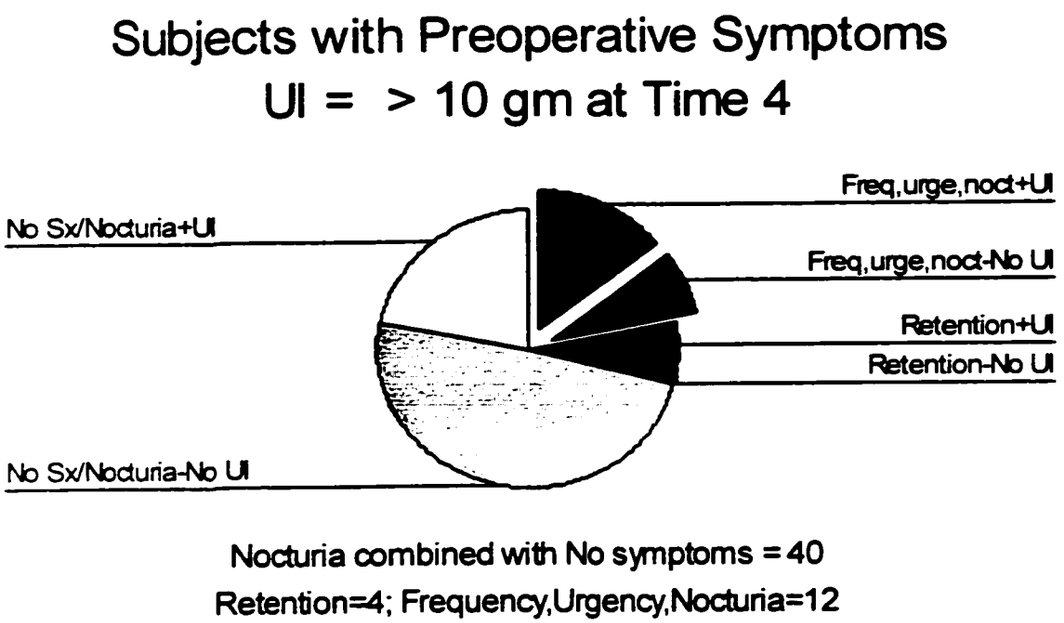


Figure 4.5. Preoperative Symptoms & Postoperative UI

Table 4.7 shows the subject, group assignment, Baseline and Time 4 urine loss for all 29 subjects with symptoms.

Table 4.7
Subjects with Symptoms At Initial Diagnosis of Prostate Cancer: Subject Number, Symptoms, Group, and Mean Gm Urine Loss At Baseline (Time 1) and Time 4

Subject #	*Group*	*Symptoms*	*Baseline $\bar{x}$ gm*	*Time 4 $\bar{x}$ gm*
3	PME	Retention	703.3	362.8
11	Control	Retention	328.6	264.1
15	Control	Retention	757.1	42.6
44	Control	Retention	151.1	6.9
6	PME	Nocturia	401.8	52.0
7	Control	Nocturia	484.4	0.9
10	PME	Nocturia	956.9	3.9
14	PME	Nocturia	144.8	4.2

17	Control	Nocturia	425.8	1.0
18	PME	Nocturia	750.5	1.6
20	PME+ES	Nocturia	31.0	1.0
22	Control	Nocturia	145.7	120.9
23	Control	Nocturia	686.3	1.0
26	PME	Nocturia	272.8	1.4
35	Control	Nocturia	154.9	7.9
53	PME+ES	Nocturia	12.0	3.8
55	PME+ES	Nocturia	5.3	7.6
60	PME+ES	Nocturia	859.5	753.4
3	PME	Frequency, urgency, nocturia	703.3	362.8
9	Control	Frequency, urgency, nocturia	43.3	4.8
13	PME+ES	Frequency, urgency, nocturia	794.7	10.0
19	PME	Frequency, urgency, nocturia	1538.6	229.3
21 **NB bladder ca 6 yrs ago	PME+ES	Frequency, urgency, nocturia	968.3	179.2
30	Control	Frequency, urgency, nocturia	736.0	11.2
33	PME	Frequency, urgency, nocturia	1054.6	236.6
41	Control	Frequency, urgency, nocturia	20.0	14.8
43	PME+ES	Frequency, urgency, nocturia	268.8	424.2
46	Control	Frequency, urgency, nocturia	395.5	277.3

56	PME	Frequency, urgency, nocturia	243.0	4.7
59	PME+ES	Frequency, urgency, nocturia	584.0	265.2

Previous Urological Surgery. As some have implicated urologic surgery in the aetiology of incontinence, a Table 4.8 shows the Time 1 and Time 4 urine loss follows (Table 4.8; a complete table of grams of urine loss by individual subject is provided in Appendix 16). Of the 5 subjects who had had previous transurethral resection of the prostate or resection of bladder tumour, only 1 had less than 10 gm urine loss at Time 4. However, the sample size was too small to draw any conclusions on these findings.

In summary, both treatment and control groups improved equally over time. Treatment did not change the mean grams of urine loss immediately after treatment or at follow up post treatment measures, nor did weeks post operatively or age. A past history of urologic surgery may have impacted continence but sample was (n=5) was too small to make any inferences.

Table 4.8
Time 1 and Time 4 Urine Loss for Subjects With History of Urologic Surgery

Case Number	Group	Baseline Urine Loss	Time 4 Urine Loss
#3 (TURP)	PME	703.3	362.8
#14 (TURP)	PME	144.8	4.2
#21 (TURBT)	PME+ES	968.3	179.2
#22 (TURP)	Control	145.7	120.9
#45 (TURP)	PME	140.1	23.5

Effectiveness of Electrical Stimulation plus Pelvic Muscle Exercises

To test for differences in urine loss at Time 2 (12 weeks after therapy)

between the two treatment groups (see Figure 4.3) an independent two-tailed t-test was used, with *PME* as one group and *PME+ES* as the other. The t-test revealed that the mean total urine loss of subjects in the PME group was not significantly different from that of subjects in the PME+ES group ($t=1.42$, $df=35$, $p=0.16$).

Further testing with repeated measures ANOVA was done to see if the two treatment groups differed in reduction of urine loss at any of the 4 measurement points (Time 1, Time 2, Time 3, or Time 4). No significant differences were detected between the two groups ($F=0.16$, $p=0.69$). Thus, the hypothesis that electrical stimulation would enhance the return to continence when compared to pelvic muscle exercises was not accepted. Figure 4.6 shows the trend lines for each of the three groups. Note a slight rise in mean gm urine loss at Time 4 for the PME+ES group.

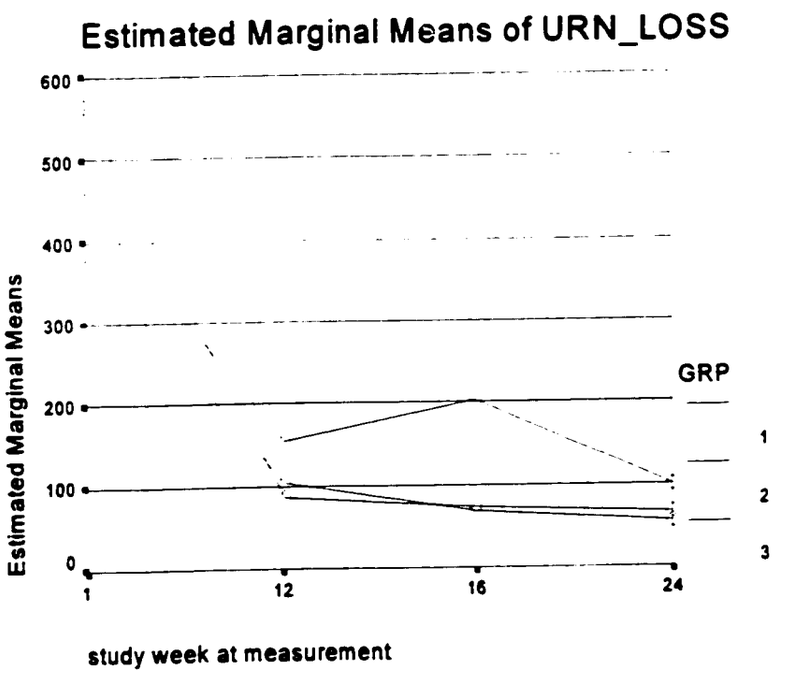


Figure 4.6: Mean urine loss by Each Group at Times 1, 2, 3, & 4

The Impact of Incontinence

It was hypothesized (Hypothesis 3) that the reported impact of incontinence as measured by the IIQ-7 would be lower at Time 2 for the treated subjects regardless of group than for the non-treated control group.

The mean IIQ-7 score decreased over time as urine loss decreased. Mean score at study entry for the whole sample (Time 1) was 54 (SD= 27; range=5 to 100). Table 4.9 shows the mean scores in each group from baseline to 24 weeks from study entry.

Table 4.9
Mean IIQ-7 Scores By Group Over Time

	Time 1 Baseline	*Time 2* 12 Weeks	*Time 3* 16 weeks	*Time 4* 24 Weeks	t P values (Comparing baseline to Time 2)
Group					
Control					
Mean (SD)	49 (31)	21 (20)	24 (25)	20 (25)	-1.24 p=0.22
Minimum	5	0	0	0	
Maximum	100	62	64	86	
PME					
Mean (SD)	59 (22)	24 (26)	23 (25)	22 (24)	
Minimum	24	0	0	0	
Maximum	95	95	88	86	
PME+ES					
Mean (SD)	54 (25)	36 (26)	35 (27)	25 (25)	
Minimum	14	0	0	0	
Maximum	100	86	90	81	
Total					
Mean (SD)	54 (27)	27 (24)	28 (26)	22 (24)	
Minimum	5	0	0	0	
Maximum	100	95	90	86	

Note: Range Of Scores= 0 to 100, with higher score indicating higher level of impact.

Mean score of the Control Group at Time 1 was 48.9 (SD=31.3) and for the Treatment Group was 56.2 (SD=24.1). At 12 weeks (Time 2) the overall

mean score was 27 (SD= 24; range=0 to 95). Mean score for the Control Group at Time 2 was 21.4 (SD=19.5) and for the Treatment Group, 29.9 (SD=26.5).

A two-tailed t-test for independent groups was used to test for differences of impact of incontinence between the two groups: *control* and *treatment*. The t-test revealed that the mean IIQ-7 at Time 2 (12 weeks from baseline and immediately after therapy for the treatment subjects) did not differ significantly between control and treatment groups (t=-1.24, df=51, p=0.22).

Next, a repeated measures ANOVA was done to test whether the IIQ-7 scores of the three groups differed among each other or differed over time (Table 4.10). The differences among Control, PME, and PME+ES groups were not statistically significant (F= 0.37, p=0.70), that is there was no overall difference on recorded impact of urinary incontinence at any of the data measurement points nor were any differences found among subjects over time (F=0.90, p=0.50).

Table 4.10
MANOVA Summary Table for Group by Time by Mean IIQ-7 Score

Source of Variance	SS	DF	MS	F	p
Among Treatment Groups	1326.72	2	663.36	0.371	0.70
Among Treatment Groups Error	73267.50	41	1787.01		
Within Subjects					
Time	31295.48	3	10431.83	37.91	0.001
Group x Time	1488.45	6	248.07	0.90	0.50
Within Subjects Error	33850.59	123	275.21		

The effect of time was highly significant (F=37.91,p=0.001). Over time and as urine loss decreases, there was a corresponding decrease in the

reported impact of urinary incontinence. This change was related to time and not to therapy. Figure 4.7 illustrates the mean IIQ-7 over time.

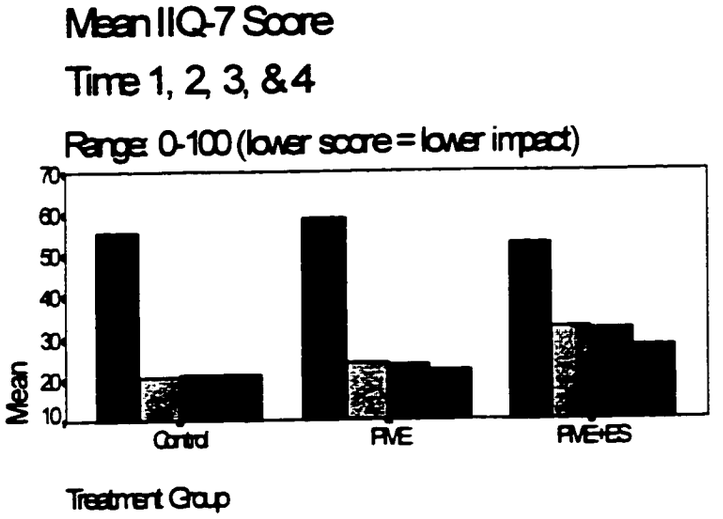


Figure 4.7. Mean IIQ-7 Scores Over Time By Group

To test the association between IIQ-7 scores and grams of urine loss, correlation coefficients were calculated. There was a moderate, positive relationship between decreased urine loss and lower IIQ-7 score. Pearson r ranged from .34, (p= 0.003) at Time 1 to .511, (p=0.001) at the final pad test (Time 4). Table 4.11 shows the correlation coefficients. Thus, as no significant differences were detected between the treatment and control groups, the hypothesis that IIQ-7 score would be lower in treated subjects was rejected.

Table 4.11
Correlation Coefficients Between IIQ-7 And Total Urine Loss At 4 Points

	Time 1	Time 2	Time 3	Time 4
IIQ-7 1	.3434 (61) P=.003			
IIQ-7 2		.4729 (52) P=.000		
IIQ-7 3			.5521 (45) P=.000	
IIQ-7 4				.5087 (37) P=.001

Quality of Life After Treatment for Urinary Incontinence

To test the fourth hypothesis that subjects who received treatment for incontinence would report higher scores on all quality of life measures at Time 2 than the non-treated control subjects, two tailed t-tests for independent groups were used with each of the six variables (physical, role, emotional, cognitive, social, and quality of life). The t-test revealed that at Time 2 (12 weeks from baseline and immediately after treatment for the 2 treatment groups) the mean scores on the EORTC quality of life instrument did not differ (Table 4.12). Some of the values are in a negative direction, suggesting that the treatment groups actually reported more symptoms and financial impact than the control group. Further analysis with a t-test for the final measure was also unable to detect any differences between the treatment and control groups.

To test for differences between the three groups over time, repeated measures MANOVA was conducted on each of the variables in Table 4.12. Although physical functioning was different between the three groups ($F=.453$, $p=0.02$), none of the other variables were statistically significant.

Looking at the individual question on quality of life, no statistically significant differences were detected among groups. Of interest is that, in this question, time was also not significant (F=2.59, p=0.06). Although graphically, on Figure 4.8, the Control and PME group appear to score much lower at baseline than the PME+ES group, these differences were not significant (F=0.04, p=0.96) (Range of possible scores: 0-100 with 0 being *very poor* and 100 being *excellent* quality of life).

Figure 4.8 shows the single question on quality of life in all three groups from Time 1 to Time 4. Both the Control and PME groups reported a lower quality of life at baseline than the PME+ES group. This difference was not statistically significant. A gradually rising (better QOL) score is noted from baseline to Time 4 at approximately 8 months postoperatively.

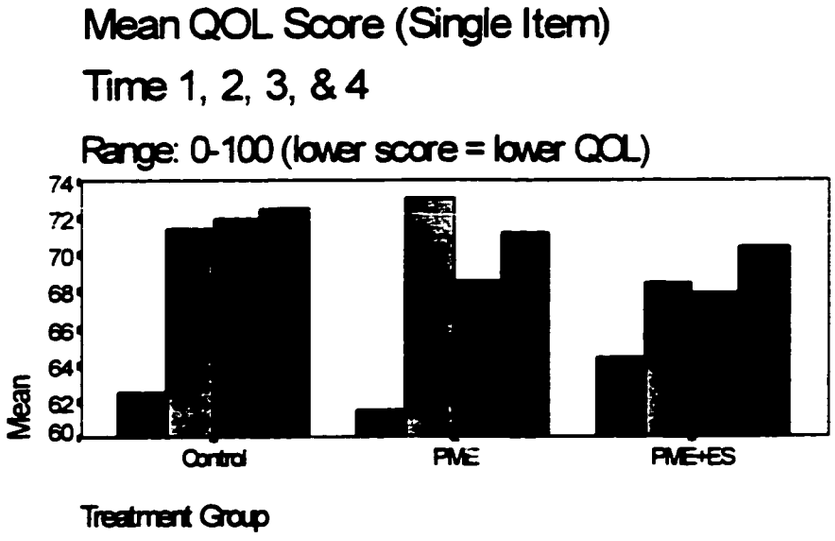


Figure 4.8. Single Question on QOL By Group Over Time

In summary, all groups reported improved physical, role, emotional, social, and cognitive functioning over time but no group differed significantly from another. Treatment did not appear to impact the reported functioning after radical prostatectomy. As expected, symptoms related to postoperative recovery decreased over time. Again, no significant differences were noted among any of the groups. Thus, the hypothesis was not accepted that therapy to treat incontinence would result in an improved quality of life.

Additional Findings

Symptom Inventory

The urinary incontinence symptom inventory (Appendix 11) was a nominal scale instrument constructed by the researcher intended to record several specific questions about incontinence including the number of pads used and the number of times wet underwear or wet clothing occurred in a given period. Full responses are included in Appendix 17.

Five questions of the Symptom Inventory addressed the subjective impact of urinary incontinence and erectile dysfunction (Table 4.13). Responses were scored on a scale of 1 to 4, with 1 being *Not at* all and 4 being *Very Much*. For each question, the descriptive statistics are first presented followed by the results of repeated measures ANOVA. Complete responses were available on 58 subjects at Time 1 (baseline) and 48 subjects at Time 4.

In response to the question, *Does urine leakage affect your life?* at Time 1, as expected, 42 of 58 (72%) subjects who responded wrote that leakage affected their lives *moderately* or *very much* (13 Control; 14 PME; 15 PME+ES). At Time 4, as continence returned or improved, only 25% subjects reported that incontinence affected their lives (3 Control; 3 PME; 6 PME+ES). Although there were no differences at any of the 4 data collection point among the 3 groups ($F=1.77$, $p=0.19$) there was a statistically significant difference

over time (F=24.72, p=0.001).

Table 4.12
Mean (SD) EORTC Quality of Life Questionnaire C-30 scores at Baseline

	Time 1 Mean(SD)	*Time 2* Mean (SD)	*Time 3* Mean(SD)	*Time 4* Mean (SD)	t	P
Functioning Scales (Range of possible scores 0 to 100 with higher score indicating higher level of functioning						
Physical					t	P
Control	70 (24)	90 (15)	89 (14)	85 (27)	.78	NS
PME	78 (28)	84 (22)	93 (10)	98 (6)		
PME+ES	90 (17)	85 (18)	90 (13)	79 (22)		
Role						
Control	54 (31)	91 (12)	92 (16)	85 (21)	.048	NS
PME	55 (34)	89 (17)	78 (37)	84 (32)		
PME+ES	68 (34)	80 (23)	87 (14)	70 (38)		
Cognitive						
Control	81 (28)	88 (20)	86 (25)	81 (30)	0.91	NS
PME	81 (28)	90 (14)	92 (9)	85 (18)		
PME+ES	82 (17)	78 (24)	81 (21)	81 (15)		
Emotional						
Control	73 (29)	87 (17)	80(28)	80 (25)	1.45	NS
PME	75 (25)	86 (15)	83 (20)	88 (16)		
PME+ES	72 (28)	69 (27)	76 (25)	74 (23)		
Social						
Control	59 (35)	85 (19)	77 (24)	86 (28)	1.11	NS
PME	50 (30)	83 (18)	78 (30)	85 (29)		
PME+ES	68 (23)	67 (22)	79 (20)	73 (25)		
Quality of life	67 (23)	66 (24)	72 (25)	72 (23)	-0.57	NS
Control	64 (19)	73 (16)	74 (14)	74 (23)		
PME	64 (19)	66 (25)	73 (22)	71 (22)		
PME+ES						

Table 4.12
Mean (SD) of EORTC Quality of Life C-30 scores

Symptom Scales (Range of scores 0 -100, higher score indicates higher level of symptom)

	Baseline (Time 1)	Time 2 Mean (SD)	Time 3 Mean (SD)	Time 4 Mean (SD)		
Fatigue						
Control	44 (26)	20 (14)	27 (24)	34 (22)	-0.65	NS
PME	33 (24)	24 (20)	19 (18)	20 (27)		
PME+ES	27 (22)	30 (26)	24 (28)	24 (24)		
Nausea & Vomiting						
Control	1 (4)	2 (8)	0 (0)	4 (10)	-0.41	NS
PME	1 (4)	2 (9)	6 (19)	3 (10)		
PME+ES	4 (11)	4 (12)	6 (19)	0 (0)		
Pain						
Control	17 (28)	10 (20)	8 (20)	17 (21)	0.55	NS
PME	14 (26)	8 (11)	6 (15)	7 (13)		
PME+ES	18 (20)	8 (21)	3 (10)	7 (19)		
Dyspnea						
Control	10 (15)	9 (19)	10 (16)	17 (22)	-1.16	NS
PME	6 (13)	9 (15)	6 (13)	8 (15)		
PME+ES	12 (20)	22 (30)	14 (22)	19 (26)		
Sleep disturbance	11 (16)	11 (16)	20 (21)	22 (26)	-0.92	NS
Control	20 (25)	20 (25)	17 (22)	14 (17)		
PME	29 (35)	29 (35)	19 (26)	29 (40)		
PME+ES						
Appetite loss	3 (10)	2 (8)	0 (0)	3 (10)	0 39	NS
Control	2 (8)	0 (0)	0 (0)	3 (10)		
PME	5 (17)	7 (26)	8 (21)	0 (0)		
PME+ES						
Constipation	13 (25)	3 (10)	8 (15)	14 (17)	-1.35	NS
Control	19 (26)	13 (28)	11 (22)	14 (30)		
PME	16 (26)	9 (20)	6 (13)	5 (13)		
PME+ES						
Diarrhea	6 (17)	7 (17)	6 (13)	3 (10)	0.13	NS
Control	15 (26)	7 (14)	0 (0)	3 (10)		
PME	5 (12)	9 (20)	18 (35)	10 (16)		
PME+ES						
Financial	21 (36)	2 (7)	8 (15)	8 (21)	-1.82	NS
Control	19 (31)	9 (23)	8 (21)	3 (10)		
PME	19 (32)	18 (21)	15 (23)	19 (26)		
PME+ES						

In the second question, it was asked whether *it would bother you if you had to spend the rest of your life with urine control the way it is now?* Initially, the thought of spending the rest of one's life needing four or five incontinent pads a day drew a negative response. Forty-one subjects replied *Very Much* and 8, *Moderately*, for a total of 49/58 (84%) responding that they would be very bothered if they had to spend the rest of their life with control the way it was at the baseline measurement. As control improved, the mean response decreased so that at Time 4, 61% of subjects would still be quite bothered with their current bladder control. The 3 groups did not differ in their responses at any of the 4 data collection points ($F=1.31$, $p=0.28$). The effect of time from Time 1 to Time 4 was statistically significant ($F=27.71$, $p=0.001$).

At Time 1, in response to the question *Does erectile dysfunction (impotence) affect your life?*, 31 of 58 (53%) subjects wrote that the effect of erectile dysfunction on their lives was *moderate* or *very much* (11 Control; 7 PME; 13 PME+ES). This response rose slightly and at Time 4, 61% reported that the effect of erectile dysfunction on their lives was *moderate* or *very much*. Neither time alone ($F=0.84$, $p=0.48$) nor group differences ($F=0.99$, $p=0.44$) were detected. Similarly, when subjects were asked *Would it bother you if you had to spend the rest of your life with erections the way they are now?*, at Time 1, 31 of 58 (53%) replied that they would be bothered *moderately* or *very much* and at Time 4, 61% reported that spending the rest of their life with erectile function as it presently was would bother them *moderately* or *very much*. Again, responses were stable over time. There were no group differences at any of the 4 data collection points ($F=0.40$, $p=0.68$). Of note is that responses did not change significantly over time ($F= 0.51$, $p=0.67$).

Finally, subjects were asked *If you had to do it again, would you choose*

radical prostatectomy as treatment for your prostate cancer? Overall, however, and despite some concerns, most men would still choose radical prostatectomy as the treatment option over radiotherapy or watchful waiting. The range of possible scores (1=*No* to 4=*Yes)* was almost equal per group at Time 1 with 26 of 58 (50%) saying *yes* and 17 (32%) stating they would *probably* choose surgery again. It is of interest that at the final pad test (Time 4), 92% of the Control group would choose or probably choose surgery compared with 71% of the PME group and 73% of the PME+ES. However these differences were not statistically significant among groups ($F=0.86$, $p=0.43$.

One man stated: "If I were informed about the type of cancer, aggressive or mildly docile, then I would make the choice [of surgery]. Now being aware of the incontinence problem and if I were to know it would continue indefinitely, then my choice would not be prostatectomy. I'm still unaware of the type of cancer [aggressive vs slow] nor the prognosis of the incontinence problem".

Prostate Cancer Module

The module is a symptom-specific instrument assessing 5 categories of symptoms specific to treatment of prostate cancer: urinary symptoms, sexual functioning, satisfaction with sexual activity, weight gain or loss, and hot flashes. Responses range from 0 to 100 with 0 reflecting no problems and 100 reflecting significant problems. ANOVA did not reveal any differences among groups at any of the 4 data collection points, with one exception. At baseline, in response to the question, *Did your condition limit your level of sexual activity*?, the control group responded more negatively than did the PME or PME+ES groups ($F=4.47$, $p=0.02$). However, this difference was not statistically significant at Times 2, 3, or 4. Table 4.14 shows the mean scores (standard deviations) of the prostate cancer module.

Table 4.13
Summary of Selected Symptom Inventory Responses
All scores: 1=Not at all; 2=A little; 3=Moderately; 4=Very Much

Question	*Time 1*			*Time 2*			*Time 3*			*Time 4*		
	Cont	PME	PME +ES	Cont	PME	PME +ES	Cont	PME	PME +ES	Cont	PME	PME +ES
1. Does urine leakage affect your life?												
Not at all	2	2	0	9	2	3	6	4	3	7	6	2
A little	4	3	4	7	7	6	6	4	7	5	8	4
Moderately	6	7	5	3	5	4	4	4	3	2	1	4
Very Much	7	6	10	2	2	5	1	1	5	1	2	2
2. Would it bother you if you had to spend the rest of your life with urine control the way it is now?												
Not at all	1	0	0	4	4	3	4	5	3	5	6	2
A little	1	1	2	5	4	5	3	2	6	5	6	2
Moderately	3	2	3	5	2	2	6	4	1	3	2	3
Very Much	14	13	14	7	6	8	4	2	8	2	3	5
3. Does impotence affect your life?												
Not at all	4	2	2	6	1	5	4	0	3	3	1	2
A little	4	6	3	5	7	1	5	4	4	3	7	1
Moderately	7	2	8	4	3	6	4	7	8	6	5	3
Very Much	4	5	5	5	5	6	4	2	3	3	4	6
4. Would it bother you if you had to spend the rest of your life with your erections the way they are now?												
Not at all	2	4	3	3	3	5	4	1	4	2	2	2
A little	5	4	3	6	6	0	1	4	3	4	4	3
Moderately	7	2	5	4	4	8	7	5	7	5	7	2
Very Much	5	5	7	5	3	5	5	3	4	4	4	5
5. If you had to do it again, would you choose radical prostatectomy as treatment for your prostate cancer?												
No	2	1	1	1	2	2	0	1	2	0	0	0
Not Sure	2	2	2	1	2	4	2	1	3	1	5	3
Probably	5	6	6	5	4	5	4	5	7	5	3	5
Yes	9	7	10	14	8	7	11	7	6	9	9	3

Table 4.14
Prostate Module Mean Scores (SD) by Group Over Time

	Time 1	Time 2	Time 3	Time 4	MANOVA
Urinary Symptoms				0=Not at all; 100=Very Much	
Control	50.7 (20.2)	27.5 (20.9)	28.3 (19.6)	26.7 (17.0)	
PME	62.3 (17.0)	32.3 (17.5)	29.2 (18.1)	30.0 (16.7)	
PME+ES	50.3 (21.5)	33.1 (23.2)	28.9 (19.5)	32.5 (17.3)	NS
N	55	52	46	43	
Did you have hot flashes?				0=Not at all; 100=Very Much	
Control	5.0 (16.4)	4.8 (15.9)	7.8 (25.1)	13.3 (24.6)	
PME	11.7 (26.2)	2.2 (8.5)	7.1 (19.3)	1.9 (8.0)	
PME+ES	11.8 (28.8)	14.6 (24.3)	6.7 (18.7)	9.1 (21.6)	NS
N	54	52	46	43	
Did you gain weight?				0=Not at all; 100=Very Much	
Control	17.3 (19.9)	20.6 (28.8)	17.5 (20.7)	24.3 (29.5)	
PME	18.7 (24.2)	26.6 (25.9)	12.8 (21.7)	25.3 (25.0)	
PME+ES	22.9 (31.6)	29.1 (36.3)	26.9 (27.8)	21.2 (34.3)	NS
N	53	52	46	43	
Did your condition limit your interest in sex?				0=Not at all; 100=Very Much	
Control	77.3 (27.6)	74.5 (27.8)	77.8 (24.1)	70.4 (33.6)	F=4.47, p=0.02**
PME	94.8 (14.3)	85.9 (29.3)	90.7 (8.81)	90.3 (10.2)	F=0.78, p=0.46
PME+ES	93.4 (10.8)	82.3 (26.1)	78.6 (29.5)	85.8 (33.1)	F=1.35, p=.27
N	53	50	44	43	
How satisfied were you with your sexual activity?				0=Not at all; 100=Very Much	
Control	16.7 (33.3)	17.6 (32.2)	25.1 (35.6)	16.7 (28.6)	NS
PME	10.4 (23.6)	22.2 (37.1)	5.1 (12.4)	10.4 (20.1)	
PME+ES	15.5 (24.8)	19.1 (28.5)	17.8 (33.1)	33.4 (42.2)	
N	51	48	44	41	
Did you lose weight?				0=Not at all; 100=Very Much	
Control	24.3 (30.9)	6.3 (17.1)	4.1 (11.3)	4.5 (17.3)	NS
PME	6.2 (18.2)	0 (.00)	7.7 (20.0)	5.8 (12.9)	
PME+ES	12.4 (16.5)	10.4 (26.4)	6.2 (18.2)	0 (.00)	
N	53	52	45	43	

Adherence to Exercise Regimen

Most men adhered conscientiously to the prescribed exercise regimen. This was a considerable time commitment by the end of the sessions working up from 10 minutes three times a day initially to 30 minutes three times a day. Such adherence reflects the determination men had in overcoming the urinary incontinence. Being in the research project and taking part in regular physiotherapy gave the men encouragement and hope that if they worked hard, they would achieve bladder control. Men in the control group did not exercise regularly.

Postoperative Concerns

The time from discharge to approximately 3 months postoperatively was described as stressful and frustrating because of a perceived lack of information about life-after-discharge and because of a perceived lack of health care professional support. Based on the informal initial interview with the researcher, the discharge period appeared to have 3 phases: (1) day of discharge to catheter removal; (2) catheter removal to approximately three months post surgery; and (3) 3 months onward. Issues raised during these phases were expressed by all subjects although the 15 men and their spouses who received home care expressed fewer concerns than those who did not.

Discharge Day to Catheter Removal

All patients were discharged with an indwelling catheter which was removed approximately 21 days postoperatively. Subjects complained of painful bladder spasms, by-passing, and haematuria. Although written information was provided on catheter care, most men stated that they were not prepared for the discomfort of the catheter nor were they clear on how to care for it or clean the drainage bag. The days from discharge to catheter removal were graphically described:"felt like I had been kicked in the rear end with a

cowboy boot" or "felt like I had a frozen hard ball stuck up there" (rectal pain). Some men went back to emergency because of catheter pain or bypassing, or haematuria. One catheter was obstructed with clots. Overall, men and their spouses felt uninformed about wound care, pain control, and catheter care. "I'm a tough old bugger and it would have helped to have the whole story".

Catheter Removal to 12 Weeks Post Surgery

Not all subjects were contacted by the researcher before catheter removal approximately 21 days postoperatively, but those who were had little or no knowledge about incontinence pads--where to go, what to use, or the amount of heavy leakage they would have for several days after catheter removal. Over the telephone, on the initial contact, one gentleman described how he felt a week after the catheter had been removed: "I was crying, sitting at the kitchen table while my wife washed all my clothes. No one told us where to go to buy diapers. If I had known it would be like this, I wouldn't have done it. They probably don't tell you because you would change your mind [and not have surgery]." Another man went back to emergency with "attack of pain" about 4 hours after catheter removal which was attributed to urinary tract infection. "I didn't know a bladder infection might occur--they should have told me".

The degree of urinary incontinence was a shock to all men. "Even though the physician spent a long time with me and answered all my questions before surgery, the only thing I heard was **Cancer**. The biggest shock is to find I am incontinent. It just hadn't penetrated and it is devastating". Another said: "I think he told me about incontinence but I didn't know he meant this". The day of catheter removal was described as the "worst day of my life"; "never knew it would be like this". One man went to emergency the evening

of his catheter removal because he was "gushing". One man stated: "I felt miffed that I didn't know this, I was naive. I didn't expect any leakage and didn't know how to handle it" and another said: "I was told to take a pad with me when I went to have the catheter tube taken out, however I was not told to put a pad on before I got off the table. It was quite devastating to flood when I stood up". Feelings were described thus: "Gives thoughts of suicide--had never thought of it before, always attacked and solved a problem or dealt with it. But now, I am out of control, there is nothing I can do. It affects my life totally. I haven't admitted to anyone who knows me that I had cancer. They might take a different attitude toward you. Nobody knows except the doctor and Henry (another patient). I tell them I had gall bladder".

All men needed reassurance that they would improve and that most men do regain control. One man needed a lot of reassurance because "the guys at church said I shouldn't have had surgery".

Three months onward

In the words of one subject speaking on the topic of postoperative recovery in general and urinary incontinence in particular: "This whole thing leaves a lot to be desired..." Another said, "The doctor told me not to get despondent but it's hard not to get frustrated". The men who did not regain most of their bladder control, were understandably upset and disappointed. "I know all about Kegel exercises. The only problem is that they no longer work for me. Thank heavens I am retiring soon. I don't know if my students can smell me or not, but I certainly can...I find the whole thing extremely embarrassing."

By 3 months, the men who still had a small amount of leakage and who required a pad "just in case" had adjusted to the inconvenience of leakage. They were ready to get on with life but erectile dysfunction interfered. Even

treatment for erectile dysfunction. It was said more than once: "I've lost my manhood". One man blamed his impotence on his wife of 40 years saying that he could not get an erection because she was having an affair. Although they wanted to be treated, most men were shy, embarrassed, and afraid to ask for help, rationalizing that the satisfaction of curative cancer surgery should be adequate. Wives were equally interested in having their spouses get treatment, in part because they worried about their husband's sense of self-esteem but also because couples had enjoyed comfortable sexual relationships prior to surgery and these had ended abruptly.

Complete lack of urine control occurred in the first days after catheter removal for nearly all individuals. The first signs of returning bladder function occurred between one to two weeks after the catheter was removed. Return to function was first heralded by a sensation of bladder filling when lying down, followed by nocturia. Next continence occurred when supine or sitting still. Night time dryness soon followed and, by 3 months, of the 180 men interviewed over the telephone, 67% were nearly dry during the day, were pleased with their progress, and did not feel the need for therapy.

Questionnaire Completion

With two exceptions, subjects completed the questionnaires without difficulty in the privacy of their homes, without the researcher present. For the two gentlemen who were functionally illiterate, the researcher read the questions to the subject and allowed a choice to be made. One man was in the control group and the other in the stimulation group. Although the responses of these two subjects could have been influenced by the presence of the researcher, every attempt was made to provide an atmosphere conducive to honest answering. Thus, the responses are included in the overall data analysis.

analysis.

Summary

The initial proposal in this study was that pelvic muscle exercises plus electrical stimulation would result in return to continence more rapidly than with pelvic muscle exercises alone. It was suggested that early treatment would have an impact on patient adherence to the treatment programme as well as be more cost effective in terms of pad usage. Intensive physiotherapy and nursing involvement were expected to help with the patient's ability to cope with incontinence, improve reported quality of life, and reduce the impact of incontinence on the subject's life. In the sample under study, no significant effect of treatment intervention could be demonstrated. However, several subjective findings about the early discharge period provide some important data about supportive interventions.

The study has also been an evaluation of one aspect of the physiotherapy incontinence programme funded by Capital Health Region and an informal evaluation of the preadmission clinic teaching programme for men with early stage prostate cancer. It has also enhanced the understanding of the impact of incontinence on quality of life, the impact of early discharge after radical prostatectomy, and has provided some longitudinal data on return of continence. Some recommendations are made with respect to intensive intervention with pelvic floor exercises prior to 12 weeks post surgery.

CHAPTER V
DISCUSSION

Radical prostatectomy, as the primary treatment of localized prostate cancer, has progressively increased. This trend has seen a fourfold rise in surgery at some American centres in the past decade (Litwiller, Djavan, Klopukh, Richier, & Roehrborn, 1995). The increase is related to several factors, including a rising incidence of prostate cancer, evidence that a number of patients will have a positive biopsy after radiation therapy, and improvements in surgical techniques with a corresponding decrease in morbidity. However, despite improved surgical techniques, urinary incontinence remains the cause of significant morbidity after radical prostatectomy, particularly in terms of quality of life. Therefore, the overall purpose of this study was to test four hypotheses. The first two evaluated the effectiveness of two frequently used postoperative strategies to increase urinary control, pelvic muscle exercises (PME) and PME augmented with electrical stimulation (ES). The third and fourth hypotheses assessed the impact of incontinence on quality of life using two standardized instruments,.

Study Participants

During the data collection period from December 1995 to March 1997, 180 men post radical prostatectomy who were at least 4 weeks post operatively were recruited. Of these 180 potential subjects, 63 met the eligibility criteria and were randomized to control, PME, or PME plus ES. There were 5 dropouts, 3 of whom had bladder neck contractures, 1 had rectal pain when he did the exercises, and 1 went on a 4 month holiday to Mexico. Subjects were typical of Canadian men who have radical prostatectomies (Gray, 1997). Their mean age was 66.8 years, 76% were retired or semi-retired, 91% owned their own homes, 74% lived in the city and 26% lived in rural farming

communities or towns less than 50,000. Most subjects were married (95%) and had children (98%). All men spoke English but two men had less than a grade 6 reading ability and required assistance with questionnaire completion. All subjects were distressed by their post operative incontinence and were motivated to participate in the project.

Urine Loss

The first hypothesis was an exploration of whether men with urinary incontinence four weeks or more post radical prostatectomy would benefit from treatment with PME's or PME's plus ES when compared to a non-treated control group. It was proposed that early intervention with pelvic muscle exercises or pelvic muscle exercises plus electrical stimulation would accelerate the improvement in bladder control which is known to occur for the first 12 months after radical prostatectomy (Donnellan, Duncan, MacGregor, & Russell, 1997; Jønler et al., 1996). The findings of this study add support to the literature that continence is regained over time. Early intervention, however, did not affect the rate of change. Both treatment and control groups improved similarly, with improvement unaffected by such factors as postoperative weeks or age. The lack of treatment effect has not been reported in the literature and was an unexpected result. Based on the work of Burgio, Stutzman, and Engel (1989), who successfully treated men post prostatectomy with biofeedback and pelvic muscle exercises, it was anticipated that subjects who were treated would improve at least 50% over those in the control group. Burgio's study differed from the present study in some important ways: advice on urge suppression and fluid management was part of the therapy, no control group was included, and men were 6 months or more post surgery. It is possible that these behavioural interventions improved the outcome of therapy. Such factors should be taken into account in future research studies.

The second hypothesis was designed to test whether electrical stimulation in addition to pelvic muscle exercises would enhance the achievement of bladder control. Electrical stimulation in women with either stress or urge incontinence has been successful in randomized, controlled trials (Sand et al., 1995). As the therapy has also been reported to be successful in men post radical prostatectomy in non-randomized studies, and because electrical stimulation is believed to enhance the proprioceptive awareness of a levator ani contraction, stimulation was chosen as the alternative strategy for incontinence therapy. Unfortunately, stimulation did not change the degree of incontinence immediately after 12 weeks of treatment nor did it change the rate of improvement over time. Looking at Figure 5.1, men who received stimulation appeared to do slightly worse than the men who received PME only at all three follow up pad tests, despite a lower mean baseline urine loss.

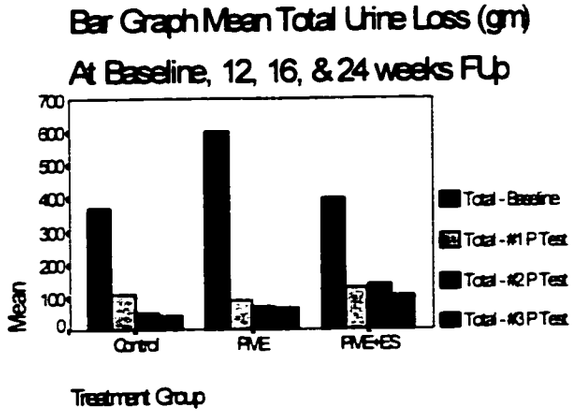


Figure 5.1. Mean Grams of Urine Loss by Group

The mean percentage change from baseline to Time 2 was 85% for the PME group and 69% for the PME+ES group. From baseline to Time 3, the percentage change was 89% (PME) and 64% (PME+ES) and, finally, from

baseline to Time 4, the percentage change was 88% (PME) and had risen to 79% for the PME+ES group.

To explore the effect of treatment further, a subset of men was chosen who were more than 37 weeks post surgery. Four men in the study (PME=1, PME+ES=3) fell into this subset and all 4 had urodynamically confirmed stress urinary incontinence. These subjects were believed to have plateaued with respect to continence recovery, and it was expected that any effect of treatment would be noticeable. Mean urine loss in the subset at baseline was 233.9 gm and immediately after treatment was 164.7 gm. Although the sample size was too small to make any statistical inferences, there may be a trend towards improvement. Figure 5.2 shows a 50% reduction in grams of urine lost in the PME subject and an approximate 25% reduction in the three PME+ES subjects.

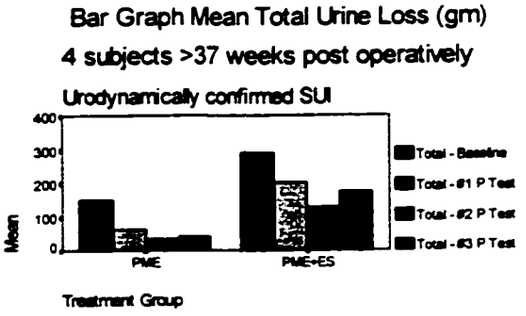


Figure 5.2. Select Subjects Mean Urine Loss

Further research is required to evaluate the effectiveness of therapy in men more than one year postoperatively and as well, to evaluate whether a 25% reduction in leakage is subjectively acceptable. A similar research project is currently underway at Emory University (Bennett, Foote, Green, Killorin, & Martin, 1997) in which men are randomized to sham or electrical stimulation

with a microgyn (Incare ™) unit. Both subjects and researchers are blinded to the assignment. Of the 39 subjects enrolled to date, 32 have improved significantly and, although it is too early to reveal the randomization status, it appears that both the sham and treatment groups are improving in a similar fashion.

Improvement Over Time

One of the notable findings of this study was the improvement in bladder control over time in all three groups, particularly from baseline to Time 2. From a review of the literature on treatment of post prostatectomy incontinence, the significance of improvement over time has not been taken into account, and, indeed, was a short-coming in the present study. The findings revealed that gross incontinence occurs after catheter removal but that an improvement may begin almost immediately. By 2 weeks after catheter removal (approximately 4 weeks post surgery), only 33% of 180 men who were contacted for inclusion in the study considered themselves incontinent enough to be potential subjects. Of the 63 men recruited, at 12 weeks from baseline (approximately 4 months postoperatively), 32% of the sample had less than 10 gm of urine loss and at the final pad test (approximately 8 months postoperatively) 49% of the sample had less than 10 gm. Thus, in the sample under study, at a mean of 8 months post operatively, 15% of subjects still had urine leakage more than 10 gm (Calculated from the 180 potential subjects, 28 of 180 had greater than 10 gm of urine loss in 24 hours at 8 months post radical prostatectomy, for an overall incontinence rate of 16%). Although no generalizations can be made about this remaining 16%, except within the context of the sample studied, the figures do fit within the rates of incontinence cited in the literature (Jønler et al., 1996).

Risk Factors for Urinary Incontinence After Radical Prostatectomy

It is unclear why some men improve over time while a remaining few continue to suffer from incontinence. However, a variety of theories have been put forward on the risk factors and aetiology of post prostatectomy incontinence, most significantly age and detrusor dysfunction.

Age

Age as a risk factor (Kerr & Zincke, 1994) may be explained, in part because detrusor instability, decreased compliance, and decreased contractility are all more common in the elderly (Eastham et al., 1996; Gormley et al., 1993; Griffiths et al., 1992; Speakman, Sethia, Fellows, Smith, 1987). In the sample chosen, however, age was not a factor. No difference was detected in grams of urine lost at baseline or at the last pad test when comparing men less than 65 years of age to those over 65 or comparing those less than 70 years to those over that age. As well, older men are more likely to be taking medications which may affect continence (Khan, Mieza, Starer, & Singh, 1991; Yalla et al., 1982). In this study, Subject #25 (PME Group) was prescribed after the baseline interview, the α-blocker Terazosin 10 mg. At Time 2, at which time he changed to an alternate antihypertensive, the subject reported an improvement in his symptoms.

Bladder Neck Contracture

One risk factor noted by Litwiller, McIntire, Schnitzer, Roehrborn (1997) and which did appear important in the sample studied was bladder neck contracture. Of interest clinically is the finding that obstruction from bladder neck contracture occurred in one potential subject less than 24 hours after catheter removal. During the course of the study, three subjects were dropped because of bladder neck obstruction occurring approximately four months after surgery. Post dilatation, in informal telephone contact, all three

experienced significant incontinence which did not resolve completely. Thus, information on bladder neck contracture, cited as occurring in as many as 12% of men after radical prostatectomy (Meade & McLoughlin, 1996), should be incorporated into a preoperative teaching package.

Detrusor Dysfunction

Detrusor instability, poor compliance, and decreased contractility have all been implicated as significant in post prostatectomy incontinence (Foote, Yun, & Leach, 1991). In this study, none of the men had had preoperative radiotherapy, trauma, spinal cord lesion, or neurological deficits which might contribute to detrusor dysfunction but two had non insulin controlled diabetes, one diet controlled and one taking Diabeta. One of these men did not regain continence. Over 50% of the sample (30/58) described symptoms of preoperative urgency, frequency, and/or nocturia. Of note is that only 3 of the 14 men with nocturia alone had persistent incontinence, whereas 67% (8/12) of those with frequency, urgency, and nocturia had persistent incontinence.

If all the men who had undergone radical prostatectomy during the study period were evaluated by interview, and only those in the research study described diurnal frequency, urgency, and incontinence, then the relative risk of incontinence in those men with preoperative symptoms would be 7.1 (71% incontinent with 3 symptoms ÷10% of men with nocturia=7.1) (Sackett, Haynes, Guyatt, & Tugwell, 1991).

Symptom-Specific Scale

The limitations of history alone in determining bladder dysfunction have been well-documented (Gray & Marx, 1997; Leach, Yip, & Donovan, 1987). It is possible that at the baseline interview, men either could not accurately recall their preoperative symptoms or, if they could remember, the

symptoms were downplayed because of current distress over urinary incontinence. Thus the actual incidence of urgency and frequency may have been higher than reported. A symptom specific scale combined with detailed face-to-face interview might detect men at risk for bladder dysfunction. If a comprehensive, sensitive instrument could be developed, those men who describe symptoms of urgency and frequency could receive further investigations with urodynamics prior to radical prostatectomy. At a recent conference on the prevention of urinary incontinence, Ananias Diokno (1997) advocated full disclosure of risk factors to all men having radical prostatectomy. Diokno and Aboseif et al. (1994) both suggest that urodynamic evaluation prior to radical prostatectomy may be indicated for men who present with detrusor or sphincter dysfunction. Urodynamic results combined with the symptom scale could provide the practitioner with some objective guidelines for counselling the patient on his relative risk of incontinence.

Intrinsic Sphincter Deficiency

Post prostatectomy incontinence has been described as *intrinsic sphincter deficiency* (Aboseif, O'Connell, Usui, & McGuire, 1996). In the female, such a description refers to a non-compliant, stiff urethra which is not amenable to conservative therapy and requires surgical intervention with a sling procedure or periurethral collagen implant. In men, only modest success has been reported with either a sling procedure (Narayan, Tewari, Kamerer, 1997) or with collagen implant (Absoeif et al.) Although modified dissection around the striated muscle has significantly improved continence outcomes, some intrinsic nerve damage may be inevitable. Anecdotally, 5 men in the physiotherapy treatment group did not have any sensation of rectal squeezing although rectal sphincter tone was normal. Several sessions of electrical

stimulation, proposed to enhance proprioception, did not improve the sensory ability to detect a levator ani squeeze. Is the nerve damage, then, more extensive than we have traditionally believed? Nerve damage and urethral scarring could contribute to a stiff, immobilized urethra. Limitations in current urodynamic techniques do not permit the detailed evaluation which may enlighten us but further research is clearly required in this area. Without a clear understanding of the mechanism of postoperative incontinence, it may not be possible to offer optimum therapy for a potentially debilitating condition.

The Impact of Incontinence

The hypothesis concerning the impact of urinary incontinence after radical prostatectomy was explored using the IIQ-7. The mean score at baseline was 54 (range 0=no impact to 100=maximum impact) and at Time 2, the mean score was 22, at Time 3 mean score was 22 and at Time 4, the mean score was 19. No differences were found between groups. The percentage difference between Time 1 and Time 2 was 59%, and between Time 1 and Time 4 was 65%. A moderate correlation was found between grams of urine loss and impact score at all measurements (Time 1: Pearson r=0.34, p=0.003; Time 4: Pearson r=0.45, p=0.001). These results suggest that the IIQ-7 may be sensitive to both urinary incontinence and the impact of incontinence on one's life. However, because the correlation is only moderate, other influencing factors such as postoperative fatigue, discomfort, and individual coping strategies must be taken into account. The moderate correlation corresponds to the original authors' psychometric testing of the Incontinence Impact Questionnaire on women with the reported correlations with incontinent episodes (r=0.32, p=0.01) and pad tests (r=0.27, p=0.01). In men post artificial urinary sphincter implant, a mean of 7.2 years post surgery,

a strong positive correlation (r=0.75) was found between self-reported pad use and impact score (Haab, Trockman, Zimmern, & Leach, 1997). The absence of the objective measure of grams of urine loss detracts from the findings since by seven years postoperatively, men may have adjusted their lives to incontinence so that the impact of incontinence is much less than it would be in the early months after surgery.

Incontinence Impact Questionnaire (IIQ-7)

Although the IIQ-7 was originally tested only on women (Uebersax, Wyman, Shumaker, McClish, Fantl, et al., 1995), it was used in this study to assess the impact of incontinence in men. The instrument has not been widely tested and no reports have considered the reliability or validity in men. Fleshner and Herschorn (1995) utilized the IIQ-7 with a group of men, some of whom had had an artificial sphincter implanted but reliabiltiy or validity were not reported.

Face validity of the IIQ-7 in this study was checked by asking subjects to verify whether the questions "made sense" or applied to them. Subjects were not told that the instrument had been tested only on females. All subjects stated that the questions were reasonable and understandable. None of the subjects found the questions to be gender specific or inapplicable.

Content validity is "the extent to which an empirical measure reflects the specific domain of content" (Carmins & Zeller, 1979, p. 20). In the case of the IIQ-7, it is whether the instrument measures the content domain of the impact of incontinence on one's daily life. Content validity was supported by the accompanying subjective reports of participants that the instrument captured those aspects of men's daily life which were affected by incontinence.

Criterion validity was estimated by comparing question (L) of the urine symptom inventory, *Does leakage affect your life?*, with the IIQ-7 score. There

was a moderate, positive correlation between the question and the IIQ-7at Time 1 and Time 4 (See Table 5.1: Spearman r_2 ranging from 0.76, p=0001 at Time 1 to 0.78, p=0001 at Time 4). Construct validity was also assessed by comparing scores of the IIQ-7 with those of the EORTC-C30, version 2.0, as well as with grams of urine lost measured by 24 hour pad test. There was a moderate negative correlation between IIQ-7 and the single quality of life (QOL) score of the EORTC, that is as impact of urinary incontinence decreased (minimum 0), QOL was reported as higher (maximum 100). The low correlation between the single QOL score and the IIQ-7 probably reflects the relatively low percentage change from Time 1 to Time 4 when compared to the percentage change of the IIQ-7 over the same time period (See Table 5.2: Pearson Correlation coefficients ranging from -.5612, p=.0001 at Time 1 to -.4876, p=.001 at Time 4).

Table 5.1
Spearman Rank Correlations Between IIQ-7 and Urinary Symptom Question: *Does leakage affect your life?*

	IIQ-7 Time 1	IIQ-7 Time 2	IIQ-7 Time 3	IIQ-7 Time 4
Leakage affect life? Time 1	.7625 p=.0001			
Leakage Affect Life? Time 2		.7692 p=.0001		
Leakage Affect Life? Time 3			.8757 p=.0001	
Leakage Affect Life? Time 4				.7854 p=.0001

Table 5.2
Pearson Product-moment Correlations Between IIQ-7 And Single Quality Of Life Score (EORTC)

	Qlife1	Qlife2	Qlife3	QLife4
IIQ-7 Time 1	-.5692 P=.0001			
IIQ-7 Time 2		-.2989 P=.017		
IIQ-7 Time 3			-.3453 P=.011	
IIQ-7 Time 4				-.4876 P=.001

Test-retest reliability was not specifically checked in this study. However, testing at 4 points over time did occur. As the interval between the measurement of IIQ-7 at Time 2 and IIQ-7at Time 3 was only one month, and because grams of urine loss had stabilized (mean at Time 2=115.5; mean at Time 3=114.2; see Appendix 16), it seemed appropriate to test the consistency of the IIQ-7 at 2 similar measurement outcomes. There was a strong, positive correlation between the two measures (Pearson r .89, p=.0001) supporting the belief that IIQ-7 is a consistent measure of the impact of incontinence.

Quality of Life

In the fourth hypothesis, it was expected that the relationship between effective treatment for incontinence and reported quality of life would be tested. The instrument used to evaluate the effect of incontinence on quality of life was the EORTC-C30, version 2.0, an instrument which has been tested widely and validated on a number of different cancer groups. The EORTC appeared to reflect the impact of surgery on one's ability to carry out normal roles but may not have been specific enough to assess the effect of

incontinence on quality of life. Despite treatment, none of the groups differed on the individual scores of the EORTC questionnaire at any of the four data collection points (Appendix 4). As well, although the total urine loss dropped dramatically from Time 1(baseline) to Time 2 at 12 weeks, a corresponding marked drop in the EORTC scores did not occur. For example, the Global Health Status/QOL questions *How would you rate your health during the past week* and *How would you rate your overall quality of life during the past week* (0=very poor, 100= excellent added together to be a single response), had a baseline mean of 64.6 (Control=67, PME=64, PME+ES=63), compared with a mean of 73.0 at 12 weeks (Control=72, PME=71, PME+ES=76). Similar findings of a weak correlation between a generic quality of life instrument (Sickness Impact Profile) and amount of urine leakage was reported by Hunskaar and Vinsnes (1991) in females. The authors proposed that it was the presence of incontinence *per se* which affected quality of life, and that only cure of the problem would improve quality of life, not just a reduction in the number of leaks. The EORTC QLQ C-30 has been shown to be sensitive to symptom, functional, emotional, and social changes related to cancer but is not specific enough to detect the impact of urinary incontinence on quality of life.

In the present study, some artifacts may have been introduced by the timing of the questionnaire. At the initial testing, the majority of respondents were less than 12 weeks postoperative and were still recovering physical and role functioning. As well, for all intents and purposes, subjects believed they had undergone curative cancer surgery. Despite gross incontinence, their perceived relief at being *cured* of a life-threatening illness may have lessened the physical impact which urinary incontinence would have on their reported quality of life. In an attempt to control for these early postoperative changes, during data analysis, a subset of the sample was chosen who were 12 or more

weeks postoperatively at baseline. Figure 5.3 shows the mean responses to the Global Health Status question for this subset. At baseline, the Control and PME subjects reported quality of life as good but post therapy, the score dropped, particularly in the PME group. Because the continence of these subjects did not improve as the participants expected (see Figure 4.4), the lower reported quality of life noted in the PME subjects or the stabilization of the PME+ES subjects may reflect a change of attitude due to participation in the study (mean gm of urine loss at Time 1: Control=146 (SD=126); PME=86 (SD=92); PME+ES=462 (SD=462); at Time 4, Control=11 (SD=0), PME=24 (SD=27), and PME+ES=127 (SD=173)). Prior to the researcher contacting them, the PME subjects may have been resigned to life with incontinence. The study was perceived as a chance for improvement or cure (although the researcher made every attempt to describe the study as testing the effectiveness of therapy). After the unsuccessful therapy and the commitment of the subject to attend 12 weeks of therapy, the low quality of life score may reflect disappointment after initial optimism. Overall, and particularly in the subgroup, quality of life after radical prostatectomy as measured by the EORTC QLQ, did not change notably from baseline to the final measure. The results suggest either that the instrument was not sensitive enough to evaluate the effect of incontinence on quality of life or that incontinence is only one of many factors which may affect one's quality of life.

Factors Which May Affect Reported Quality Of Life

For the sample as a whole, at least two possibilities could be considered with respect to the low correlations between incontinence and the Global Health status/QOL score. The first is that urinary incontinence is just one of several factors which determine how one would rate quality of life; and second, quality of life is not a stable phenomenon but rather changes over time. In the

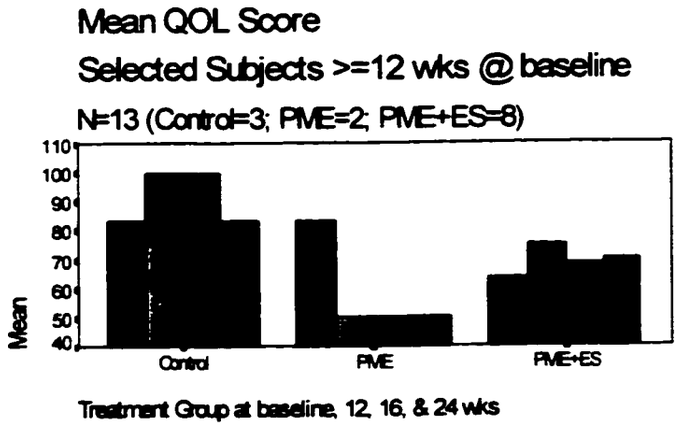


Figure 5.3. QOL Scores (Selected Subjects≥ 12 weeks post surgery)

case of the former, issues as large as recent retirement, onset of other health problems such as asthma, arthritis, inguinal hernia, and erectile dysfunction, all occurred to certain subjects. Such perceived or real health problems and life events probably interfered with both functional and emotional well-being. In the case of the latter, as time progressed, men's attitudes toward being incontinent may have changed. Initially, curative surgery was enough to rate one's quality of life as high despite high grams of urine loss. Six months later, with fewer grams of urine loss but still requiring a pad, men may rate quality of life as relatively poor. Herr (1994) provides some evidence for a change of attitude over time in men with incontinence after radical prostatectomy. Despite significant incontinence, 83% of subjects 3 years or less after surgery reported that they would choose radical prostatectomy again, whereas only 47% more than 5 years postoperatively would choose surgery. Further follow up of the current study group at one and two years may add support to Herr's finding. Moreover, as Herr and Hunskaar and Sandvik (1993) point out, the patient perception of incontinence is subjective and may explain why there is

not a strong correlation between severity of symptoms and the impact of incontinence. In the present study, for some men at approximately 8 months postoperatively, 200 gm was significant but not problematic and quality of life was rated as high. For others at the same end point, 9 gm was too much and quality of life was rated as poor. To truly assess the impact of incontinence on men post radical prostatectomy, continent counterparts must be included in the analysis.

One of the most poignant findings in this study, and one which has not been addressed in the literature, involves the degree of distress experienced by subjects in the early recovery period. Much of the stress may have been reduced by improved methods of communication, so that the patients' actual experiences were more congruent with their expected ones, findings also presented by others in evaluations of surgical patients after discharge from hospital (Interdisciplinary Patient Outcome Standards Task Force, 1996).

Currently, the research has focused on the components of quality of life and how to measure these aspects with valid and reliable instruments. Less attention has been paid to the theoretical foundations of quality of life (King et al., 1997). One framework proposed by Michalos (1986) is that of discrepancy theory. Such theory is based on discrepancies between what is expected during therapy and what actually happens. It has been pointed out that successful coping with events occurs when outcomes meet expectations (Linder-Petz, 1982). It is proposed that the reactions of many of the participants of this study would be explained by a theory of discrepancy and that one method of reducing the difference between the expected and real outcomes is enhanced communication, an integral factor in all care. Such differences between patient expectation and reality are well expressed by one subject: "It is with deepest disappointment that I now face this condition and

the disastrous and abrupt change in my total way of life. It is also with the same degree of disappointment that I feel toward the outcome of the surgery which is contrary to having been told that my present condition would last approximately 6 weeks after surgery". In addition to full preoperative counselling about the risks of incontinence (Diokno, 1997), enhanced communication, support, and regular contact with a health professional may improve the coping abilities of patients (Herr, 1994).

Informal Assessment Of Quality Of Life

Comprehensive quality of life assessment cannot be measured by only one instrument or method, a point which Aaronson et al. (1993) emphasize in the introduction to the EORTC scoring manual. Even the most sensitive of quality of life instruments cannot replace the therapeutic aspect of face-to-face exchanges. This study, for example, utilized a cancer specific quality of life instrument, an incontinence impact questionnaire, and face-to-face interviews to gain an understanding of life after radical prostatectomy. During the informal interviews, subjects expressed many concerns affecting their quality of life in the early stages after discharge. With early discharge (Day 3 or Day 4 post radical prostatectomy) and same-day admission, there appeared to be limited opportunities for nurses and physicians to prepare the patient and his family for post-operative events. While the early recovery period of any surgery is stressful, there were some specific concerns that men in this study expressed, ranging from lack of information about prostate cancer itself to obtaining laboratory results. By far the most frequently stated concerns however, involved those related to the indwelling catheter, bladder spasms, rectal pain, fatigue and, following removal, inevitable urinary incontinence. The concerns expressed relate, in part, to the patients' inability to process the information conveyed to them during pre and postoperative discussions with

both urologists and nurses.

In this study, the impact of incontinence and the stress expressed immediately postoperatively was due, in part, to incomplete opportunities for the clinician and the patient to communicate and, in turn, for the patient to receive support. Of note, is that the men who were randomized to therapy all expressed great appreciation for the support and encouragement which the physiotherapist provided, even if the therapy itself did not significantly improve the incontinence. This major psychological benefit was truly the *therapy* within the physiotherapy realm. Clearly, supportive intervention is worthwhile but the form of that support requires further investigation.

The value of on-going support in the months after recovery from prostate cancer treatment has been noted by several authors (Grégoire, Kalogeropoulos, & Corcos, 1997; Montie, 1994; Sharp, Blum, & Aviv, 1993) but none have addressed the immediate postoperative period where there is a marked difference in needs. The possibilities immediately postoperatively are several. Telephone intervention is an effective method of providing patients with information and assistance. Alter et al. (1996) conducted a pilot study with 8 patients receiving chemotherapy for bowel cancer. Biweekly telephone sessions by a nurse clinician resulted in patients reporting an improved ability to communicate with their physician and an improved understanding of the treatment related stressors. Aaronson et al. (1996) conducted a randomized, controlled trial (N=180) in which a single telephone intervention was tested to determine the patients' comprehension of the clinical trial in which they had been asked to participate. In addition to having a better understanding of the research study, the intervention group was significantly better informed about the risks and side effects of treatment and the availability of alternate therapy. For men post radical prostatectomy, a telephone call from the

nursing unit soon after discharge may go far to allay anxiety for both the patient and his spouse. Peer support may also be an option.

Factors Which Affect Information Exchange in the Pre-radical Prostatectomy Period

Patients are key players involved in making choices regarding their treatment and regimens. Many factors support or sabotage the patient's active role: the information he receives prior to making treatment decisions and the support he experiences both personally and professionally. Although the sample was selected and did not include men who were continent, some common themes were noted, which have been expressed in other surveys of more representative groups where individuals have described the information they have received as not meeting their needs (Webber, 1990; Breemhaar, van den Born, & Mullen, 1996; Kent et al., 1996; Interdisciplinary Patient Outcomes Standards Task Force, 1996). In the present study and based on the subjective reports, there appeared to be gaps between what the health care professional expected the patient had understood in terms of preoperative and early discharge teaching and what the patient actually said he understood. Subects were disappointed, frustrated, and hoped they would not have to spend the rest of their lives with lack of bladder control. Some also admitted that the physician may have told them about incontinence during their preoperative visits but that the diagnosis of cancer prevented them from processing that information. Such gaps in information utilization proved to have significant implications for nursing care. During the baseline interviews and informal telephone conversations, men seemed unprepared for the early days of recovery after hospital discharge. The following discussion considers some of these concerns within the context of learning theories.

Communication between a man with prostate cancer and his physician

plays an integral role in the perceived quality of care. The way in which information is delivered and understood helps determine if the actual experiences postoperatively are congruent with expected ones. A link between information exchange and specific outcomes of satisfaction, attitude to proposed treatment, reduction of concern, and health understanding has been noted (Anderson & Sharpe, 1991; Frederickson, 1993). However, many factors challenge the health care professional's ability to ensure that men who are candidates for radical prostatectomy do indeed receive and understand important information. These factors include but are not restricted to poor timing of information (Valanis & Rumpler, 1987), inability to retain information (Krupat, 1986), inability to understand the medical nature of the information (Egiker, Kirscht, &Becker, 1994), and a perceived or real lack of support (Krol, Sanderman, & Suurmeijer, 1993; Taylor, Bandura, Ewart, Miller, & Debusk, 1985). Trends in the literature suggest that a variety of approaches to providing pre and postoperative information are beneficial. Yet time, which is usually at a premium, forces nurses and physicians to provide information during a single interaction which, in turn, may not allow patients to absorb information or formulate questions.

The literature is inundated with techniques to promote a patient's understanding about his or her condition. Printed material is relatively inexpensive but must be written at a level which is easy to comprehend (Estey, Kemp, Allison, & Lamb, 1992; Weiss, Reed, & Kligman, 1995). In the sample studied, two men were functionally illiterate and 28% had less than Grade 8 education. Videotapes are relatively successful in providing consistent information and encouraging more patient participation in decision-making (Schapir, Meade, Nattinger, 1997). Group education provides a mutual exchange of ideas and support (Taal et al., 1993). Computers have been

successful in educating people about a variety of health concerns (Egiker, Kirscht, & Becker, 1994; Fredette, 1990; Glimelius, Birgegard, Hoffman, Kvale, & Sjoden, 1995; Wallerstein, 1992). Although these strategies have met with success in certain groups, they depend on a certain amount of technological skill or available equipment. Communication itself, as most significant cognitive factors, may be augmented with other teaching strategies but cannot be replaced.

Limitations in the available resources present a barrier to implementing more physician appointments to discuss concerns. However, within these realistic limitations, communication with the patient certainly may be enhanced. Pertinent written information which describes in particular how to care for the indwelling catheter and the leg bag, why bladder spasms occur and what to do about them, warning signs of infection or blocking catheter, rectal pain, and wound care would go far to shorten the knowledge-gap. A section of the pamphlet could address the procedure for catheter removal, a description of the amount of incontinence to be expected, and where to obtain incontinence products. An initial telephone contact from the nursing unit one or two days after discharge and again a few days later may help "trouble shoot" problems. Encouraging the patient to call back with any concerns or setting a specific call back appointment may also alleviate some anxiety. Finally, referral to home care should be routine. In this study, patients who received home care expressed fewer concerns than those who did not.

Communication may also be improved by encouraging the patient to include his spouse or a family member at all appointments with the physician and with the nurses at both preadmission clinic and on the nursing unit after surgery. It may also help considerably if patients had written information provided prior to the initial appointment about the diagnosis of prostate

cancer. Future research could consider the educational level of the spouse and the impact of regional differences in pre and postoperative concerns. In this study, 15 men (26%) lived in rural communities.

Limitations Of The Study

There were several limitations to this study, including sample heterogeneity, inconsistent application of the therapy protocol, lack of specificity of the EORTC instrument for study of men after radical prostatectomy, and lack of urodynamic confirmation of bladder stability.

Sample Heterogeneity

A major limitation of this study was the heterogeneity of the sample with subjects ranging from 3 weeks to 4 years postoperatively. It was not recognized by the researcher until several months into the project that a relatively rapid and predictable improvement in incontinence would occur from the time of catheter removal to approximately 12 weeks postoperatively. Such a recognition meant that the lack of difference between groups was most likely due to improvement over time rather than due to the interventions being tested. Thus from October 1996 until March 31, 1997 when recruitment was completed, the researcher did not enroll subjects until after the 12 week milestone. Unfortunately, the number of subjects who fit this criteria were small in number and the potential for determining whether treatment indeed resulted in improvement was limited. Further research would define selection criteria more stringently--more than 100 grams of urine loss on 24 hour pad test, more than 12 weeks postoperatively. Moreover, including men who were more than several months post surgery further contributed to variation in the sample. In hindsight, while these men all had urodynamically proven stress urinary incontinence, it could be suggested that those men who continue to leak after a certain postoperative point are different from those who are, for

example, 12 weeks post surgery. Scarring around the bladder neck and at the distal urethral sphincter may occur over time. Including these gentlemen in the project initially seemed appropriate, particularly since their continence status had plateaued and any reduction in urine loss should be attributable to therapy.

As well as weeks post surgery, operative technique may have varied between surgeons. Ideally only patients from one surgeon should participate. However, time limitations necessitated a more eclectic sample. For further research on therapy after radical prostatectomy, it is recommended that subjects be chosen who were more than 12 weeks postoperatively. Two baseline measures would be taken prior to commencement of therapy to confirm that subjects had indeed stabilized with respect to urine loss. As well, a minimum urine loss on 24 hour pad test would be set, for example 50 gm. Finally, as Burgio, Stutzman, and Engel (1989) reported, behavioural strategies may affect outcome and should be incorporated into the study protocol.

Study Protocol

The study was designed so that subjects would receive treatment twice a week for 12 weeks. The limitations of the clinical setting prevented continuous treatment as per the design. Some subjects took vacations during their therapy and the research assistant physiotherapist was on holiday for 4 weeks in December 1996 which interrupted therapy for 3 men, resulted in one drop out, and further slowed subject recruitment. The time interruption could have been prevented if the researcher had purchased the electrical stimulation equipment and hired one research assistant to focus only on study patients. Budget restrictions in part, prevented such an approach. More importantly, the researcher wanted to maintain an interdisciplinary approach to incontinence therapy and felt it was important to involve the assistance of a

physiotherapist who was expert in muscle physiology and rehabilitation.

Limitations Of The Quality Of Life Instruments

Quality of life is a subjective concept which is, therefore, difficult to quantify (Hanestad, 1990). Any instrument is subject to errors of measurement, and quality of life instruments such as the EORTC-C30, are no exception. Individual responses could be affected by the belief that the prostate cancer was cured, by the passage of time, by responding in ways to please the researcher, or responding to questions more positively than is really true. Hanestad calls these measurement errors "mood-of-the-day effects, response acquiescence, and idealization tendency" (p. 31). In the EORTC-C30 instrument, questions 20 and 25, for example, refer to cognitive abilities. In order to appear in a positive light to the researcher, these responses could have been "not at all" when in fact, they should have been "very much". Moreover, cultural and educational differences among subjects may have affected responses because of different meanings attached to words such as *tense, worry, irritable*, or *depressed*. Finally, one's perceived quality of life may be influenced by time, particularly in the early stages of recovery from major surgery. If so, then the positive changes noted in reported quality of life may not be related to urinary continence, but simply due to increased energy and endurance in performing day-to-day activities. Randomization controlled for random errors of measurement and utilization of the IIQ-7 provided another measure of similar content which helped verify the responses. The informal interviews with subjects provided valuable data for improving care of men with incontinence after radical prostatectomy. It is possible that continent men at equal stages of recovery would provide similar responses to the EORTC questions, particularly since the questionnaire was designed as a generic questionnaire for prostate cancer rather than a specific one for men who are

incontinent post-radical prostatectomy. Further research interviewing continent men is required to confirm this belief.

Lack of Urodynamic Confirmation of Bladder Stability

A marked limitation in determining why some improved and others did not was the lack of postoperative urodynamic evaluation, except in the three subjects who were more than 18 months post surgery. It is possible that non-responsive subjects had a detrusor component which also contributed to urinary incontinence. Yet, the three men who did have genuine stress urinary incontinence did not improve after therapy.

Implications of the Study

Although some reports have compared nerve sparing surgery or bladder neck preservation with urinary continence, none have reported objective data on the relationship between surgical technique and urine loss. A detailed chart review of the participants with respect to operative procedures, and preoperative and postoperative complications may contribute to the understanding of postoperative urinary incontinence.

The discomfort caused by postoperative catheterization causes considerable distress for the majority of men post radical prostatectomy, findings reported by others (Mathewson-Chapman, 1995). Early catheter removal could be studied, replicating a randomized controlled trial by Niesel, Olbert, Hartung, & Breul (1997) in which a cystogram was performed at day 7. If no extravasation occurred, patients were randomized to removal on day 7 or day 21 (standard protocol). Early catheter removal did not lead to increased postoperative complications. Alternate catheters could also be studied. Current practice includes the use of a 20F red rubber catheter with a 30 ml balloon. Advances in catheter development with lubricant impregnated surfaces may result in less urethral irritation.

Spouses' perception of post radical prostatectomy experience requires further exploration. Feelings such as fear, helplessness, overwhelming household responsibilities, and financial worries have been described for spouses of female patients who have breast cancer (Carter, & Carter, 1994; Keitel, Zevon, Rounds, Petrelli, & Karakousis, 1990; Northouse & Peters-Golden, 1993; Ptacek, Ptacek, & Dodge, 1994). In addition to significant psychological distress, spouses reported less support for themselves than their partner reported (Northouse, 1988). In a qualitative study exploring the experience of diagnosis of prostate cancer and its impact on their lives, couples articulated frustrations and coping strategies similar to the husbands of wives with breast cancer (Heyman & Rosner, 1996). In the early phase of accepting the diagnosis of prostate cancer, men described inertia, loss of control, and frustration in trying to gather information in order to make a treatment decision. Similar sentiments were expressed in the present study. One man stated: "I didn't tell my wife for a month--I had to work things out." Another described his attempts to retrieve his biopsy report: "I was very frustrated when I had to chase the physician for results and waiting for those reports was very hard." Having someone take the time to discuss the treatment options was very important: "The urologist took the time to explain to us what my situation was and what options were available. Time was not a factor. He scheduled an hour but implied he would stay with us longer if necessary. His attitude and concern from first appointment to the present has been excellent". Finally, while the impact of urinary incontinence has received some attention, the associated impact of erectile dysfunction has been almost completely overlooked.

Incontinence therapy has become an accepted responsibility for nurses. Many therapeutic regimens, however, while implemented with the expectation

of effectiveness, have not been well studied with randomized, controlled trials. Neither electrical stimulation nor pelvic muscle exercises for men with urinary incontinence have been systematically evaluated. The results of the study not only emphasize the importance of outcome based practice but also suggest that intervention is not effective in treating post radical prostatectomy urinary incontinence in the early weeks postoperatively. Such results which have not been previously reported and require further exploration. For example, which subset of men might benefit from therapy? Very importantly, the visits to the physiotherapist provided a tremendous psychological lift and all subjects stated that the therapy was worthwhile. The benefits of and type of support which can be provided in a cost-effective, yet humanistic way require further investigation. Moreover, the informal subjective responses of the participants provided considerable insight into the stressors which affected men in the early discharge period.

Finally, several advantages of an interdisciplinary approach to treatment of incontinence presented themselves. These included (1) combined expertise in patient education and clinical practice along with expertise directed to physiology and muscle training; (2) an enhanced appreciation by the researcher and research assistant for the skills of both disciplines (in this case nursing and physiotherapy); and (3) financial advantages in terms of equipment, shared research funds, and available space.

Conclusion

Conclusions from this study include the following: (1) there was rapid, initial improvement in return to continence up to 12 weeks postoperatively; (2) treatment with pelvic muscle exercises and/or electrical stimulation did not enhance the degree of continence recovery in the early phases of recovery; (3) the Incontinence Impact Questionnaire (IIQ-7) has the potential to be a

reliable and valid instrument for assessing the impact of incontinence in men; (4) quality of life was reported as low in the early weeks after radical prostatectomy but this result may have been to postoperative fatigue rather than incontinence itself; (5) the consequences of incontinence after radical prostatectomy, based on subjective descriptions, were worry, embarrassment, curtailment of activities, and disappointment.

This study leaves questions about the effectiveness of incontinence therapy in the early weeks after radical prostatectomy. It has laid the groundwork for more research which may provide the much-needed answer to those questions. As well, issues of quality of life were found to be highly significant, clearly affecting adjustment in the early postoperative period. Several suggestions were put forward with respect to preoperative teaching and early postoperative care. The study has also included evaluation of one aspect of the physiotherapy incontinence programme funded by Capital Health Region and an informal evaluation of the preadmission clinic teaching programme for men with early stage prostate cancer. It has enhanced the understanding of the stressors affecting men in the early postoperative days after radical prostatectomy, increased the awareness of the impact of incontinence on quality of life, and provided some longitudinal data on return of continence.

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Appendix 1: Incidence of Urinary Incontinence Post Radical Prostatectomy

INCIDENCE OF URINARY INCONTINENCE POST RADICAL PROSTATECTOMY					
Author	Year	N	Followup	Author Description of UI & Incidence	Erectile dysfunction
Bass & Barrett	1980	36	6 months	Perfect Control: 50% Minimal Stress: 33% Moderate SUI (1-3 PPD): 6% Total UI: 11%	
Braslis et al	1995	79: 28 1/12 prior to surgery; 51 12/12 post op (does not state how sample recruited)	12/12	1. Wet with coughing or sneezing: 57% never, 30% occasionally; 4% always 2. Leak spontaneously: 61% never, 33% occasionally, 6% always. 3. Pad use: 78% never; 10% occasionally, 6% always. 6% regarded UI as big problem.	1/51 potent 20/51 using erection aid
Elder et al	1984	30 (prior TUR) 122 (RP only)	6 months	Pad or clamp: 20% of TUR; 5% of RP	
Foote et al	1991	26 (7 had UI preop incontinence due to Detrusor instability)	3, 6, 12 months	% with UI at 3, 6 and 12 months >3 PPD 54% 38% 35% <2 PPD 46% 31% 23% Dry 0% 31% 42%	
Fowler	1985	81	6 months	Mild UI: 10% Severe SUI or Total: 6%	

Gibbons et al	1984	231	6 months	Complete Control: 92% Wear pads for dampness: 3% Wear applicance for collection: 5%	
Hauri	1977	30		Complete Continence: 100%	
Hohenfeller & Jonas	1978	309	up to 7 years	Incontinence: 3.1%(suprapubic prostatectomy)	
Kopecky et al	1970	83	@ 5 years: Mortality = 17 5 lost to Fup @ 10 yrs Mortality = 25 8 lost to Fup	"Some degree" of UI in 20/73 pts = 27% Total UI: 1%	5 could achieve orgasm; 2 had functional erections (only 23/83 pts answered this question.
Leandri et al	1992			UI: Normal: dry during normal & strenuous activities, 0 pads or appliances; stress UI: loss of urine during strenuous activities and a pad for protection; total UI: no urinary control. Follow up of 484 of 620 eligible patients. 434/484 (90%) had complete continence @ 6/12 (majority dry at 3/12) 95% dry at 12/12 Patients < 70 years 97% dry " " > 70 years 94% dry	Full potency (same as preop); partial potency (quality worse than preop) or erectile dysfunction (unable to have intercourse) @ 6/12 30% full, 38% partial; @ 12/12 56% potent & 15% partial (Fup 106/167 men); eval by mailout questionnaire to pt & spouse.

Middleton	1987	193	Up to 10 months	Mild UI: 1% SUI: 42% Total UI: 15% Persistent & Significant UI: 1.6%	
O'Donnell et al	1990	65	1, 3, 6, 12 months	% with UI at 1, 3, 6 & 12 months Continent: 15, 34, 17, 7% Infrequent (0 PPD): 4, 18, 17, 7% Occasional accident (1PPD): 17, 21, 11, 3% Occasional Wetness (1-5 PPD): 23,20,3, 0% Freq. wet (>5 PPD): 11, 4, 0, 0% External Catheter: 20% 0, 0, 0% Indwelling Catheter: 6, 0, 0, 0%	
Rudy	1984	16	6 weeks, 3 & 6 months	% with UI at 6 wks, 3 & 6 mon. None: 0, 6, 12% Mild SUI (occas. pad): 12, 25, 75% Mod. (continuous pad use): 38, 25, 0% Severe (sev.PPD): 25, 6, 6% Total UI: 6, 6, 6% Urge: 6, 0, 0%	
Steiner	1991	593	1 year	Complete Control: 92% SUI (dry lying down; pad for strenous activities): 8% Total UI: 0%	
Veenema	1977	159 (1951-1970)	up to 20 years	Normal Voiding: 68% SUI: 18% Total UI: 13%	

Walsh, Quinlan et al 1994 Walsh, Partin, et al	1990	593	≥ 1 year	Continent: 92% Mild SUI (≤1PPD): 6% Mod SUI (>1PPD): 2%	Erectile dysfunction : 32%
Young, Davis, & Johnson	1926	24		Perfect urinary control: 49% Fair control: 16% Incontinence by day, walking: 29% Complete incontinence: 13%	

*SUI= Stress Urinary Incontinence
UI= Urinary incontinence
PPD=pads per day

Appendix 2: Research-based PME's

RESEARCH-BASED PELVIC MUSCLE REGIMENS					
Author, Date, Discipline	Sample, Design	Method	Length of Programme	Outcome Measures	Results & Comments
Bø et al (1990) Physio	N=52 randomly assigned to 2 groups.	Group I also received 45 minutes of intensive instruction with 1 physiotherapist once a week. The physio regimen consisted of long lasting contractions supplemented with 3-4 fast contractions after each longlasting contraction. Group II followed the usual protocol only and were seen at the end of 6 weeks. Exercise Regimen: A. instructed in pelvic floor anatomy, vaginal instruction of muscle contraction and observation with a vaginal balloon catheter (doesn't mention if written instructions were provided) B. Home exercise as above + 45 minute 1x/week instructor-led session in standing, sitting, lying and kneeling position with knees apart The instructions: contract as hard as possible, hold for 6-8 seconds. At the end of each contraction do 3-4 fast contractions. In each position 8-12 contractions were done plus added fast contractions in each position.	All received the protocol of 8-12 maximal pelvic muscle contractions three times a day for six weeks. Followup @ 6/12	Subjective score of urinary leakage, **urinary leak** index (1-5, 1=never, 5=always leak with activities such as sneeze, walk etc. **Pad test** (validated by Hagan et al, 1988) **PVR** **VUDT** at baseline and at 6/12 **Vaginal strength**-method validated by Bo et al 1990 Patients tested monthly	Results at 6/12 14 intensive, 5 HE self-report continence ULI 3.0-1.9 & 3.1-2.6 Pad Test 27 - 7.1g UPP ns change in either group PMStrength GP. 1: changed up to 6/12; GP 2: change only after 1/12, then stabilized Conclusion: intensive regimen worked significantly better.

Burns et al (1993) Nursing, urology & psychology	Compared biofeedback with pelvic muscle exercises alone; randomized to PME or PME + biofeedback N=135, final N=123 women over 55 with SUI	Biofeedback with vaginal probe recording EMG activity providing visual feedback, nurse administered Bio: A. relax, contract for 3 seconds (quick flicks) B. contract, sustain up to 10 seconds, relax 10x @ 8 weekly biofeedback sessions Exercise: Video demonstrated exercise programme 4 sets of 20 (10 quick, 10 sustained) Increase by 10 per set over 4 weeks till daily maximum of 200 exercises was attained.	Both groups met with therapist weekly to review dairy and urine loss and (a) to receive biofeedback and (b) to receive more PME instruction. Compliance was helped by weekly telephone calls and appointment cards.	**Subjectiv e**-reported UI in 24 hour diary "Mild" <7x/wk; moderate 8-21x/wk; severe >22x/wk **EMG** performan ce of peak contractio n **UDT's**-- UPP with full bladder in standing position-- no change from pre-post Rx	No signif diff b/w bio + PME to PME's alone., but there was a >54% improveme nt in both treatment grps compared to 6% improvment in controls.
Dougherty et al (1989; 1992; 1993) Nursing & Physio.	N=65, ages 35-75 with "mild to moderate incontinence (average 2.6 episodes / week (1-50 g-- nb ICS considers ≤ 2g as not consequential)	After pelvic examination and digital instruction, information was reinforced with an audiotape which the subject used for the 16 weeks of therapy. The tape began with 3.3 minutes of relaxation followed by instructions on hard, steady contraction, not to retighten during the contraction, to begin at the tone and stop at the tone, then relax fully. Called a graded exercise programme and its purpose was to develop endurance. Start with 10 second contraction, repeat 15 times (level 1) and add 10 contractions every 4 weeks (25 contractions = Level 2, 35 = Level 3, 45 = Level 4).	Patients were followed by telephone weekly and submitted a diary every 2 weeks.	Max & Sustained vaginal pressure; diary.	Compliance to regimen was 80% (of the 3x/wk regimen) Urine loss decreased from 2.6 to 1 episode per week Max and sustained vaginal pressure changed from baseline to post therapy. Comments: No random assignment to differing regimens.

Henalla et al (1988) OB & geriatric medicine	two hospitals and two therapist programmes Measured by pad test 32 patients with SUI in Group 1 104 Randomly assigned to 4 groups-- Group 1 PME x 3/12 vs 3 other groups which are not desribed.	Programme: vaginal exam by the patient 1. Fast twitch fibres with quick contractions--contract, relax, contract, relax 2. Slow twitch fibres with sustained 3-4 second contractions with patient counting to 5. Equal numbers of slow and fast twitch exercises performed with frequency increasing until every hour daily with each session lasting 10 minutes.	Follow up weekly		No difference between the 2 hospitals; patients with Sx of SUI of less than 1 year did better (but urine loss not described--probably patients with Sx <1 year had less urine loss) one third did not respond to therapy. Authors question compliance.
Sleep and Grant (1987) Nurse and epidem-iologist	N=1609 ambitious sample size but no real measure of whether patients had UI to begin with--assumed	Compared the standard post partum programme to intensive programme of PME Written instructions In hospital group (standard) was given verbal + written instruction over the 48 hour period post partum then followed up by community physio or nurse. Intensive group-received daily individual instruction by a midwife in hospital (instruction not described) Intensive group: kept a diary for 4 weeks to act as a "memory" aid			By week 4 were doing self digital exam for vaginal muscle strength Mail in questionnai re showed no diff. in response between the two groups. Subjective measures only; do not mention response rate.

Appendix 3: Clinical Reports of PME's

CLINICALLY BASED PELVIC MUSCLE EXERCISE REGIMENS IN THE RECENT LITERATURE					
Author, Date & Discipline	Subjects	Method	Follow up	Outcome Measures	Results
Elia & Bergman, (1993) Gynae.		Pelvic exam and perinometer Contract 10 seconds, relax 10 seconds In 3 different positions 1. standing on toes; 2. standing with legs abducted and elbows on a chair; 3. supine 2x/week group classes x 1.5 hrs x 6 weeks then, 1x/week Plus exercise at home 15 minutes a day.		1 hour pad test; UPP	Subjective- 7/36 cured; 13/36 improved; 16/36 no change (grade III UI) UPP changed in patients who improved (? significant)
Henderson (1988) Nursing	Case study of 5 female patients with MS & SUI	Instructions on a written sheet Tighten, count to 10, relax, repeat 100x Insert finger to check contraction Use stop test to check Do 100 x per day for life.			4 of 5 patients improved.
Laycock, (1987); Knight & Laycock (1994) physio		Kegels 300 contractions / day + use of perinometer BID Programme of "little and often", some quick 1 second contractions, some lasting for 10 seconds, incorporate into the daily activities of standing, sitting, and lying; using the "stop test"; always squeeze with activity; use digital examination plus diary (daily or weekly).			

Norwood (1990) Physio	For urge not stress incontinence 2 case studies	Method of instruction-taught pme's (not stated if with vaginal examination), taught anatomy of pelvic floor; taught to contract while keeping abdominal, gluteal, and adductors relaxed. Exercise every half hour in any position, gradually increasing from 2 to 10 seconds plus at 6/52 add quick contractions with each urge to void. Follow up was at 2 weeks, 6 weeks and 3 months with success measured at per diary and patient		Symptoms decreased; bladder capacity increased	.
Tchou et al, (1988) Physio	N=14 with SUI	After vaginal examination, VUDTs to Dx SUI Each subject instructed then had 30 minute training sessions 2x/week plus exercised daily at home Subjects used diary to record exercises 1. stop/start stream 2. Overflow exercise-- squeeze thighs, buttocks, abdominal muscles -- "overflow of contraction" into PF muscles 3. posterior pelvic tilts to increase strength of lower abdominal muscles and other abdominal exercises 4. "later" discontinued overflow exercise and performed only pelvic floor contraction, gradually increasing frequency and duration		Patient motivation measured by diary (scale 1-4)	Did not measure urine loss pre-post; 9/14 had negative stress test.

Appendix 4: EORTC Quality of Life Instrument (QLQ-C30, version 2)

EUROPEAN ORGANIZATION FOR THE RESEARCH AND TREATMENT OF CANCER (EORTC) Quality of Life Instrument (QLQ-C30, version 2.0)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:_____

Your birthdate:_____

Today's date:_____

	No	Yes
1. Do you have any trouble doing strenuous activites, like carrying a heavy shopping bag or a suitcase?	1	2
2. Do you have any trouble taking a long walk?	1	2
3. Do you have any trouble taking a short walk outside of the house?	1	2
4. Do you have to stay in a bed or a chair most of the day?	1	2
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2

During the past week:

6. Were you limited in doing either your work or other daily activities?

1	2	3	4
Not at all	A Little	Moderately	Very Much

7. Were you limited in pursuing your hobbies or other leisure time activities?

1	2	3	4
Not at all	A Little	Moderately	Very Much

8. Were you short of breath?

1	2	3	4
Not at all	A Little	Moderately	Very Much

9. Have you had pain?

1	2	3	4
Not at all	A Little	Moderately	Very Much

10. Did you need to rest?

1	2	3	4
Not at all	A Little	Moderately	Very Much

11. Have you had trouble sleeping?

1	2	3	4
Not at all	A Little	Moderately	Very Much

12. Have you felt weak?

1	2	3	4
Not at all	A Little	Moderately	Very Much

13. Have you lacked appetite?

1	2	3	4
Not at all	A Little	Moderately	Very Much

14. Have you felt nauseated?

1	2	3	4
Not at all	A Little	Moderately	Very Much

15. Have you vomited?

1	2	3	4
Not at all	A Little	Moderately	Very Much

16. Have you been constipated?

1	2	3	4
Not at all	A Little	Moderately	Very Much

17. Have you had diarrhea?

1	2	3	4
Not at all	A Little	Moderately	Very Much

18. Were you tired?

1	2	3	4
Not at all	A Little	Moderately	Very Much

19. Did pain interfere with your daily activities?

1	2	3	4
Not at all	A Little	Moderately	Very Much

20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?

1	2	3	4
Not at all	A Little	Moderately	Very Much

21. Did you feel tense?

1	2	3	4
Not at all	A Little	Moderately	Very Much

22. Did you worry?

1	2	3	4
Not at all	A Little	Moderately	Very Much

23. Did you feel irritable?

1	2	3	4
Not at all	A Little	Moderately	Very Much

24. Did you feel depressed?

1	2	3	4
Not at all	A Little	Moderately	Very Much

25. Have you had difficulty remembering things?

1	2	3	4
Not at all	A Little	Moderately	Very Much

26. Has your physical condition or medical treatment interfered with your family life?

1	2	3	4
Not at all	A Little	Moderately	Very Much

27. Has your physical condition or medical treatment interfered with your social activities?

1	2	3	4
Not at all	A Little	Moderately	Very Much

28. Has your physical condition or medical treatment caused you financial difficulties?

1	2	3	4
Not at all	A Little	Moderately	Very Much

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

30 How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

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Version 2.0

Scoring Procedures for the EORTC Core Quality of Life Questionnaire

The questionnaire includes functional scales and symptom scores. The five functional scores and single quality of life score were scored in a similar manner: the raw scores for the individual items within the scale were first summed, then divided by the number of items within the scale. These scale scores were then linearly transformed such that all scale responses ranged from 0 to 100, with a higher scale score representing a higher level of functioning. The nine symptom scores were linearly transformed such that all scales ranged from 0 to 100 with a higher score representing a higher level of symptomatology or problems. If some items were missing, but at least half from each scale were answered, then the standard equations were used for calculating the scores. If more than half the items were missing, then the response was recorded as missing. For single-item measures, the score was set to missing (Fayers, Aaronson, Bjordal, & Sullivan, 1995). There is no Summary score for the EORTC quality of life instrument.

The five functional scores (physical, role, emotional, cognitive, and social) are separate variables, as are the quality of life score and the symptom scores of dyspnoea, pain, fatigue, sleep, appetite, nausea and/or vomiting, constipation, diarrhea, and financial difficulties. This allows evaluation of specific variables on the overall quality of life score.

Appendix 5: EORTC Prostate Cancer Module

EUROPEAN ORGANIZATION FOR THE RESEARCH AND TREATMENT OF CANCER (EORTC)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:_____

Your birthdate:_____

Today's date:_____

During the past week:

29. Did you have to urinate more frequently than is normal for you?

1 2 3 4

Not at all A Little Moderately Very Much

30. Did you have difficulty controlling your urination?

1 2 3 4

Not at all A Little Moderately Very Much

31. Did you have pain when you urinated?

1 2 3 4

Not at all A Little Moderately Very Much

32. Was your sleep during the night disturbed by the need to urinate?

1 2 3 4

Not at all A Little Moderately Very Much

33. Did you have hot flashes?

1 2 3 4

Not at all A Little Moderately Very Much

34. Did you gain weight?

1 2 3 4

Not at all A Little Moderately Very Much

35. Did your condition limit your interest in sex?

1 2 3 4

Not at all A Little Moderately Very Much

36. Were you limited in your ability to get or maintain an erection?

1 2 3 4

Not at all A Little Moderately Very Much

37. Did your condition limit your level of sexual activity?

1 2 3 4

Not at all A Little Moderately Very Much

38. Overall, how satisfied were you with your level of sexual activity?

1 2 3 4

Not at all A Little Moderately Very Much

39. Did you lose weight?

1 2 3 4

Not at all A Little Moderately Very Much

Thank you for completing this questionnaire.

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Appendix 5(a)

Scoring for EORTC Prostate Cancer Module

Questions 29-32 (urinary symptoms) were summed, divided by 4 and linearly transformed to give one "urinary score" ranging from 0-100. Questions 33 (hot flashes), 34 (weight gain), 38 (satisfaction with sexual activity), and 39 (weight loss) were single item responses which were linearly transformed to range from 0-100. Questions 35-37 (sexual function) were summed divided by 3 and linearly transformed to give a single "sexual" response ranging from 0-100.

Appendix 6: Incontinence Impact Questionnaire (IIQ-7)

INCONTINENCE IMPACT QUESTIONNAIRE SHORT FORM (IIQ-7)

Some men find that accidental urine loss affects their lives. The questions refer to feelings, relationships, and activities which might be affected by urine leakage. For each question, check the response that best describes how much you feel you have been affected by urine leakage.

Has urine leakage affected:

1. **Household chores?**
   0 1 2 3
   Not at all Slightly Moderately A Great Deal

2. **Physical recreation such as walking, swimming?**
   0 1 2 3
   Not at all Slightly Moderately A Great Deal

3. **Entertainment activities such as movies, concerts?**
   0 1 2 3
   Not at all Slightly Moderately A Great Deal

4. **Travel by car or bus more than 30 minutes away from home?**
   0 1 2 3
   Not at all Slightly Moderately A Great Deal

5. **Participation in social activities outside your home?**
   0 1 2 3
   Not at all Slightly Moderately A Great Deal

6. **Emotional health (nervousness, depression, etc.)?**
   0 1 2 3
   Not at all Slightly Moderately A Great Deal

7. **Feeling frustrated?**
   0 1 2 3
   Not at all Slightly Moderately A Great Deal

Questions 1 & 2: physical activity; Questions 3 & 4: travel; Question 5: social relationships; Questions 6 & 7: emotional health

Appendix 6 (a): Scoring for the IIQ-7

SCORING FOR THE IIQ-7

"Item responses are assigned values of 0 for "not at all", 1 for "slightly", 2 for "moderately", and 3 for "greatly". To allow for missing responses, the average score of items responded to, rather than the total, is taken. The average, which ranges from 0 to3, is multiplied by 33 1/3 to put scores on a scale of 0 to 100. Empirically, the omission of a single item from the short form will not affect the validity of the total score which was estimated by the correlation of long and short form scores. A slight decrement in validity will occur with the omission of two items. If there are more than two items missing, then a total score should not be calculated.

This number provides a single index of life impact associated with urinary incontinence, which subsumes separate domains of physical activity (items 1 and 2), travel (items 3 and 4), social activites (item 5), and emotional health (items 6 and 7). The IIQ-7 does not have separate subscale scores" (Uebersax, Wyman, Shumaker, McClish, Fantl, et al., 1995, p. 134).

Appendix 7: Frequency/Volume Record

FREQUENCY/VOLUME RECORD

Date:_____ Name:_____

Time	Amount Urinated	Leakage on pad? (Yes or No)	Liquid Intake	Comments
6-8 am				
8-10 am				
10-12 am				
12-2 pm				
2-4 pm				
4-6 pm				
6-8 pm				
8-10 pm				
10-12 pm				
Overnight (Just make a check mark for nighttime voids--no need to measure				

Investigator Comments:

Number of voids in 24 hours_____

Nocturia_____

Maximum void_____

Minimum void_____

Number of wet pads in 24 hours_____

Weight of pads

Pre_____ Post_____

Weight of wettest pad_____

Comments:

Appendix 8: 24 Hour Pad Test Instructions

24 HOUR PAD TEST INSTRUCTIONS

We wish to measure as closely as possible the leakage you have on a normal day. To do this we ask you to wear the pads provided. Please change them every 2 hours during the day and at night if you wake up and feel wet.

Steps to follow:

1. Put on the first pad when you wake up in the morning.
   Mark **Time On** on the ziplock bag.

2. Change the pads every two hours even if they do not seem wet. Place the used pad in the ziplock bag and seal tightly.
   Mark **Time Off** on the ziplock bag. The bag will not leak or smell.

3. Keep a record of how much urine you pass--measure the amount with the measuring cup provided.

4. Keep a record of how much you drink--for example 1 cup of coffee, 1 glass of juice.

5. Wear a pad when you go to bed but do not change the pad unless you wake up and feel the pad is wet.

6. Katherine Moore or her research assistant will collect the pads and record at _____.

If you have any questions about the pad test or any part of this project, please call:

Katherine Moore, PhD candidate, Faculty of Nursing, University of Alberta at 492-4635 or at home: 433-0195.

Thank you for helping with this project.

Appendix 9: Pelvic Muscle Exercises for Men

PELVIC MUSCLE EXERCISES FOR MEN

Pelvic Muscles are layers of support muscles. They help stop urine and stool leakage. After your operation, your pelvic muscles are weak. You may leak urine. Pelvic muscle exercises help you gain control. This handout tells you how to do these exercises.

How to do pelvic muscle exercises: Three easy steps:

1. Lie down with your knees bent with feet and knees apart about 10 inches or 25 cm.

2. Concentrate on pelvic floor muscles and relax all other surrounding muscles of the stomach, buttock, and thighs.

3. **Squeeze** the rectal muscles with a firm hold, **hold** for 5 to 10 seconds, then relax for about 10 seconds.

4. Repeat the firm squeezes and relaxation for a total of 12 to 20 times in one session.

Do a set of 12 to 20 muscle contractions **three times a day**. You may exercise sitting or standing instead of lying down.

Imagine you are trying to stop yourself from passing gas. Squeeze the muscle around the rectum. The rectal muscle should move **but the buttocks, thighs, and stomach must stay relaxed. These muscles should not move at all.** You should feel and see the base of your penis twitch and contract in.

YOUR SCHEDULE

SQUEEZE firmly for 5-10 Seconds

RELAX for 10-20 Seconds. Repeat the contractions 12 to 20 times.

Do the exercises 3 times a day.

Appendix 10: Pelvic Exercise Check List

Pelvic Exercise Check List: Dates:________________ Name______________

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning							
Afternoon							
Evening							

Please place a check mark in the day and time that exercises are done.

Pelvic Exercise Check List: Dates:________________

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning							
Afternoon							
Evening							

Please place a check mark in the day and time that exercises are done.

Pelvic Exercise Check List: Dates:________________

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning							
Afternoon							
Evening							

Please place a check mark in the day and time that exercises are done.

Pelvic Exercise Check List: Dates:________________

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning							
Afternoon							
Evening							

Some people find doing regular exercises difficult to do. If you did not do the exercises at any time please leave the square empty. Return the sheet back to the physiotherapy office at the end of the month. Thank you.

Appendix 11: Urinary Incontinence Symptom Inventory

URINARY INCONTINENCE SYMPTOM INVENTORY

Please circle the answer which best describes your symptoms **during the past week.**

A. During the past week have you have problems with urine control?

1. never have a problem with urine control
2. lose control less than once a week
3. loss of control several times per week
4. loss of control several times a day

B. When do you wear pads? (please check all that apply)

1. Never wear pads
2. Only when exercising such as walking
3. When leaving the home for more than 10 minutes
4. At all times during the day but not at night
5. At all times including during the night

C. How often is your underwear wet because of urine leakage?

1. never
2. once a week
3. more than once a week but not every day
4. every day

D. How often is your clothing wet because of urine leakage?

1. never
2. once a week
3. more than once a week but not every day
4. every day

E. How often do you have to change your underwear during the day?

1. never
2. once
3. more than once

F. How often do you have to change your clothing during the day?

1. never
2. once
3. more than once

G. How much money have you spent on pads in the past week?

1. $1.00 or less
2. $1.00 to $5.00
3. $5.00 to $10.00
4. More than $10.00 in the past week

H. Did you practice any exercises to improve urinary control?

1. yes
2. no

I. How upset have you been by any of your problems with urine control?

1. not upset at all
2. slightly upset
3. upset
4. quite upset
5. extremely upset

J. If you leak urine, when is it likely to happen? (check all that apply)

1. getting up out of a chair
2. getting out of bed
3. coughing or laughing
4. walking less than 1 block
5. walking more than 1 block
6. in the late afternoon
7. at night
8. with an urge to pass urine

K. If you wear pads, how many do you use during any 24 hour period? What type do you use?

1. Benefits (blue)
2. Depends (green, elastic straps)
3. penile pouch
4. face cloth
5. towel
6. women's pad
7. other

L. Does urine leakage affect your life?

1	2	3	4
Not at all	A Little	Moderately	Very Much

M. Does erectile dysfunction (impotence) affect your life?

1	2	3	4
Not at all	A Little	Moderately	Very Much

N. Would it bother you if you had to spend the rest of your life with erections the way they are now?

1	2	3	4
Not at all	A Little	Moderately	Very Much

O. Would it bother you if you had to spend the rest of your life with urine control the way it is now?

1	2	3	4
Not at all	A Little	Moderately	Very Much

P. If you had to do it again, would you choose radical prostatectomy as treatment for your prostate cancer?

1	2	3	4
No	Not Sure	Probably	Yes

Comments (use the back of the page if you wish):

Thank you for taking the time to complete this questionnaire. All information about you will remain confidential.

Appendix 12: Demographic Information

DEMOGRAPHIC INFORMATION ID_____

1. Age_____ (years)

2. Date of Radical Prostatectomy_____ (Months)

Please circle the best answer for the following questions:

3.
1. Married or Living Common-Law
2. Widowed, Living with Children
3. Widowed, Living Alone
4. Single, Never Married
5. Divorced, Living Alone
6. Divorced, Living with Children
7. Other: _____

4. What is your Household Income ? (Gross per year)

1. Less than $20,000
2. $20-40,000
3. $40-50,000
4. More than $50,000

5. Education (Highest grade completed)

1. Grade 8 or less
2. Grade 8-12
3. Grade 12
4. College
5. University

6. Employment

1. Employed Full-time
2. Employed Part-time
3. Not Employed (Retired)
4. Not Employed (can't find work

7. How would you describe your current health?

1. Very healthy--do not limit any activities
2. Mainly healthy--feel well most of the time
3. Somewhat healthy--often do not feel well
4. Mainly unhealthy--seldom feel well

8. Living accomodations

1. House
2. Apartment
3. Condominium/Town house
4. Rent
5. Own

9. Religious Affiliation

1. Do not follow a prescribed religion
2. Follow a prescribed faith
3. Attend church/temple regularly

10. Who is your main source of support?

1. Spouse or partner
2. Children
3. Friends
4. Other (minister, social worker, nurse, physician etc)

11. How satisfied are you with this support?

1. Very satisfied
2. Moderately satisfied
3. A little satisfied
4. Not at all satisfied

Thank you for completing this form. All information about you will remain confidential.

Appendix 13: Information Sheet

INFORMATION SHEET

Efficacy of conservative management of urinary incontinence post radical prostatectomy: impact on urine loss and quality of life

Investigator:
Katherine Moore RN, PhD Candidate
Faculty of Nursing
3rd Floor Clinical Sciences Building
University of Alberta, Edmonton
492-4635 (machine); 433-0195 (home)

Supervisor
Marion Allen, RN, PhD
Faculty of Nursing
University of Alberta
Telephone: 492-6411

PURPOSE OF THIS STUDY: You are being asked to participate in a study on leakage of urine (incontinence) after prostate surgery. The purpose of this study is to compare three different ways of treating incontinence. The three methods involve **pelvic muscle exercises. Pelvic muscle exercises** help tighten the urine control muscles at the base of the bladder. You have an equal chance of being in each group.

THE THREE TREATMENTS ARE:

- Standard treatment with written instruction about exercises,
- Intensive treatment with pelvic muscle exercises or,
- Intensive treatment with exercises and electrical stimulation.

STANDARD TREATMENT involves the researcher describing the exercises to you and giving you some written information about pelvic muscle exercises. You will then be free to do the exercises when you wish at home.

INTENSIVE TREATMENT involves treatment with a physiotherapist two times a week. Some men will also be treated with a newer treatment for incontinence called **electrical stimulation. Electrical stimulation** is done with a small rectal probe which sends a pricking impulse to the muscles which control leakage. Stimulation is believed to increase the ability to do pelvic muscle exercises properly. Treatment with stimulation is not harmful and is not painful. There are no known side effects or rectal tenderness from having electrical stimulation. Stimulation has been used on many men with

incontinence.

TIME REQUIRED: You will be asked to fill out some surveys about the amount of incontinence you have and about your quality of life after surgery for prostate cancer. You will also be asked to keep a record for 1 day of how many times you pass your urine, the amount you pass, and the number of pads you use. This information will tell how much leakage you have during a normal day. You will be provided with the pads you need. You will be asked to complete the forms and pad test after the treatments are completed.

The questionnaires and pad tests will be repeated three times: in approximately 3 months, 4 months, and 6 months. Each time the researcher will come to your home.

TAKING PART: You will be contacted by the researcher in seven days to discuss the project further. At that time the researcher will also ask you if you would like to participate. Your participation in this study is entirely voluntary. If you decide to withdraw from the study at any time, your care by any health care professional will not be affected.

CONFIDENTIALITY: If you take part in this study, all information about you will remain confidential. Your name, your doctor's name, and the hospital name will not appear in any reports. All records concerning you will be stored in a locked filing cabinet to which only the researcher has access.

Your physiotherapy expenses at Northtown Physiotherapy will be covered by the researcher.

If you have any questions about the research study, please call Katherine Moore, RN, PhD Candidate at the Faculty of Nursing University of Alberta at 492-4635.

Appendix 14: Consent Form

CONSENT FORM

Research Title: ***Efficacy of conservative management of urinary incontinence post radical prostatectomy: impact on urine loss and quality of life.***

INVESTIGATOR
Katherine Moore RN, PhD Candidate
Faculty of Nursing
3rd Floor Clinical Sciences Building
University of Alberta, Edmonton
492-4635 (machine)

SUPERVISOR
Marion Allen, RN, PhD
Faculty of Nursing
University of Alberta
492-6411

PURPOSE: Men who have surgery for prostate cancer may have urine leakage (incontinence). The purpose of this study is to compare three different methods for treating incontinence. The three treatments are:

- standard treatment with exercises which men do at home,
- intensive exercises to tighten the muscles which control leakage, or
- intensive exercises and electrical stimulation.

We would like to know if intensive treatment is better than exercises alone. There is an equal chance of being in each group.

The intensive treatments will be twice a week for 12 weeks at the office of a specially trained physiotherapist. Treatment will be at the North Town Physiotherapy office. Before and after treatment, we will measure how much incontinence occurs in 1 day. As well, you will be asked to fill out questionnaires about your bladder function and your feelings about your quality of life.

RISKS AND BENEFITS: There are no known risks from electrical stimulation or pelvic muscle exercises. Stimulation has been used safely in many people with incontinence and there are no reports of side effects. You may not benefit from physiotherapy but the results will still help nurses, physicians and physiotherapists when they suggest therapy for men with urinary leakage. This may help improve the care that nurses give to patients.

TIME REQUIRED: At the beginning of the study, in your own home you will

be asked to keep a record for 1 day of how much you drink and urinate and you will wear some incontinence pads which are changed every 2 hours when you are awake. You will also be asked to fill out some forms about urine control and your feelings about your quality of life. This part of the study will take 1 day. After the treatments are completed, the tests will be repeated two more times at your convenience. The two groups who have intense exercises will visit the physiotherapist twice a week for 30 to 45 mintues. Treatment may last as long as 12 weeks.

The questionnaires and pad tests will be repeated three times: in approximately 3 months, 4 months, and 6 months. Each time the researcher will come to your home.

You will be provided with the incontinence pads. Physiotherapy will be provided at no cost to you or Alberta Health.

PARTICIPATION: You do not have to be in this research study if you do not wish to be. If you decide to be in the research study, you may drop out at any time by telling the researcher. You do not have to answer any questions or discuss any subject in the interviews or questionnaires if you do not want to. Taking part in this research study or dropping out will not affect your care in the hospital or in the community.

CONFIDENTIALITY: Your name will not appear in this research study. Only a code number will appear on forms or question sheets. The researcher will erase your name and any other identifying material from the questionnaires. All questionnaires and notes will be kept in a locked cabinet separate from consent froms or code list for seven years after completion of the research study. Consent forms will be kept for at least five years. Data may be used for another research study in the future, if the researcher receives approval from the appropriate ethics reveiw committee.

The information and findings of this research study may be published or presented at conferences, but your name or any material that may identify you will not be used.

QUESTIONS OR CONCERNS: If you have questions or concerns about this research study at any time, you can call the researcher at the number above.

CONSENT: I acknowledge that the above research procedures have been

described. Any questions have been answered to my satisfaction. In addition, I know that I may contact the person named below, if I have further questions either now or in the future. I have been informed of the alternative to participating in this research study. I have been assured that records relating to this study will be kept confidential. I understand that I am free to drop out at any time. I understand that if I do not participate in the research study my care will not be affected. I understand that if any knowledge from the research study becomes available that could influence my decision to continue in this research study, I will be informed promptly. I have been given a copy of this form to keep.

_____ _____

(Signature of Participant) (Date)

_____ _____

(Signature of Researcher) (Date)

Appendix 15: Mean Weeks Post op to Time #2, #3, & #4

Number of weeks post op at study entry, and at Time 2, Time 3, and Time 4 with mean, median, & mode				
Group	*Time 1 (Baseline)*	*Time 2*	*Time 3*	*Time 4*
Control n=	*21*	*21*	*21*	*16*
Mean	7.4	20.0	26.3	31.8
Median	7.0	20.0	26.0	32.0
Mode	4.0	20.0	22.0	28.0
Range	4 - 17	13 - 31	19 - 36	26 - 45
PME n=	*18*	*17*	*16*	*17*
Mean	14.7	29.1	35.4	39.7
Median	7.0	20.0	27.0	32.0
Mode	5.0	20.0	20.0	29.0
Range	4 - 132	14 - 149	20 - 153	25 - 157
PME+ES n=	*19*	*19*	*19*	*16*
Mean	35.2	49.8	57.7	53.7
Median	11.0	24.0	29.0	33.5
Mode	7.0	16.0	26.0	28.0
Range	3 - 208	16 - 225	20 - 241	28 - 176
Total n=	*58*	*58*	*57*	*48*
Mean	18.9	32.5	38.9	41.2
Median	8.0	20.0	27.0	32.0
Mode	7.0	20.0	26.0	28.0
Range	3 - 208	13 - 225	19 - 241	25 - 176

Appendix 16: Individual Pad Test Results

Treatment Group	Case	Statistics	Time - Baseline #1	Time - #2 P Test	Time - #3 P Test	Time - #4 P Test
Control	1		514.20	3.30	3.40	6.90
	2		176.80	29.40	18.70	5.30
	3		6.30	5.50	2.50	4.20
	4		484.40	1.00	2.20	1.00
	5		43.30	7.80	8.30	4.80
	6		328.60	220.00	144.50	264.40
	7		457.10	457.90	30.90	42.60
	8		425.80	2.10	4.60	.
	9		145.70	93.20	120.00	.
	10		686.30	5.10	2.00	2.00
	11		736.00	100.00	16.40	11.20
	12		154.90	7.80	6.40	7.90
	13		372.10	23.80	5.0	.
	14		20.00	24.90	14.80	.
	15		708.30	14.80	4.90	3.80
	16		470.20	95.20	49.90	3.60
	17		157.70	10.60	7.50	6.90
	18		395.50	702.40	530.30	1129.40
	19		627.30	148.70	.	265.80
	20		272.70	17.40	15.60	11.20
	21		921.50	208.00	357.0	.
	Total	N	21	21	20	16
		Mean	385.94	103.76	67.28	54.11
		Median	395.50	23.80	11.55	6.90
		Sum	8104.70	2178.90	1345.60	919.90
		Minimum	6.30	1.00	2.00	1.00
		Maximum	921.50	702.40	530.30	277.30

Treatment Group	Case	Statistics	Time - Baseline #1	Time - #2 P Test	Time - #3 P Test	Time - #4 P Test
		Range	915.20	701.40	528.30	276.30
		Standard Deviation	256.94	176.26	137.40	103.08
PME	1		703.30	380.00	232.60	362.80
	2		401.80	50.90	66.70	52.00
	3		965.90	2.20	3.10	3.90
	4		144.80	.	.	4.2
	5		750.50	155.10	7.10	1.60
	6		1538.60	385.90	494.60	229.30
	7		613.90	8.30	6.90	8.70
	8		272.80	2.70	3.50	1.40
	9		710.40	40.00	13.60	10.90
	10		1054.60	219.30	154.80	236.60
	11		840.30	4.30	2.80	4.70
	12		292.60	10.10	1.00	1.00
	13		140.10	25.00	24.10	23.5
	14		413.90	18.10	.	14.10
	15		151.30	63.70	36.70	42.80
	16		21.50	6.00	5.00	4.6
	17		243.00	5.40	5.3	4.7
	18		922.10	112.5	247.10	.
	19		drop out	rectal pain		
	20		drop out	Mexico		
	Total	N	18	17	16	17
		Mean	565.63	86.89	73.51	69.90
		Median	513.90	32.50	10.35	8.70
		Sum	10181.40	1564.00	1323.20	988.50
		Minimum	21.50	2.20	1.00	1.00
		Maximum	1538.60	385.90	494.60	362.80

Treatment Group	Case	Statistics	Time - Baseline #1	Time - #2 P Test	Time - #3 P Test	Time - #4 P Test
		Range	1517.10	383.70	493.60	361.80
		Standard Deviation	403.30	123.01	131.38	113.52
PME + ES	1		drop out --	stricture		
	2		585.60	3.90	1.10	1.00
	3		794.70	2.10	3.10	10.30
	4		686.90	316.70	399.30	278.90
	5		31.00	1.00	1.00	1.00
	6		968.30	178.40	535.40	179.20
	7		492.10	215.70	387.60	.
	8		406.40	66.90	96.40	7.40
	9		658.40	253.40	226.40	187.70
	10		140.30	87.50	49.20	102.50
	11		6.70	1.40	1.00	1.00
	12		574.50	228.70	85.70	98.40
	13		1344.80	509.30	595.70	.
	14		286.80	359.20	301.70	424.20
	15		12.00	5.50	5.7	3.8
	16		97.30	3.40	1.00	1.00
	17		5.30	20.20	3.4	7.6
	18		62.20	9.7	3.5	1.0
	19		584.00	217.5	390.4	265.2
	20		859.50	473.8	753.4	.
	21		drop out	stricture	.	.
	22		drop out	stricture		Z
	Total	N	19	19	19	16

Treatment Group	Case	Statistics	Time - Baseline #1	Time - #2 P Test	Time - #3 P Test	Time - #4 P Test
		Mean	452.46	155.49	202.15	98.17
		Median	492.10	87.50	85.70	8.95
		Sum	8596.80	2954.30	3840.90	1570.70
		Minimum	5.30	1.00	1.00	1.00
		Maximum	1344.80	509.30	753.40	424.20
		Range	1339.50	508.30	752.40	423.20
		Standard Deviation	385.12	168.11	242.23	132.07
All	Overall Total	N	58	58	57	48
		Mean	463.50	115.47	114.21	72.48
		Median	419.85	27.20	14.10	7.50
		Sum	26882.90	6697.20	6509.70	3479.10
		Minimum	5.30	1.00	1.00	1.00
		Maximum	1538.60	702.40	753.40	424.20
		Range	1533.30	701.40	752.40	423.20
		Standard Deviation	352.23	158.69	185.60	115.68

Appendix 17: Urine Symptom Inventory Summary Scores

Symptom Inventory Responses: Questions A-K*
Scoring: Nominal data summed and mean score taken
C= Control Group, PME=Pelvic Muscle Exercise Group, PME+ES=Exercises + Electrical Stimulation
*Appendix 11 shows the questions in detail

Question	*Total 1*			*Total 2*			*Total 3*			*Total 4*		
	C	PME	PME +ES	C	PME	PME +ES	C	PME	PME +ES	C	PME	PME +ES
A. During the past week have you had problems with urine control?												
1. Never 2. <1x/wk 3. Several x/wk 4. Several x/day	4	4	4	3	3	3	3	3	3	2	3	3
B. When do you wear pads?												
1. Never 2. Exercising (walking) 3. Leaving home >10mins 4. All times except @ nt. 5. Always	5	5	5	4	4	3	4	3	3	4	3	3
C. How often is your underwear wet because of urine leakage?												
1. Never 2. 1x/wk 3.>1x/wk 4. Every day	2	3	2	2	2	2	2	2	2	2	2	3
D. How often is your clothing wet because of urine leakage?												
1. Never 2. 1x/wk 3.>1x/wk 4. Every day	2	2	2	1	2	2	1	2	1	2	2	2
E. How often do you have to change your underwear during the day?												
1. Never 2. Once 3. More than once	2	2	2	1	1	2	1	1	2	1	1	1
F. How often do you have to change your clothing during he day?												

1. Never 2. Once 3. More than once	1	1	1	1	1	1	1	1	1	1	1	1
G. How much money have you spent on pads in the past week?												
1. <$1.00 2. $1.00-5.00 3. $5.00-10.00 4. >$10.00	4	4	4	2	2	2	2	2	2	2	2	2
H. Did you practice any exercises to improve urinary control?												
1. Yes 2. No	1	1	1	1	1	1	1	1	1	1	1	1
I. How upset have you been by any of your problems with urine control?												
1. Not upset 2. Slightly 3. Upset 4. Quite 5. Extremely	3	3	3	2	2	3	2	2	2	2	2	3
J. If you leak urine, when it is likely to happen?(Check all that apply)*												

1. Getting out of a chair	0.8 (.4)	0.8 (.3)	0.6 (.4)	.5 (.5)	.5 (.5)	.4 (.5)	.8 (.4)	.8 (.4)	.7 (.5)	.5 (.5)	.6 (.5)	.4 (.5)
2. Getting out of bed	.5 (.5)	.4 (.5)	.4 (.5)	.1 (.3)	.1 (.3)	.2 (.4)	.5 (.5)	.6 (.5)	.6 (.5)	.1 (.3)	.1 (.3)	.2 (.4)
3. Coughing or Laughing	.2 (.4)	.2 (.4)	.4 (.5)	0 (.2)	.1 (.3)	0 (.2)	.6 (.5)	.5 (.5)	.6 (.5)	.4 (.5)	.8 (.4)	.6 (.5)
4. Walking more than 1 block	.3 (.5)	.3 (.4)	.3 (.5)	.2 (.4)	.2 (.4)	0 (.3)	.1 (.4)	.0 (.2)	.1 (.3)	0 (.3)	.1 (.3)	.2 (.4)
5. Walking less than 1 block	.6 (.5)	.7 (.5)	.5 (.5)	.5 (.5)	.3 (.5)	.4 (.5)	.4 (.5)	0 (.3)	.2 (.4)	.3 (.5)	.3 (.5)	.5 (.5)
6. In the late afternoon	.6 (.5)	.8 (.4)	.4 (.5)	.4 (.5)	.5 (.5)	.4 (.5)	.5 (.5)	.6 (.5)	. 4 (.5)	.4 (.5)	.5 (.5)	.4 (.5)
7. At night	.3 (.4)	.2 (.4)	.6 (1.4)	.1 (.3)	.1 (.4)	.2 (.4)	0 (0)	0 (.2)	.2 (.4)	0 (0)	0 (.2)	.2 (.4)
8. With an urge to pass urine	.4 (.5)	.6 (.5)	.5 (.5)	.4 (.5)	. 3 (.5)	. 5 (.5)	.5 (.5)	.1 (.4)	.5 (.5)	.4 (.5)	.2 (.4)	.4 (.5)
***Mean (SD)**												
K. If you wear pads, how many do you use during any 24 hour period?												
	3.4	4.9	2.8	1.5	1.6	1.9	1.9	1.7	2.5	1.3	1.7	1.5