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THE UNIVERSITY OF ALBERTA

AN EVALUATION OF TWO SUCTION TECHNIQUES IN RELATION TO ICU NOSOCOMIAL PNEUMONIAS

by

CATHERINE JOAN (CARTER) SNELL

A THESIS

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Date: April 15, 1988

DEDICATION

My family have always encouraged me to reach for my goals, helped me to laugh at life and patiently supported me in many ways, not only with their love, but also their time and even computer expertise. This thesis is dedicated with love and thanks to all of my family:

T. Mark Snell

William (Bill) and Joan Carter

Barb, Nasir & Dru Kara

Susan & Ted Tsagkaris

Judy Carter

Charlotte (Jeanne) Richards

" If I have the gift of prophecy and can fathom all mysteries and knowledge, and if I have a faith that can move mountains, but have not love, I am nothing." (Corinthians I:13)

ABSTRACT

Endotracheal suctioning is a procedure frequently performed on critically ill patients who, as a group, face exceedingly high risks of acquiring nosocomial pneumonias. It has been assumed that breaks in aseptic technique during endotracheal suctioning will result in pneumonia, but very little research has been published in which such a relationship has been investigated.

A sample of 171 endotracheally intubated subjects was obtained from a large metropolitan medical/surgical ICU. Subjects were randomly assigned to two different suctioning techniques. One technique required the use of conventional sterile disposable catheters and frequent disconnection of the endotracheal tube from the ventilator. The second technique required the use of a multi-use catheter enclosed in a sterile plastic sheath which forms a closed system between the patient and ventilator. Data were collected for a minimum of 48 hours and a maximum of 144 hours (six days) on all subjects, dependent upon how long each remained intubated.

Considerable attrition was experienced over time. At three days 69 subjects remained and at six days 31 remained. No statistically significant differences were found in the distribution of infections or colonization between the two suctioning groups, although the multi-use catheter group had more subjects with pneumonia at both three and six days. At three days, the multi-use group contained significantly more subjects who had aspirated ($p = .003$) and received significantly more

frequent suctioning ($p = .021$) when compared to the conventional group. There were, however, no significant differences in the frequency of suctioning between subjects at each level of infection. All analyses were two-tailed with an alpha level of 0.05.

The lack of a statistically significant difference suggests that either of the two suctioning methods may be used without altering the subjects' risk of infection. Small sample sizes were a problem, however. In the absence of a difference, the choice between suctioning methods can be based instead on factors such as cost-effectiveness, efficiency and physiologic requirements. It is recommended that suctioning frequency continue to be performed only as needed, rather than on a regularly scheduled basis. Further ICU studies are needed comparing other types of catheters and techniques prior to generalizing these results.

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INTRODUCTION

Patients admitted to an Intensive Care Unit (ICU) are generally critically ill. They face many potential complications as a result of their primary disease or injury, which could further endanger their lives. It is important that ICU patients be protected as much as possible from additional complications, such as nosocomial (hospital-acquired) pneumonia. Mortality rates for ICU patients with nosocomial pneumonias have been reported as high as 28% to 65% (Bryant et al, 1972; Craven et al, 1986; Salata et al, 1987). Further, Bryant et al reported at least 89% of their subjects' deaths were directly attributable to pneumonias.

In addition to the high risks of mortality associated with nosocomial pneumonias, ICU patients acquire these infections much more frequently than patients in other wards of the hospital. Approximately 0.5 to 5.0% of all hospital patients have been found to develop nosocomial pneumonia, with the upper frequencies occuring more commonly among those patients in university teaching hospitals (Sanford & Pierce, 1979). These frequencies are relatively low, particularly when contrasted with frequencies of between 20 and 41% which are found among ICU patients (Bryant et al, 1972; Potgieter, Linton, Oliver & Forder, 1987; Salata et al, 1987). Of all pneumonias which occured in one hospital over a five year period, Wenzel et al (1983) found 41% of the pneumonias were in ICU patients. High frequencies of pneumonia in ICU patients are also reflected in surveillance data from a local teaching hospital. A seven month surveillance of one ICU in that hospital

revealed an incidence of 20.5 pneumonias per 100 ICU discharges or deaths (Infection Control Unit, 1985) and, in a later prevalence study, 33.3% of the same ICU's patients were found to have nosocomial pneumonias (Infection Control Unit, 1986).

Although it is known that ICU patients face greater risks of pneumonia and subsequent mortality, the predominant sources by which the patients acquire these pneumonias are unclear. There is an interaction between three elements in the development of nosocomial pneumonias. These three include the immunological state of the host, the type of potential pathogen, and the route with which the organisms enter (Fuchs, 1979). The route of entry for the pathogens is of concern to ICU personnel as it represents a means by which patients' risks of acquiring pneumonia may be reduced. It is not always possible to change the host factors or the types of organisms predominant in an ICU. The relative contributions of various factors as routes of entry have been studied, but none has been conclusively demonstrated to be the most important factor with which to explain the source of the organisms involved in the pneumonias.

The organisms may originate from within the patients. Critically ill patients have been noted to develop oropharyngeal colonization (growth of potential pathogens in the absence of infection), particularly with gram-negative organisms (Stamm, 1981). Overgrowth of these oropharyngeal organisms could result in micro-aspiration of the organisms into the lower respiratory

tract, and ultimately in a pneumonia (Sottile et al, 1986). The presence of an endotracheal tube with a properly inflated cuff does not prevent this micro-aspiration (Elpern, Jacobs & Bone, 1987). Critically ill patients may not have adequate defenses against these organisms and pneumonia may result. Aspiration of gastric contents and gastric flora may be another internal source of potential pathogens. As most patients in ICU experience micro-aspirations of oropharyngeal secretions and some aspirate gastric secretions, one would expect the frequency of nosocomial pneumonias to be even greater than it is if this were the primary source of nosocomial pneumonias.

External routes for potential pathogens exist, such as with the use of contaminated equipment or with breaks in asepsis during respiratory procedures. Respiratory equipment, such as ventilators and humidifiers, was once thought to be a primary source of the pneumonia organisms. However, the findings of several research investigations have indicated that the organisms found in the ventilatory equipment actually originate from the patient and spread to the tubing (Craven, Goularte & Make, 1984; Malecka-Griggs & Reinhardt, 1983). Since the advent of modern sterilizing techniques and improved standards for care of respiratory equipment, the role of ventilators and respiratory nebulizers has now been described as negligible (Dixon, 1983). Respirometers were found to be contaminated in one study (Cross & Roup, 1981), and

suctioning connective tubing has also been reported to be contaminated (Cunningham & Sergent, 1983).

There is evidence to indicate that nosocomial pneumonias may originate from the direct contamination of patients by organisms on the hands of ICU personnel (Larson, 1979). In a study of ICU patients receiving mechanical ventilation for more than 48 hours, Craven et al (1986) observed that the group acquiring nosocomial pneumonias received increased manipulation of their ventilator tubings. The investigators concluded that the increased frequency of tubing manipulation could have created greater opportunities for introduction of organisms into the respiratory tract.

Organisms may also be introduced into patients' lower respiratory tracts during other procedures which require frequent manipulation of the respiratory tract, and which may damage the respiratory tract's normal defenses. Examples of such procedures are endotracheal intubation and endotracheal suctioning. Both procedures are necessary to maintain patency of the patient's airway, however, they have also been found to damage the protective mucociliary lining of the respiratory tract (Graybill, Marshall, Charache, Wallace & Melvin, 1973; Jung & Gottlieb, 1976). If organisms are introduced into the damaged area in sufficient quantities, a pneumonia could develop. Many procedure manuals contain warnings stating the need to use strict aseptic technique during endotracheal suctioning as a means of preventing pneumonias. There has been very little published research in which

such a relationship between endotracheal suctioning and nosocomial pneumonias has been investigated or established. Larson (1970) noted an increase in the frequency of suctioning was associated with an increase in the incidence of respiratory colonization in ICU patients. Unfortunately, the types of subjects used by Larson and other investigators, and the equipment used in some of the studies do not permit generalization of these results to endotracheally intubated ICU patients.

The risks of ICU nosocomial pneumonias are of concern to ICU personnel, particularly those who perform procedures such as endotracheal suctioning. In most ICU's it is frequently the nurse who determines the need for the patient to be suctioned and who performs the procedure. The role of nursing procedures such as endotracheal suctioning in the etiology of ICU nosocomial pneumonias must be determined in order to decrease the risks ICU patients face. The purpose of this study was to expand the body of knowledge available regarding the relationship between endotracheal suctioning and ICU nosocomial pneumonias. This information could then be used to provide future directions for research and improved nursing care of intubated, ventilated ICU patients.

LITERATURE REVIEW

The literature reviewed was primarily from the years 1970 to 1987, with a focus on adult ICU subjects. The literature was identified through a Medline search for all years, followed by a manual search for the years 1982 to 1987 to verify the accuracy of the Medline search. Most of the materials located were available through the University of Alberta John Scott library, or their interlibrary loan service. The remainder of the materials were obtained through either hospital suppliers or the Canadian Laboratory Centre for Disease Control.

The development of nosocomial pneumonia is a complex process which depends on a variety of risk factors. Each of these risk factors will be addressed, followed by an examination of the potential role of endotracheal suctioning in the etiology of ICU pneumonias. The review concludes with a discussion of a relatively recent development in endotracheal suctioning equipment - the Trach Care catheter (Ballard Medical).

Risk Factors

Various risk factors have been noted to contribute to the development of nosocomial pneumonias. These factors may be broadly grouped into three categories: (1) host factors, (2) characteristics of the organism, and (3) portals of organism entry (Fuchs, 1979). Each of these risk factors interact in such a way that patients may develop nosocomial pneumonias if various combinations of these factors exist. Each category of risk factors

will be discussed with a focus on issues relevant to endotracheally intubated ICU patients.

Host factors

The category of host risk factors includes those aspects of the patients, their disease or their therapy which may compromise their normal responses against infection. The respiratory tract is normally considered to be sterile below the level of the larynx (Stratton, 1986). Respiratory defense mechanisms which exist to maintain this sterility include the filtering of air as it passes through the nasopharynx, and the removal of organisms from the respiratory tract by the upward actions of a ciliated mucous lining (Janson-Bjerklie, 1983). There are six major categories of host risk factors which may either inhibit or overwhelm these defenses. The six include: trauma to the mucociliary lining; oropharyngeal colonization with potential pathogens; drugs which alter the immune system; specific diseases or failure of body systems; a malnourished state; and advanced age of the patient. Each of these host risk factors will be discussed, again with a focus on the adult ICU patient.

Trauma to the mucociliary lining.

It has been demonstrated by various researchers that certain procedures will denude mucociliary lining of the respiratory tract. These procedures include: endotracheal intubation (Graybill, Marshall, Charache, Wallace & Melvin, 1973); the application of negative vacuum pressure during suctioning (Jung &

Gottlieb, 1976; Kuzenski, 1978); the mere insertion of suction catheters in the absence of vacuum pressure (Kleiber, Kratzfield & Rose, 1988; Link, Spaeth, Wahle, Penny & Glover, 1976); and the use of bronchoscopes (Fuchs, 1979). The presence of the endotracheal tube and the performance of suctioning not only bypass the body's normal filtering functions, but have also been found to decrease the mucous velocity in the mucociliary lining (Sackner, 1978; Sackner, Landa, Greeneltch & Robinson, 1973) and to decrease the mucosal blood flow with extreme endotracheal tube cuff pressures (Podjasek, 1983). If organisms are introduced into the respiratory tract, there are few natural local defenses left to prevent an infection.

Oropharyngeal colonization.

The stress of the illness itself could lead to adhesive oropharyngeal colonization. Patients have been noted to develop this oropharyngeal colonization within 24 to 48 hours of an ICU admission, often with gram-negative organisms, and in the absence of obvious sources of the organisms (Bartlett, O'Keefe, Louie & Gorbach, 1986; Higuchi & Johanson, 1982; Stamm, 1981). Higuchi and Johanson (1982) investigated 32 surgical patients prospectively. Half of the patients developed an increased buccal attachment of Pseudomonas organisms postoperatively, and of these subjects, 69% became colonized with that organism. The investigators described a relationship between the presence of respiratory colonization and having experienced major operations, as well as between

colonization and the presence of chronic respiratory disorders. The rate of colonization was noted to rapidly increase with most patients on ventilators (Higuchi & Johanson) and with patients who received instrumentation of the respiratory tract (Graybill, Charache, Wallace, & Melvin, 1973). Micro-aspiration of oropharyngeal secretions containing potential pathogens may then occur, from which a pneumonia may result (Higuchi & Johanson, 1982; Schlenker & Hubay, 1973; Sottile et al, 1986).

Sottile et al (1986) microscopically examined 25 endotracheal tubes immediately after patients were extubated. In 68% of the tubes, bacterial aggregates were noted in a glycocalyx which adhered to the inside the of endotracheal tubes. There were no bacterial forms noted in 7 of the tubes (28%), but these endotracheal tubes had only been in patients for a mean of 2.6 days compared to an average of 9.2 days for the other tubes. The investigators suggested that once formed, bacterial aggregates may be dislodged from the inside of the endotracheal tube during suctioning creating the potential for the development of pneumonia.

Drugs.

Although ICU patients may be immunosuppressed as a result of the severity of their disease, the use of some drugs can further depress their defenses against infection. In a retrospective chart review of 212 patients, Graybill, Marshall and Charache (1973) found that most patients with nosocomial pneumonias had either

experienced respiratory trauma from procedures or else had received either immunosuppressant drugs or antibiotics prior to developing the pneumonia. In prospective studies of ICU patients, neither Salata et al (1987) nor Craven et al (1986) found that immunosuppressants were a significant factor in those subjects who developed pneumonia. Craven et al reported that prior antibiotic use and greater numbers of gram-negative organisms were found in the group of ICU subjects which had more pneumonias. This group of subjects was receiving ventilator tubing changes every 24 hours whereas the other group received changes every 48 hours. The investigators attributed the difference in frequency of pneumonias to the more frequent manipulation experienced with tubing changes every 24 hours. Other researchers, each using sample sizes of between 140 and 762 subjects, also noted a predominance of prior antibiotic use in the subjects who acquired nosocomial pneumonias, again with primarily gram-negative types of organisms (Chavigny & Fisher, 1983; Price & Sleigh, 1970; Rose & Babcock, 1975). Some investigators, using samples of between 36 to 83 subjects, reported no difference in the pneumonia and non-pneumonia groups with respect to antibiotic use (Mylotte & Beam, 1981; Rogers & Osterhaut, 1970; Salata et al, 1987).

Tobin & Grenvik (1984) suggest that the role of the gastrointestinal tract in the development of pneumonias may increase with the use of cimetidine and antacids, due to resulting changes in the gastrointestinal flora. In studying 233 ICU

patients; Craven et al (1986) found cimetidine only to be a significant variable in the development of pneumonia when in combination with more frequent ventilator circuit changes, the presence of an intracranial monitor, and the fall-winter season.

Anaesthetic agents are another group of drugs thought to compromise patients' defenses. An increased number of pneumonias were found in surgical patients who received general anaesthesia (Cross & Roup, 1981; Gross, Neu, Aswapokee, VanAntwerpin & Aswapokee, 1980). The combination of anaesthesia and sedation decreases the effectiveness of patients' normal respiratory clearance mechanisms, leading to potential hypoventilation and pneumonia (Veazey & Wenzel, 1979).

Diseases or system failures.

Defense mechanisms of ICU patients may also be compromised with any disease which results in diminished renal or liver function, vascular insufficiency, or decreased levels of consciousness. These types of disorders were present with greater frequency among the patients who developed pneumonia than among those patients without pneumonia (Bartlett, O'Keefe, Tally, Louie & Gorbach, 1986). Graybill, Marshall, Charache, Melvin and Wallace (1973) reported a high correlation between mortality and azotemia in those subjects who had pneumonia.

A multicentre surveillance program for nosocomial infections was conducted by the Canadian Laboratory Centre for Disease Control (Riben, Wells & Trotman, 1986). In addition to finding

increased frequencies of vascular, renal, neurological, pulmonary and hepatic disorders among subjects with pneumonias, one of the most common conditions co-existing with the pneumonia was the presence of an extrapulmonary infection in the previous two weeks.

Malnutrition.

Patients may become malnourished while in the ICU. Illness increases a patient's caloric requirements, yet while in ICU, patients often receive well below their normal caloric intake. Protein malnutrition results in a decrease in secretory antibodies in the respiratory tract and in humoral immunity, and if the malnutrition is prolonged, atrophy of the liver, spleen, marrow and lymph tissues (Kiethley [illegible]83). With decreased defenses, the patient may not adequately ward off potential pathogens.

Advanced age.

The age of a patient may also be an influencing factor in the efficiency of patient defense mechanisms. The immune functions of the elderly gradually diminish with age (Stratton, 1986). Some researchers have reported that a significant number of subjects with nosocomial pneumonias (and nosocomial infections of all types) were in the over 60 year age group (Cross & Roup, 1981; Gross, Rapuano, Adrignola & Shaw, 1983; Rogers & Osterhaut, 1970; Scheckler & Peterson, 1986). However, in two recent studies of ventilated ICU subjects, age was not found to be a be a significant variable in the development of nosocomial pneumonias (Craven et al, 1986; Salata et al, 1987).

There are many host factors which may diminish patients' defenses against infection. ICU patients often exhibit at least one or more of the host risk factors on entering the unit and may experience more as their condition progresses. The efficiency of their immune systems will determine, in part, whether or not a pneumonia will result if organisms are introduced or aspirated into their respiratory tracts. Those patients who are most critically ill or debilitated will be at greatest risk of acquiring an infection. The patient with relatively intact immune functions, however, may not necessarily avoid a nosocomial pneumonia. Another factor is important in the development of pneumonia - the characteristics of the organisms introduced.

Characteristics of the Organisms

Certain characteristics, such as the type, virulence and amount of the organism which have been introduced into the respiratory tract, will determine whether the patient will be able to fight a potential infection. The type of organisms most often responsible for ICU nosocomial pneumonias has changed from the gram-positive type organisms predominant in the past to primarily the gram-negative type, especially gram-negative rods (Larson, 1985; Stratton, 1986). Gram-negative organisms are also the type most commonly found with the spontaneous oropharyngeal colonization which occurs in ICU patients (Johanson, Pierce, Sanford & Thomas, 1972; Redman & Lockey, 1967; Rose & Babcock, 1975; Schlenker & Hubay, 1973). There is concern with the

predominance of gram negative organisms as a result of the virulence of the organisms.

Gram-negative pneumonias are considered to be more virulent (Price & Sleigh, 1970; Tobin & Grenvik, 1984) and to be associated with higher mortality rates than gram-positive pneumonias (Craven et al 1986; Rogers & Osterhaut, 1970). Patients who survive gram-negative type pneumonias may also experience greater morbidity, as the organisms can create greater inflammation and tissue damage in the lungs than gram-positive organisms (Reynolds, 1986). The inflammation and damage could result in residual fibrosis and scarring of the lungs. Other concerns with gram-negative organisms include a possible impairment of defenses in the critically ill against gram-negative organisms (White, Nelson, Winkelstein, Booth & Jakab, 1986), the growing resistance of gram-negative organisms to various antibiotics (Stamm, 1981), the ability of gram-negative organisms to easily tranfer that resistance to other organisms (Crowley, Edwards & Mellinger, 1986; Thomas, Jackson, Melly & Alford, 1977), and the poor penetration of anti-gram-negative agents into the pulmonary secretions (Stamm, 1981).

Although gram-negative organisms may be present and are virulent, the amount of the organisms present is also important. According to Johanson, Pierce, Sanford & Thomas (1972) and Larson (1970), only 23 to 27% (respectively) of the subjects whose lower respiratory tracts were colonized subsequently developed pneumonia. Most of those subjects who did progress to pneumonia

were colonized with gram-negative organisms. Micro-aspiration of colonized oropharyngeal secretions may occur (Elpern, Jacobs & Bone, 1987), as may aspiration of gastric secretions containing pathogens, particularly in patients with nasogastric tubes (Tobin & Grenvik, 1984). Pneumonia may not result from the aspiration unless the subject is overwhelmed with the amount of the organisms present in the aspirate (Fuchs, 1979). An accidental instillation of the contaminated ventilator condensate during the repositioning of a patient could overwhelm the patient's remaining defenses (Craven, Goularte & Make, 1984).

ICU patients comprise a high risk cohort for developing nosocomial pneumonias. The patients may not have the defenses available to fight potential pathogens introduced into their lower respiratory tracts. It is necessary to determine the primary portals of entry for these organisms in order to reduce the patients' risks of pneumonia.

Portals of Organism Entry

Organisms may be introduced into the lower respiratory tract via routes which are either endogenous or exogenous to the patient. Endogenous routes are those in which the organism has come from another part of the patient, and exogenous routes are those in which organisms originate from outside of the patient.

Endogenous routes.

An endogenous portal of entry exists when the patients' normal flora move from one site of the body into another, or when

pathogens from one site are spread to another site. Two main endogenous routes include the aspiration of either oropharyngeal or gastric contents into the lungs, and the hematogenous spread of organisms from one site of infection to another.

Aspiration of either oropharyngeal organisms or gastric contents has been frequently cited as a potential source of nosocomial pneumonias (Dixon, 1983; Higuchi and Johanson, 1982, Sottile et al, 1986). The frequency of aspiration of posterior oropharyngeal secretions was compared between healthy sleeping volunteers and non-intubated patients with decreased levels of consciousness (Huxley, Viroslav, Gray & Pierce, 1978). The investigators found that 70% of the comatose patients aspirated oropharyngeal secretions and even 45% of the healthy subjects aspirated small amounts of secretions. Only 10 comatose patients were compared with 20 healthy volunteers, but based on these results, the investigators concluded that a decreased level of consciousness contributed to the risk of aspiration. Patients with decreased levels of consciousness are often intubated in order to maintain the patency of their airway, but they may still experience micro-aspiration of secretions around the endotracheal tube cuff, in either supine or head-elevated positions (Elpern, Jacobs & Bone, 1987; McCrae & Wallace, 1981; Mehta, 1972). Decreased levels of consciousness were not found to be a significant factor in a study examining aspiration with intubated ICU subjects (Elpern, Jacobs & Bone, 1987). By placing small

amounts of methylene blue on the posterior pharynx of subjects, the investigators found that 77% of the 31 subjects showed the dye in anywhere from 3 to 100% of their sputum samples, regardless of cuff inflation, head elevation or the use of small nasogastric feeding tubes. Aspirations were noted with greater frequency when the cuffs of the tracheal tubes were inflated to occlusion rather than when a minimal leak technique of cuff inflation was used, and when a nasogastric feeding tube was in place. Most intubated ICU patients have nasogastric tubes in place so it may be difficult to determine whether it is the endotracheal tube or nasogastric tube which is a more important risk factor for the aspiration of secretions.

The presence of extrapulmonary infections within the two weeks preceding a nosocomial pneumonia was noted to be one of the most common acute conditions co-existing with the nosocomial pneumonias in a Canadian surveillance study (Riben, Wells & Trotman, 1986). Approximately 20% of patients with multiple infections later developed nosocomial pneumonias. Cross and Roup (1981) found that among 107 subjects with nosocomial pneumonia, those subjects with extrapulmonary infections had a mortality rate twice as great as those without extrapulmonary infections. The investigators, however, did not indicate if there were any differences in the incidences of nosocomial pneumonia between those subjects with and those without extrapulmonary infections.

Many ICU patients, therefore, may either aspirate or experience hematogenous spread of organisms from extrapulmonary infections. In addition to these endogenous portals of entry, patients are also at risk of exposure to sources of organisms externally. The respiratory tract is not a closed system and organisms may be introduced during procedures which invade the respiratory tract. Every ICU patient has at least one piece of external equipment or requires at least one treatment with which organisms could be introduced into the body. This external element comprises the exogenous portal of organism entry.

Exogenous routes.

Exogenous routes of organism entry are created when organisms are transmitted to the patient by external sources. Three common exogenous routes are via the use of contaminated ventilatory devices, the instrumentation of the respiratory tract, or the transmission of organisms on the hands of ICU personnel.

Ventilators and respiratory equipment were long considered to be the primary source of respiratory pathogens. With the advent of improved sterilization techniques and standards for the care of ventilators, ventilators are now less commonly sources for organisms. In a study of 233 ventilated ICU patients, Craven et al (1986) did not find ventilator use to be a significant variable in the group which developed nosocomial pneumonias, although organisms which may multiply in the condensate may still pose a

threat if the condensate is accidentally instilled into the patient.

Mainstream ventilator humidifiers, reservoirs and nebulizers generate aerosols of a size small enough to enter the lungs. Rhame, Streifel, McComb and Boyle (1986) studied one of each of the major types of bubbling humidifiers for ventilators. After contaminating the reservoir solution with Pseudomonas organisms, the bubbling humidifiers were found to render these organisms airborne in varying degrees, depending on the make of humidifier. The wick-type of humidifiers were the only ones which did not create aerosols. The investigators, however, did not heat the reservoir solutions as would have been done in the clinical setting. Other researchers have demonstrated that reservoirs and humidifiers are an unlikely source of pathogens, as any organisms in the solutions are killed at the normal operating temperatures of the ventilator (Goularte, Manning & Craven, 1987; Harris et al, 1973; Craven, Goularte & Make, 1984). Cross & Roup (1981) found all nebulizer fluid cultures in their study to be sterile, but 31% of the respirometers used were colonized, one of which was directly associated with a fatal case of pneumonia. Respirometers were not discussed in any other research reports.

Ventilator devices may act as potential exogenous routes of entry for organisms. Based on the research published, it would appear that, as long as sterilization and care guidelines for equipment are adhered to, ventilator devices are not a frequent

route of entry. The association between ICU patients with nosocomial pneumonias and ventilators could be due to the need for instrumentation of the respiratory tract of critically ill patients who are on ventilators.

Instrumentation of the respiratory tract has also been reported as a factor in the transmission of potential pathogens. LeFrock, Klainer, Wu and Turndorf (1976) studied 68 ICU patients and 30 healthy volunteers during nasotracheal suctioning. Transient bacteremia was noted in 17.6% of the ICU patients versus 0.3% of the control group. Storm (1980) found a similar transient bacteremia after suctioning 3 out of 10 newborns and concluded that the trauma to the mucociliary lining allowed the introduction of organisms colonizing in the respiratory tract into the bloodstream. In a report of a case study, Timms and Harrell (1975) described the presence of a bacteremia in a patient following fiberoptic bronchoscopy, although no blood or trauma was apparent at the time of the bronchoscopy. Bronchoscopies have also been associated with the development of fevers and/or new radiographic chest infiltrates following the procedure. Pereira at al (1975) prospectively studied 100 subjects who had bronchoscopies performed. Fever or radiographic changes developed in 16 of the patients, with some fevers lasting as long as 48 hours. The investigators did not report the significance of the frequency of the complications, but did note that a patient age greater than 60 years and the presence of lesions on endoscopic exam were factors

significantly associated with the development of complications post-bronchoscopy.

The combination of a severely ill patient and trauma to the respiratory tract may predispose the patients to respiratory infections and bacteremia. If potential pathogens were carried into the lower respiratory tract with respiratory devices, they would be deposited on the already traumatized (and highly vascular) mucosal lining. The organisms may originate from the oropharynx or be introduced via contaminated equipment. The manipulation of equipment, rather than the equipment itself, may be an important exogenous source of organisms.

Larson (1985) stated that the major route for transmission of the organisms responsible for infections in critical care is the direct contact with the hands of personnel. In a study of 103 ICU staff and 50 controls, Larson found at least one or more types of gram-negative organisms on 21% of the personnel. The group who exhibited gram-negative organisms on their hands most frequently consisted of those who washed their hands less than eight times a day, and more males than females. Frequency of handwashing has been a problem in many infection control efforts. Albert and Condu (1981) observed ICU staff in two hospitals at high traffic times, pretending to measure traffic flow. Handwashing was observed after only 41% of patient contacts, with doctors performing the least frequent washing and respiratory technologists the most. Larson (1985) found a similar pattern while studying 193 ICU personnel.

When a role model was present in a group of doctors on rounds, handwashing occured after 48.1% of patient contacts, and after only 24.1% of patient contacts when no role model was present. When patients were known to be infected and were on isolation, handwashing occured after only 44.8% of patient contacts. There are potential limitations to both studies as they were observational in nature, but the results of both indicate the limited frequency of handwashing in ICU.

If the personnel are carrying potential pathogens on their hands, the organisms may not be completely removed even with careful handwashing. Two different cleansing solutions were evaluated by Knittle, Eitzman and Baer (1975). Gram-negative organisms were found on 86% of 282 consecutive cultures from the hands of nurses. Following washes with Phisohex, 80% of the cultures continued to demonstrate gram-negative organisms. After switching to Betadine washes, there was a reduction in growth but 50% of the cultures continued to demonstrate gram-negative organisms.

The hands of one respiratory therapist were found to be the source of an outbreak of organisms which were originally thought to be from ventilatory equipment (Buxton, Anderson, Werdegar & Atlas, 1978). The therapist was contaminating newly sterilized equipment as he was setting the equipment up. Craven et al (1986) suggested that a similar mechanism may be responsible for one of the findings in their study of ventilated ICU patients. It was

discovered that presence in the group receiving ventilator tubing changes every 24 hours instead of every 48 hours was a significant variable for those subjects who developed nosocomial pneumonias. Craven et al concluded that the significance of the frequency of tubing changes was probably due to the increased manipulation of the ventilator tubings. This would allow for greater opportunities for contamination of the equipment and ultimately the patient.

The question remains as to where the organisms on the hands of the personnel come from. Johanson, Pierce, Sanford and Thomas (1972) studied ICU patients and their environments. The investigators found similar organisms in the patients' environments and on the patients' hands as in their respiratory tracts. The close proximity of ICU patients, the frequent contacts the patients receive from personnel, and the manipulation of the respiratory support equipment are all conducive to the transmission of organisms from patient to patient on the hands of personnel. The importance of handwashing in this close environment is even greater in light of the resistance and virulence of the organisms.

Each of the three elements involved in the development of pneumonia are clearly interactive - the host factors, the characteristics of the organism present and the portals by which the organism may enter the body. Nurses in ICU are dealing with severely ill, immunocompromised patients, and have been found to

carry gram-negative organisms on their hands. One of the most frequently performed treatments for intubated ICU patients is that of endotracheal suctioning. This procedure involves manipulation of the patients' respiratory tracts and ventilatory equipment, providing the potential for patient contamination. Endotracheal suctioning may act as a portal of entry for organisms, particularly if hand-contamination of the suctioning equipment has inadvertently taken place. Previous research related to suctioning and pneumonias is presented, followed by a description of a relatively new method of suctioning.

Endotracheal Suctioning and Pneumonia

It is frequently necessary for nurses (and respiratory or physiotherapy personnel) to perform endotracheal suctioning on intubated patients, as the patients are unable to effectively clear their own respiratory secretions. Suctioning is associated with many potential complications, such as the induction of hypoxia (MacKinnon-Kessler, 1983; Gonzalez, Erchowsky & Ahmed, 1983), the precipitation of cardiac dysrhythmias (Young, 1984), the creation of trauma to the respiratory tract lining (Jung & Gottlieb, 1976), as well as the production of fear and anxiety in the patient (Billingsley & Radford). There are many techniques and types of suctioning equipment available, with little consistency found between hospitals (or units) in the method or equipment used (Cunningham & Sergent, 1983). The nursing and respiratory

literature are replete with admonitions to use strict aseptic technique in order to avoid pneumonia, however there is little research evidence to support or refute this position.

In an early study of tracheostomy care (which includes suctioning), the respiratory colonization of 24 subjects receiving "meticulous" tracheostomy care was compared with 18 subjects receiving "standard" tracheostomy care (Reinarz, Wells & Murphy, 1968). The meticulous care included the use of gloves, disposable catheters and no reservoir solution, but the standard care was not fully described. Those subjects receiving standard tracheostomy care colonized with gram-negative organisms more rapidly than those subjects receiving meticulous care, but by four days the colonization counts were equal between groups. Harris and Hyman (1984) conducted a similar study using 209 subjects who had received head and neck surgery and required tracheostomies. Ten hospitals were used, four in which "sterile" technique was performed during tracheostomy care, three in which "clean" technique was performed, and three in which a mixture of clean and sterile techniques were used. Subjects were scored for the presence of infection using a newly designed weighted measurement tool based on laboratory and subjective subject data. The tool was reported to have a criterion-related validity of 84.75%, but the measurement used as the criterion was based on the subjective opinion of an observer. It is unknown if the observer was blind to the outcome of the tool measurement, or whether the observer was

the same for each measurement. No significant difference in the number of infections was found between groups, although a trend was noted toward greater numbers of infections in the groups which received sterile tracheostomy care. This trend may be explained by the use of a new measurement tool to diagnose infections which had limited validity, but the researchers also observed a few notable differences. In the hospitals using the sterile technique, the procedures were frequently not adhered to and handwashing was rarely observed before and after suctioning. The nurses in hospitals using the clean technique were observed to be more consistent in their techniques. The differences in these observations were not quantified.

Bluemle (1970) investigated the effects of tracheal suctioning on tracheal bacterial counts under two conditions: first, if the same catheter was used to clean the mouth and tracheostomy; and second, if separate catheters were used to clean the tracheostomy and mouth. Reusable rubber catheters were used and stored in disinfectant between treatments. No significant differences were found, but a total sample of only four subjects was used. Furthermore, the practice of storing and reusing rubber catheters is no longer commonly in use.

Of the three studies found on suctioning and contamination or infection, all were based on samples of subjects with tracheostomies. Generalization of the study results to patients with endotracheal tubes cannot be assumed. Specifically, factors

such as proximity of the skin to the tube and length of stay differ between tracheostomy and endotracheally intubated patients. The proximity of the skin to the tracheostomy opening may allow the introduction of contaminants or normal skin flora (Fuchs, 1979), which may not be a factor with an endotracheal tube. In addition, tracheostomy patients tend to be hospitalized for longer periods of time, often previously having been intubated for a long time, both factors being commonly associated with increased risks of respiratory infection. Salata et al (1987) found that an increased length of intubation time was significantly associated with pneumonia in their group of ICU subjects.

The only published research investigating respiratory colonization and infection using subjects with nasotracheal or endotracheal tubes was reported by Larson (1970), although some subjects with tracheostomies were also included in the sample. Larson reported that the incidence of respiratory colonization increased along with the frequencies of nursing procedures such as suctioning, cuff deflation, use of the manual bagger, number of saline instillations and manipulation of the humidifiers and ventilators. The significance of this increase was not described, nor was the impact of these procedures on the rate of infections described. A common factor in each of the nursing procedures investigated was the need to manipulate the airway, lending support to the theory that pneumonias could result from breaks in aseptic technique during suctioning.

The contamination rate of suction apparatus in ICU was investigated by Cunningham & Sergent (1983). New suction connection tubings were handled for three minutes, and then were left in place for subsequent suctioning. A broth of 25 ml. of brain-heart infusion was then poured through the connection tubings and the suction catheters at each of four time intervals. Significant contamination of the connective tubing was noted immediately after handling, and after eight hours of using the connection tubing, new suction catheters also became contaminated with the same organisms as in the tubing. A sample of only five connection tubings was used, but if the results hold true in larger studies, they further support the potential role of hand-contamination of suctioning equipment in the development of nosocomial pneumonias.

As noted, there is little consistency used across hospitals as to the type of suctioning equipment used or the technique employed. As new types of catheters are designed and introduced into units, each is reported to be safer for the patients and easier for the staff to use. One relatively new type of catheter is the Trach Care catheter.

Trach Care Catheter

A catheter has been developed which is reported to be protected from outside contamination by the use of a sterile protective plastic sheath (Figure 1). The Trach Care catheter system was originally designed to reduce the hypoxia associated

with disconnecting patients from a ventilator for suctioning. This hypoxia may be significant, particularly if patients are receiving levels of positive end expiratory pressures of more than 10 cmH_2O, or oxygen concentrations of 60% or more (Billingsley & Radford, no date; Fleischman, 1985; Ritz, Scott, Coyle & Pierson, 1986). The suction catheter is enclosed in a sterile collapsible plastic sheath and, once attached to the ventilator and patient's endotracheal or tracheostomy tube, it forms a closed system. Suctioning and instillations can be performed without disconnecting the patient from the ventilator, or without needing to delay the suctioning while equipment trays are prepared. The catheter only needs to be disconnected every 24 hours to be replaced with a new sterile catheter during ventilator circuit changes. The outside of the suction catheter is cleaned during withdrawal of the catheter back into the plastic sheath by passing through a membrane valve inside the patient connection (Figure 1). The inner lumen of the catheter is cleaned by injecting sterile saline through a sidearm instillation port while applying suction. The suction control valve is closed to the outside, and locks on or off to avoid inadvertent application of the suction pressure.

Fleischman (1985) has suggested that the catheter will result in improved infection control. First, patients' secretions are not sprayed around the bedside. Secondly, the nurse is not at risk of acquiring organisms or hand infections through the suction control valve, as may happen with the open control valve on standard

catheters (Fleischman, 1985; Rosato, Rosato & Plotkin, 1970). Other reported benefits of the Trach Care catheters include increased patient feelings of security during suctioning (Billingsley & Radford, no date; Fleischman, 1985), and decreased costs when compared to the number of standard catheters needed in a comparable time period (Fleischman, 1985; University of Alberta Hospitals, 1984). In spite of the reported benefits, the safety of leaving the catheter in place for 24 hours has been questioned, as has whether or not the catheter is actually protected from outside contamination.

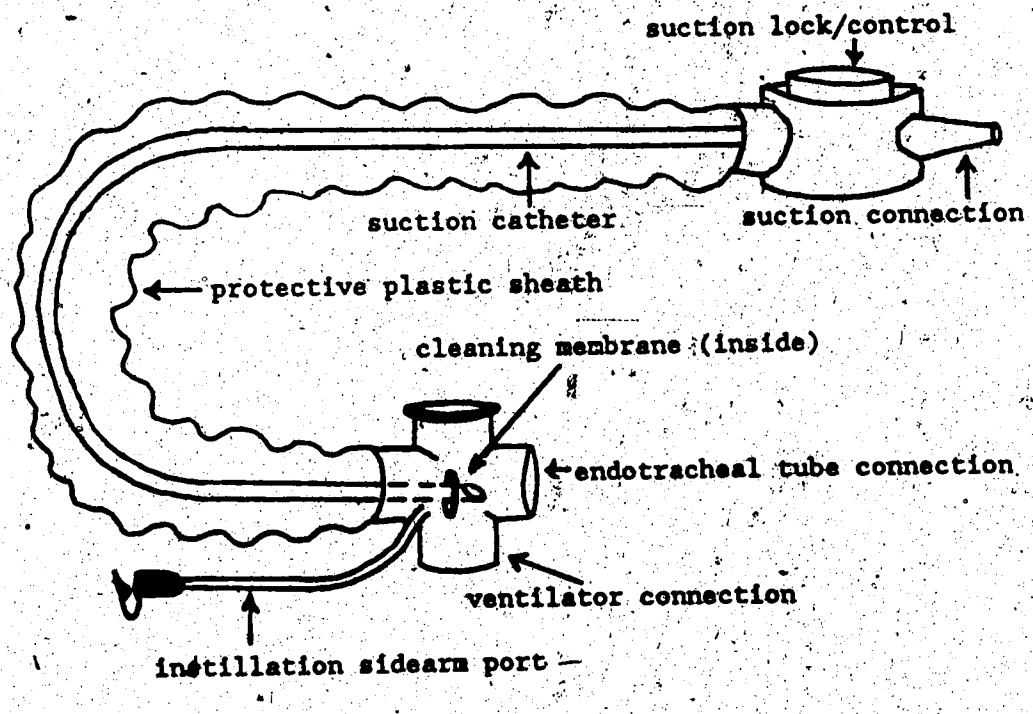


Figure 1. The Trach Care catheter.

Ritz, Scott, Coyle & Pierson (1986) compared the tips of Trach Care catheters which had been left connected to 30 patients for 24 hours to the tips of standard sterile disposable catheters used once to suction the same patients at the end of the 24 hour period. Endotracheally aspirated sputum samples were also obtained at this time with a sterile disposable catheter. The tips of the catheters were placed in N-acetyl-L-cysteine then all specimens were plated on MacConkey, blood and chocolate agar. No new types of organisms were found on either kind of catheter tip or in the sputum samples when compared to prestudy sputum samples. There were also no significant differences found between the Trach Care or sterile disposable catheter tips in either their rate of contamination or their colony counts. Billingsley & Radford (no date) performed a similar experiment with a sample of seven patients, and found that the Trach Care catheter had at least equal if not less contamination than the standard sterile catheters.

Summary

A critically ill patient serves as an immunocompromised host and is prone to many virulent organisms in the ICU. These organisms may be from either endogenous or exogenous sources. Of concern to ICU personnel are the exogenous sources of entry for potential pathogens, as these may perhaps be controlled or limited. Measures such as routine changes of equipment and improved sterilization have been introduced in ICU but the problem

of nosocomial, pneumonias persists. Poor handwashing practices, the persistence of gram-negative organisms on the hands even after washing, and the predominance of gram-negative type pneumonias suggest that there could be an element of direct hand contamination in the development of nosocomial pneumonias. The respiratory tracts of ICU patients are entered frequently for endotracheal suctioning. The trauma induced by the procedure and the opportunities for contamination of the equipment may allow the introduction of the organisms and the infections. There is very little published research available in which an association between endotracheal suctioning and respiratory colonization or infection is investigated. This type of investigation is important as a means of determining safer methods of patient care in the ICU.

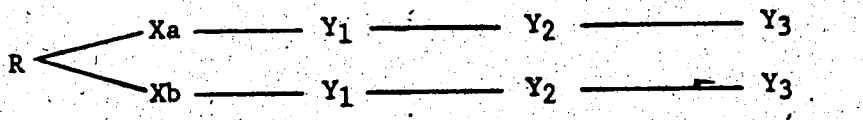
ICU patients require suctioning and it is not possible to withhold suctioning from one group or another. It is possible that the Trach Care catheter may decrease the direct innoculation of organisms into the respiratory tract by limiting hand exposure to the catheter. If this is correct, a difference would be expected between subjects receiving suctioning with the Trach Care catheter in the number of infections developed. This theory is the basis behind the research hypotheses.

METHODS

The study design, hypotheses and operational definitions are presented, followed by a description of the setting and sample used, and the data collection procedures. Unique ethical considerations were associated with this study which are discussed.

Study Design

A mixed factorial study design (Christensen, 1985) was used to compare two methods of suctioning at three time intervals in a six day period for each subject (Figure 2). The control group received all suctioning with Gentle-Flo catheters (American Hospital Supply), a standard steriledisposable type of catheter. The experimental group received all suctioning with Trach Care catheters, a multi-use catheter enclosed in a sterile plastic sheath.



X_a = Gentle-Flo (standard) catheter group
X_b = Trach Care catheter group
Y_1 - Y_3 = data collection times for each subject

Figure 2. Mixed factorial study design.

Hypotheses

1. There will be significantly fewer subjects with colonization of the lower respiratory tract in the Trach Care catheter group than in the Gentle-Flo (standard) catheter group.

2. There will be significantly fewer subjects with ICU nosocomial pneumonia in the Trach Care catheter group than in the Gentle-Flo catheter group.

3. Those subjects who develop ICU respiratory tract colonization with potential pathogens will be suctioned significantly more frequently than those subjects negative for respiratory colonization or infection.

4. Those subjects who develop ICU nosocomial pneumonias will be suctioned significantly more frequently than those subjects negative for either respiratory colonization or infection.

Operational Definitions

ICU Respiratory Tract Colonization

For the purposes of this study, the development of respiratory tract colonization at least 48 hours after entry into the study was considered to be ICU respiratory tract colonization.

Respiratory tract colonization.

Respiratory tract colonization is the presence of significant numbers of recognized potential pathogens in the lower respiratory tract, in the absence of local or systemic reactions in the host (Bureau of Infection Control, 1985). For the study, this was

determined by the presence of potential pathogens in the endotracheal sputum sample in quantities of at least 3+ when the patient did not meet all the criteria for either probable or definite pneumonia.

Potential pathogens.

Any organisms which could result in an infectious reaction in the lower respiratory tract may be considered as potential pathogens. The following organisms were included: all gram-negative rods, Branhamella catarrhalis, Streptococcus groups A, B, C, D and G, Streptococcus pneumoniae, and Staphylococcus aureus.

ICU Nosocomial Pneumonia

For the purposes of this study, any probable or definite pneumonia which developed at least 48 hours after entry to the study was considered to be ICU nosocomial. The criteria for probable and definite pneumonia were adapted from those of Salata et al (1987), with the assistance of an ICU/infectious diseases specialist and an ICU/pulmonary specialist. The pneumonia categories (probable and definite) were combined for the purposes of analysis.

Probable pneumonia.

Probable pneumonia was demonstrated by the presence of new or progressive pulmonary infiltrates, plus at least two of the following: purulent sputum; a rise in temperature of at least 1 degree Celsius and greater than 38.2 rectally, or hypothermia; and leukocytosis, or at least a 25% increase in circulating

leukocytes. Subjects were also classed as having probable pneumonia if they met the criteria for definite pneumonia but had an extrapulmonary infection present.

(i) new or progressive pulmonary infiltrates - the presence of opacities on the chest X-ray which are compatible with pneumonia, as determined by a 2/3 majority agreement between three ICU radiologists.

(ii) purulent sputum - the presence of less than 10 squamous epithelial cells per low power field (Murray & Washington, 1975) and greater than 25 polymorphonuclear neutrophils per low power field (Joyce, 1986; Salata et al, 1987; VanScoy, 1977) on the gram stain of an endotracheally aspirated sputum sample.

(iii) hypothermia - a temperature of less than 36.0 degrees Celsius (rectally) or less than 35.7 degrees orally, occuring at least least four hours following surgery with general anaesthesia.

(iv) leukocytosis - a white blood count of 10,000 or more, or the presence of more than 10% bands in the differential.

Definite pneumonia.

Definite pneumonia exists in the presence of new or progressive infiltrates, plus one of the following: pleural or blood cultures positive for the same organism as the endotracheal sputum sample, or; the presence of a new fever or hypothermia, and leukocytosis, and purulent sputum. No evidence of a non-infectious

basis reason could exist for the latter parameters, nor could the subjects have evidence of extrapulmonary infections.

(i) fever - any temperature equal to or greater than 38 degrees Celsius (orally) or equal to or greater than 38.3 degrees rectally.

(ii) new fever - the occurence of a fever after at least 24 hours of demonstrating a normal temperature.

(iii) new hypothermia - the occurence of hypothermia after at least 24 hours of demonstrating a normal temperature.

Suction Episode

A suction episode is a time period in which the catheter is passed into the respiratory tract as many times as needed to clear the secretions. In the study setting used, this has been observed to average approximately four passes of the suction catheter down the endotracheal tube per episode.

Study Setting and Sample

Setting

The study was conducted in the General Systems Intensive Care Unit (GICU) at the University of Alberta Hospitals. The GICU patient population during the study included post-surgical patients for observation or stabilization, medical patients with failure of at least one or more body systems, trauma patients, and patients following drug overdoses or suicide attempts. Six of

the beds in GICU were isolation rooms, so patients with sepsis and resulting failure of one or more body systems were also admitted.

Both the Gentle-Flo and the Trach Care catheters were in use in the GICU prior to the study. The choice of catheter was based primarily on each nurse's catheter preference, and occasionally on the suggestions of the unit respiratory technologists. All ventilator circuits were changed every 24 hours by the respiratory technologists, and the Trach Care catheters were changed at this time if they were in use. Sterile trays and other equipment needed for suctioning with Gentle-Flo catheters were changed with every suction episode. The 500 ml. bottles of sterile saline for instillation were also changed at least every 24 hours. The frequency of suctioning and instillations were not altered for the study.

Subject Selection

A convenience sampling procedure was used to obtain subjects. All patients admitted to GICU between January and September 1987 who met the inclusion criteria were potential subjects. Inclusion criteria were: (1) endotracheal intubation for no more than 4 hours prior to study entry, or no more than one suctioning episode since intubation; (2) 16 years of age or more; (3) no known pneumonia at the time of entry to the study; and (4) likely to remain intubated for at least 48 hours or more. If subjects met these criteria, a consent to participate was sought. During the study, 349 endotracheally intubated patients were admitted to the

GICU, 183 of which met the subject selection criteria. Twelve of the eligible subjects were not included: 9 of which the investigator was unaware of their presence in the GICU; 2 of which were not expected to remain intubated long enough, when in fact they did; and 1 for whom a second physician's consent was unavailable in time to include the patient. The final sample entered into the study was composed of 171 subjects.

Staff Orientation to the Study

In the GICU, suctioning is performed primarily by nurses, with the assistance of respiratory technologists and physiotherapists. Procedures between the hospital's various ICU's differ, and often staff use the procedure they are most comfortable with. A brief video was made which demonstrated the correct suctioning procedure for both catheters. Inservices were provided with the video for nursing, physiotherapy and respiratory staff, both before and during the study. In addition, written reviews of the protocols and the research design were given to all GICU staff, including medical personnel.

Procedures and Data Collection

Entering Subjects to the Study

The subjects were randomly assigned to a suctioning group by means of a coin toss. Once determined, the assigned method of suctioning was to be used at all times by GICU personnel, unless a subject's condition warranted otherwise. Only two subjects were

dropped from the study due to a change in catheter assignment (both from Gentle-Flo to the Trach Care catheters). A sign was placed at each subject's bedside indicating that they were in the study and the assigned method of suctioning was written on the front of their bedside chart, and on the respiratory section of their care plan.

The suctioning procedures used were those already existing in the GICU (Appendices A & B). Suctioning with the Gentle-Flo catheters required the respiratory tract to be opened to air, manipulation of the respiratory tract with manual bagging units, and equipment to be set up. Two people were needed for the procedure, in order that the person suctioning could remain sterile. The Trach Care method required only one person as the system remained closed to external sources unless a sputum specimen was required. If manual ventilations needed to be given, the system was broken at a site six inches distal to the endotracheal tube.

Gathering of Data

Data were collected from each subject for a minimum of 48 hours and a maximum of 144 hours (six days), depending on the length of time the subject remained intubated. The time period was chosen as symptoms of nosocomial pneumonias have been found to appear within two to four days - usully within 72 hours - after innoculation with pathogens (Graybill, Marshall, Charache, Wallace & Melvin, 1973; Lowy, Carlisle, Adams & Feiner, 1987;

Potgeiter, Linton, Oliver & Forder, 1987). A six day maximum was chosen for a number of reasons: if the subject was observed for two 72 hour periods, subjects not contaminated initially would be noted in the second 72 hour period; the GICU physicians tended to perform tracheostomies on patients intubated for longer than six to seven days; and it was assumed that pneumonias or colonization occuring after six days would likely not be related to a procedure subjects had already experienced for six days. Data collection was discontinued for subjects if they were extubated, given a tracheostomy or transferred to another unit during their participation in the study, or if the nursing or medical staff thought a change in catheter group was warranted for the subject.

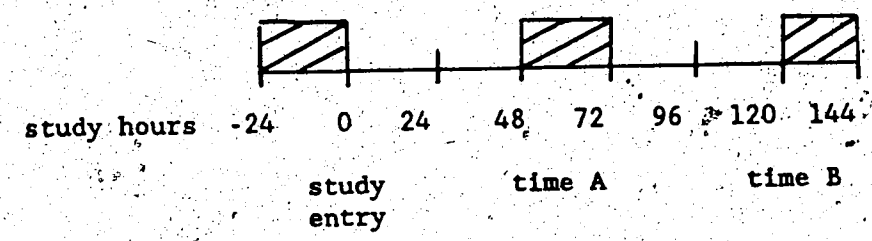


Figure 3. Data collection times during study.

Data were collected for each subject at the closest time to each of three data collection intervals (Figure 3): 0 hours (study entry); 48 to 72 hours (Time A); and 120 to 144 hours (Time B). If a subject had not completed at least 48 hours in an interval, data from that interval were not used. Three major groups of data were collected for each subject at each interval: biographical data,

including information about the subject's course of illness; diagnostic data required to determine the presence of pneumonia or respiratory colonization; and suctioning and respiratory procedure data.

Biographic data.

Some variables were collected only when the subject entered the study and included the following: the subject's age and gender; length of hospital stay prior to study entry; type of endotracheal tube present; diagnosis; the highest APACHE II (a severity of disease score) within 24 hours of entering the study; the body system in failure; and the primary factor precipitating the failure. The classification system for body system failure and precipitating factors was that used in the guidelines for the APACHE II score (Draper, Knaus & Wagner, 1985; Knaus, Draper, Wagner & Zimmerman, 1985).

Other variables were expected to change over time and were collected based on events which occured in the 72 hours preceding each data collection time. These variables included: whether or not the subject received chemotherapy, antibiotics or corticosteroids; the number of hours intubated prior to entering the study; presence of possible aspirations; presence of a Glasgow coma score of less than 8 in the absence of general anaesthesia; presence of a nasogastric tube or administration of nasogastric tube feedings; and the number of surgeries with general anaesthesia.

Diagnostic data.

Diagnosis of pneumonia in ICU patients can be extremely difficult to determine as symptoms may be masked. There are a variety of diagnostic criteria found in the literature, for which validity or reliability estimates are not reported. The set of criteria initially chosen for this study were those of the Canadian National Nosocomial Infection Surveillance Study (Bureau of Infection Control, 1982). It was later found that some of the criteria were too subjective, producing varying results, and other criteria were vaguely defined. Further, it was learned that the Bureau of Infection Control were planning to change the criteria. The diagnostic criteria from Salata et al (1987) were thus chosen for this study, as outlined in the operational definitions.

For each of the three data intervals, subjects were classified as having respiratory "colonization" or "pneumonia" , or as "negative" if neither criteria were met. The diagnosis was based on data from the 24 hours preceding each time interval. The information required to make these diagnoses for each subject included selected subject parameters, blood and sputum samples, and chest x-rays.

(i) subject parameters - the subject's temperature, any blood culture reports, and physician documentation of probable or definite extrapulmonary infections were recorded.

(ii) blood and sputum samples - the subjects' white blood counts and, if available, their differentials were recorded. The

nursing or respiratory staff obtained endotracheally aspirated sputum samples during the data collection interval, using the GICU protocol for the [redacted]ned suctioning technique and a sterile Sputum Trap (Chesebrough-Ponds). The samples were then sent, usually within an hour, to the Microbiology Department for gram stain, and culture and sensitivity analysis.

Once in the laboratory, the sputum specimens were processed using the hospital's routine procedures, with the addition of a quantification of the squamous epithelial cells and the polymorphonuclear neutrophils on the gram stain. The cultures included a four quadrant plating technique on blood agar with a Staphylococcal streak (incubated in carbon dioxide at 37 degrees Celsius for a minimum of 24 hours), and on MacConkey agar (incubated in oxygen for 24 hours at 37 degrees Celsius). Plates were then graded for the presence of organisms according to how many quadrants the organisms were detected in, ranging from 1+ to 4+. Actual quantitative correlates for this system were not used, however, a specimen scored as 1+ was considered to contain less than 10 colonies of an organism while a specimen scored as 2+ or greater was considered to contain more than 10 colonies of an organism.

Measures were taken in order to maximize the quality and reliability of the sputum samples. These measures included the following: rapid transport of the specimen to the laboratory, and the occasional refrigeration of the samples when the microbiology

department was closed (Jacobson, Burke & Jacobson, 1981); and obtaining the sputum sample with a new sterile catheter after the first pass of the catheter, in order to remove any exudate which may occur from the local irritation of the endotracheal tube and confound the results (Stratton, 1981).

(iii) chest x-rays - Chest X-rays were a required component of the diagnostic data. Supine chest X-rays were taken at the time of intubation, and every morning on all GICU patients. The chest x-rays taken at the time closest to a data collection interval were marked for the radiologists. Once all other data collection was complete for a subject, all x-rays were retrieved for each subject starting from approximately two days before entering the study (if available) to a few days after the study period ended for that subject. Based on the subject's overall progression of x-ray changes, the radiologists independently determined whether the subjects had new or progressive opacities which would be compatible with pneumonia on the films marked for each subject's data collection interval times. Each marked film was scored for the presence of changes as positive, possible or negative. The radiologists then conferred for a majority group decision. A decision of "possible" changes was treated as a "positive" when all of the diagnostic findings were combined.

Suctioning and respiratory related data.

The final group of data required was information related to the endotracheal suctioning and other respiratory related

variables for each subject. Many nurses, technologists and therapists were involved with each subject, making observations of all suctioning episodes difficult. A checklist (Appendix C) was designed for use at each subject's bedside. Following a suctioning episode, the staff only needed to place a checkmark beside the time, using the column corresponding to whether the suctioning protocol was followed or not. Staff also noted whenever any accidental disconnections, bronchoscopies or unusual events occured. The checklist was pretested immediately prior to the study to determine any problems the staff had in using or understanding the form. Minor changes were made in column headings and explanations of the columns, but otherwise the staff generally reported that the form was easy to complete and required very little of their time. The suctioning data forms for each subject were checked daily to ensure they were being completed. The staff involved were asked to complete any missing information to the best of their recollection if it was noted that a checklist was incomplete for certain time periods.

Additional respiratory related data which were noted for each time interval and included: the number of hours ventilated; the number of times endotracheal instillations of lidocaine were given; the number of times respiratory parameters were measured with a respirometer; and the number of times nebulizer medications (such as atropine or Ventolin) were administered.

Ethical Considerations

The use of intubated patients in ICU, many of whom are not conscious presented unique ethical considerations. Under section 20.1 of the Dependent Adults Act (Province of Alberta, 1985), only the patient himself can give consent for treatment. In the absence of this capability, the court may appoint a guardian deemed to be unbiased or, if the treatment is considered to be essential or potentially beneficial to the patient, two physicians licensed in the province may sign on the patient's behalf. Following consultation with the faculty from the University of Alberta Faculty of Law (E. Pickard - personal communication, October 20, 1986), with the Public Guardian for the Province of Alberta (A. Russell - personal communication, Oct.20, 1986) and approval by both the Faculty of Nursing and University of Alberta Hospitals ethics review boards, it was decided that two physicians could be used to provide consent for GICU subjects with decreased levels of consciousness (Appendix D). This decision was made because endotracheal suctioning is a treatment is already performed on all intubated ICU patients, the two types of catheters and procedures were already in use in the unit, and the investigator would not interfere in clinical decisions to change a subject's therapy or, if necessary, the suction group. Additionally, if a significant benefit was noted with either catheter during the study, it was agreed that the study would be stopped to allow a change to that

catheter. In this way, patients could benefit from participation in the research.

Whenever possible, subjects were asked to sign their own consent, after receiving a verbal and written explanation of the study (Appendix E). Most patients who require intubation are hypoxic and in distress or, if they are recently intubated, they may still be under the influence of the narcotics or sedatives used for intubation. It was, therefore, not common for subjects to sign their own consents. If a subject had recently been sedated, but both the bedside nurse and researcher agreed that the subject was alert (as indicated by written comments or gestures), the subject was asked to sign the consent and, in this instance, the bedside nurse was asked to sign as a second witness.

In the interests of full disclosure, it was decided that if the subjects had not signed their own consent, their family (if present) would be informed of the study as well. When it was possible, the investigator explained the study to them, and gave them the written explanation of the study (Appendix E). The family were asked to sign a form acknowledging that the study had been explained to them (Appendix F). It was emphasized that this form was not a consent for participation, and only for the researcher's records. It is recognized that families of ICU patients are already under a great deal of stress, particularly if their family member has been recently intubated for respiratory support. Although the families cannot legally give consent, they were told

that if it would upset them to have their family member included, it would not be done. No one refused to sign. If and when the subject was alert enough to understand the explanation, the study was explained and the subject was given a chance to withdraw from the study. No one withdrew.

The option to use the consent of two physicians for subjects unable to provide their own consents was extremely important to the conduct of the study. Only 11 of the 171 subjects (6.43%) were able to sign their own consents prior to entering the study. The remaining 160 subjects were included on the basis of the physicians' consent. After inclusion in the study, only 41 (23.97%) more of the 171 subjects or their families were able to sign either the patient portion of the consent or the family acknowledgement forms. The remaining 69.6% of the subjects were either not able to sign an informed consent, had been extubated and transferred out of the unit or died before the investigator was able to obtain their added consents, or else their families were not available.

RESULTS

The characteristics of the subjects initially entered into the study are described, followed by: the results of testing the hypotheses; the effects of attrition on the sample size and sample characteristics; a comparison between the two suctioning groups for pathogen growth; and the reliability and validity of the instruments used for data collection.

Sample Characteristics

A total of 171 subjects were entered into the study. this sample was composed of 102 males (59.6%) and 69 females (40.4%). The most predominant body systems in failure were the gastrointestinal and respiratory systems (Table 1), with trauma or infections accounting for the majority of system failures (Table 2). The majority of the subjects had received surgery with anaesthesia at least once in the 72 hours prior to entering the study, and another quarter of the patients had Glasgow coma scores of less than 8 in the absence of surgery (Table 3). Two subjects were nasotracheally intubated initially, but reintubated orally within 24 hours of entry to the study. All others were orally intubated. The endotracheal tubes used were Portex tubes with low pressure cuffs for 169/170 (98.8%) of the subjects.

As the subjects were randomly assigned to groups, the assumption was made that the sample characteristics would be distributed evenly between suctioning groups. In light of the attrition experienced in both groups, this assumption could not be

maintained for the final sample and differences between groups will be discussed elsewhere.

Table 1.

Body Systems in Failure at Study Entry

System	n (%)
Gastrointestinal	58 (33.9)
Respiratory	46 (26.9)
Cardiovascular	32 (18.7)
Neurological	28 (16.4)
Renal, Metabolic and Haematologic	7 (4.1)
Totals:	171 (100.0)

Table 2.

Precipitating Factors for System Failure at Entry

Factor	n (%)	Factor	n (%)
Trauma	34 (19.9)		
Infection	20 (11.7)	Overdose	8 (4.7)
Sepsis	16 (9.4)	Exacerbated chronic disorder	7 (4.1)
Bleeding	14 (8.2)	Peripheral vascular disease	6 (3.5)
Obstruction	12 (7.0)	Post-arrest	6 (3.5)
Congestive Heart Failure	12 (7.0)	All others with < 5 subjects per category	17 (9.9)
Post-O.R. ventilation	11 (6.4)		
Neoplasm	8 (4.7)		
subtotal	127 (74.3)	subtotal:	44 (25.7)

Table 3.

Subject Risk Factors on Entry

Total N-171

Factor	n (%)	Factor	mean score
Surgery prior	101 (59.4)	Age in years	56.78
Aspirated prior	19 (11.1)	APACHE II	19.89
Coma score < 8	44 (25.7)	Hospital days prior	12.47

Tests of the Hypotheses

In order to test the hypotheses, only those subjects who had remained in the study at least 48 hours, who had no infection or colonization on entry to the study could be included. The two major areas of interest in the hypotheses were any differences in the distribution of the three infection levels between the two suctioning groups and in the frequency of suctioning between the levels of infection. A two-tailed significance level of 0.05 was used for all statistical tests in the study.

Infection Levels Between Suctioning Groups

By Time A (48 to 72 hours in the study), only 69 of the original 171 subjects were eligible for analysis. By Time B (120 to 144 hours in the study) only 31 subjects were eligible for analysis. The distribution of the three levels of infection (new pneumonia, respiratory colonization or neither) between the two suctioning groups can be seen in Table 4.

Table 4.

Subjects at Levels of Infection by Suction Groups

	# OF SUBJECTS IN EACH SUCTION GROUP					
	TIME A			TIME B		
INFECTION LEVEL	Gentle-Flo	Trach Care		Gentle-Flo	Trach Care	
negative for colonization/pneumonia	22	20		13	8	
new respiratory colonization	5	7		3	2	
new pneumonia	6	9		1	4	
Totals:	33	36	69	17	14	31

It was hypothesized that the Trach Care suctioning group would have fewer subjects with respiratory colonization or pneumonia than the Gentle-Flo suctioning group, due to fewer theoretical opportunities for hand-contamination during the use of the Trach Care suction catheter. Chi-square tests did not reveal any significant differences between the suctioning groups in the levels of infection at either Time A or Time B. It was noted, however, that there was a tendency toward increased pneumonias in the opposite group from that hypothesized - more subjects in the Trach Care group developed pneumonia at both Time A and Time B.

There were small numbers of subjects in the pneumonia and colonized cells at both Time A and Time B. By Time B there were expected frequencies less than five in four out of six cells (66.7%). A new category was created by collapsing the colonized and infected categories into a category called "the presence of infective changes". Chi-square analyses were repeated for both Time A and Time B data, comparing the presence or absence of infective changes between suctioning groups. Neither analysis was significant although there were more subjects with infective changes in the Trach Care group at each time. There were still 25% of cells with expected frequencies less than five at Time B.

Effects of Suctioning Frequency on Infection Levels

It was hypothesized that the subjects who developed either respiratory colonization or pneumonia would have received suctioning more frequently than those without pneumonia or

colonization. The frequency of suctioning reported for each subject was divided by the number of hours they had been in the study, in order to account for differences betweeen subjects in the length of time they were in the study. The suctioning frequency ratio was calculated for both Time A and Time B data (Table 5).

Oneway analysis of variance was performed for both time periods. No significant differences were noted in the frequency of suctioning between the three levels of infection at either time period.

Table 5.

Suctioning Frequency Ratio by Levels of Infection

INFECTION LEVELS	(N = 69) Times suctioned per hour at Time A	(N = 31) Times suctioned per hour at Time B
Negative	.28	.27
New Colonization	.31	.28
New Pneumonia	.29	.30

The ratio of frequency of suctioning was also compared by using the collapsed infection categories. Student's t-tests were done to compare the suctioning frequency ratio between those subjects with infective changes and those with no infective changes, using the data from both Time A and Time B. Neither t-test revealed any significant differences.

The suctioning groups were compared for differences in suctioning frequency. The mean number of times suctioned per hour was calculated for each suctioning group. At Time A, Gentle-Flo subjects were suctioned approximately once every 3 hours and 51 minutes (Table 6), while Trach Care subjects were suctioned approximately once every 3 hours and 8 minutes. This difference was statistically significant ($p = .021$) using a t-test. The frequency ratio of suctioning at Time B was not significantly different.

Table 6.

Suctioning Frequency Ratio by Suction Groups

Suction Group	(N=69) Time A	(N=31) Time B
Gentle-Flo	0.26*	0.26
Trach-Care	0.32*	0.30

(*) = suction groups significantly different ($p = .021$)

Effects of Longitudinal Attrition

The original sample entered into the study consisted of 171 subjects. It was expected that, as their conditions improved, subjects would be extubated and dropped from the study. This dropout led to a change in the composition of the suctioning groups over time, as healthier subjects left the study and more seriously ill subjects remained. The attrition experienced meant that it could no longer be assumed that random distribution of

subject characteristics existed between groups. The effects of attrition on the sample size and sample characteristics are described.

Sample Size Effects

A total of 93 subjects were dropped from the original sample of 171 subjects, as they had not completed 48 hours in the study (Table 7). There were 78 subjects with complete diagnostic data sets who remained intubated at least 48 hours (two days). Additional subjects were dropped if they were found to have either colonization or pneumonia on entry to the study, as it would not be possible to assess nosocomial changes with these subjects. A final sample size of 69 was used for the Time A (48 to 72 hour) data interval. 33 of these subjects were in the Gentle-Flo group, and 36 subjects were in the Trach Care group.

Table 7.

Effects of Attrition on Sample Size

Attrition factor	(N=171) Time A	(N=78) Time B
Extubated	69	23
Changed suction groups	1	1
Tranferred to other ICU	4	2
Received tracheostomy	3	5
Died	13	6
Missing diagnostic data	3	0
Totals:	93	37
Remaining sample:	78	41
Subjects with prior colonization/pneumonia:	9	10
FINAL SAMPLE:	69 = 33 Gentle-Flo 36 Trach Care	31 = 17 Gentle-Flo 14 Trach Care

By Time B (120 to 144 hours), 37 more subjects were dropped from the sample (Table 7) and an additional 10 subjects demonstrated prior respiratory colonization or infection. A final sample size of 31 subjects was used for Time B, with 17 subjects in the Gentle-Flo group, and 14 in the Trach Care group.

Sample Characteristics with Attrition

The suctioning groups differed on a number of variables between Time A and Time B. The groups were compared on the basis of descriptive variables (such as age, APACHE II score and previous days in hospital), disease characteristics and selected risk factors for pneumonia.

Descriptive variables.

Over time, the average age and APACHE II score for subjects remaining in the study increased slightly (Table 8). The Trach Care subjects at both Time A and Time B had been in hospital for more days prior to entering the study than the Gentle-Flo subjects. At Time A there were also more men in the Trach Care group than in the Gentle-Flo group.

The suction groups were compared at both Time A and Time B on the basis of each of the descriptive variables. T-tests (and Chi-square tests where appropriate) did not reveal any significant differences in the descriptive variables between either suction group, at either time period. The average age and APACHE II scores of the subjects remaining in the study increased over time, as the

more severely ill subjects were primarily the ones who remained intubated.

Table 8.

Descriptive Variables Between Suction Groups

	MEAN SCORE FOR GROUPS				
	Entry	Time A		Time B	
VARIABLE	GF + TC	GF	TC	GF	TC
Age in years	56.78	60.24	59.39	60.94	60.64
APACHE II	19.89	22.15	22.03	23.88	19.36
Hospital days	12.47	7.61	9.78	5.82	7.21
	n (%)	n (%)	n (%)	n (%)	n(%)
Males	102 (59.6)	17 (51.5)	22 (61.1)	12 (70.6)	6 (42.9)
Females	69 (40.4)	16 (48.5)	14 (38.9)	5 (29.4)	8 (57.1)
Totals:	171	33	36	17	14

GF = Gentle-Flo suction group
TC = Trach Care suction group

Disease characteristics.

Of the subjects still in the study at Time A, 100% of the Gentle-Flo subjects and 88.8% of the Trach Care subjects had failure of one of four systems (Table 9): the cardiovascular system; neurological system; respiratory system; or the gastrointestinal system. The remaining four subjects in the Trach Care group were admitted with renal, haematologic or metabolic failure. There were more subjects in both groups at Time A who had respiratory and gastrointestinal problems, with more respiratory failures present in the Trach Care group. At Time B, approximately

50% of subjects in each group were admitted with failure of the respiratory system.

Chi-square analyses were performed comparing the distribution of the four major systems between the two suctioning groups. There were no significant differences between the two suctioning groups as to the types of system failures present at either Time A or at Time B.

Table 9.

Types of System Failures Between Suctioning Groups

Body System in failure	TIME A GROUPS GF n (%)	TIME A GROUPS TC n (%)	TIME GROUPS GF n (%)	TIME GROUPS TC' n (%)
Cardiovascular	8 (24.2)	5 (13.9)	6 (35.3)	0 (0)
Neurological	7 (21.2)	7 (19.4)	2 (11.8)	3 (21.4)
Respiratory	9 (27.3)	13 (36.1)	8 (47.1)	7 (50.0)
Gastrointestinal	9 (27.3)	7 (19.4)	1 (5.8)	3 (21.4)
Renal/Metabolic & Haematologic	0 (0)	4 (11.2)	0 (0)	1 (7.2)
Totals:	33 (100.0)	36 (100.0)	17 (100.0)	14 (100.0)

GF = Gentle-Flo group
TC = Trach Care group

The factors which precipitated the system failures were also examined for each suctioning group. At both Time A and Time B the same factors predominated. Approximately 50% of subjects in each suctioning group at each time had their system failure precipitated by one of three factors: trauma; infection of any site; or septic shock (Table 10). The Trach Care group had a higher percentage of subjects with infections of any type.

although more subjects in the Gentle-Flo group were considered to be septic than in the Trach Care group at both times. The categories of precipitating factors for each suctioning group which contained less than three subjects per category were grouped together under the heading "other factors".

Table 10.

Precipitating Factors for System Failure by Suction Group

	TIME A GROUPS		TIME B GROUPS	
	GF	TC	GF	TC
Factor	n (%)	n (%)	n (%)	n (%)
Infection-any site	2 (6.1)	7 (19.4)	1 (5.9)	6 (42.8)
Trauma	8 (24.2)	7 (19.4)	5 (29.4)	2 (14.2)
Sepsis	5 (15.2)	4 (11.1)	5 (29.4)	1 (7.2)
Neoplasm	4 (12.1)	0 (0)	- (-)	- (-)
Congestive heart failure	2 (6.1)	3 (8.3)	- (-)	- (-)
Bleeding	1 (3.0)	4 (11.1)	- (-)	- (-)
Other factors (< 3 subjects/factor)	11 (33.3)	11 (30.7)	5 (29.3)	5 (35.8)
Totals:	33 (100.0)	36 (100.0)	17(100.0)	14(100.0)

GF - Gentle-Flo group
TC - Trach Care group

Risk factors between suction groups.

Suctioning groups were also compared on the basis of several risk factors which existed in the six days preceding each data collection time period. The risk factors were divided into nosocomial risk factors which were endogenous to the subjects and those which were exogenous to the subject.

(i) endogenous factors - Each of the endogenous risk factors from Time A were compared using Chi-square tests (Table 11). The presence of aspiration was significantly different between groups ($p = .003$). There were no significant differences detected between groups for the rest of these factors, although there were a larger number of subjects with Glasgow coma scores of less than 8 in the Trach Care group at Time A.

Table 11.

Endogenous Risk Factors by Suction Group

	TIME A GROUPS		TIME B GROUPS	
	GF (N=33)	TC (N=36)	GF (N=17)	TC (N=14)
RISK FACTOR	n (%)	n (%)	n (%)	n (%)
Antibiotics	28 (64.9)	30 (83.4)	15 (88.3)	14 (100.0)
Steroids	7 (21.2)	9 (25.0)	0 (0)	6 (42.8)
Chemotherapy	3 (9.1)	2 (5.6)	1 (5.9)	0 (0)
Coma score < 8	12 (36.4)	16 (48.5)	6 (35.3)	3 (21.4)
Aspiration	0 (0)*	10 (27.8)*	0 (0)	1 (7.1)
Extrapulmonary Infections	14 (42.4)	15 (41.7)	9 (56.7)	7 (50.0)
Tube feedings	5 (15.6)	4 (11.1)	6 (35.3)	4 (28.6)

GF = Gentle-Flo group
TC = Trach Care group

(*) = significant difference between suction groups ($p = .003$)

(ii) exogenous risk factors - each of the exogenous risk factors which occured in the six days previous to each time period were compared between the suction groups (Table 12) using t-tests.

The only exogenous factor significantly different between suction groups was the number of accidental disconnections from the ventilator which occured in the six days prior to Time B. More

disconnections occured with the Trach Care group. There were more frequent parameter measurements, sidestream aerosol medications, and reintubations in the Trach Care group at both times, but these were not found to be statistically significant differences.

Table 12.

Exogenous Risk Factors by Suction Group

	MEAN # TIMES/GROUP			
	TIME A GROUPS		TIME B GROUPS	
RISK FACTOR	GF	TC	GF	TC
Breaks in suction asepsis	.03	.03	.00	.08
Protocol modifications	2.18	2.33	4.41	4.50
Parameter measurements	3.24	3.71	4.41	6.43
Aerosol medications	3.18	5.03	8.29	15.00
Endotracheal lidocaine	1.06	2.17	5.29	3.64
Bronchoscopies	.15	.08	.35	.15
Accidental disconnections	.36	.76	.25*	1.62*
Reintubations	.09	.15	.12	.38

(*) = suction groups significantly different (p=.015)

GF = Gentle-Flo group
TC = Trach Care group

Differences between infection levels.

The subjects were also compared for differences in descriptive characteristics and risk factors at various levels of infection. Only the data from Time A were used, due to the larger sample size at that time.

(ii) descriptive variables : no significant differences were found between the levels of infection for any of the descriptive variables at Time A (Table 13), using one way analysis of variance. The APACHE II score of the pneumonia subjects at time A

was considerably higher than for subjects at other levels, and the pneumonia subjects had been in hospital for more days prior to entering the study.

Table 13.

Descriptive Characteristics for Infection Levels (Time A)

	INFECTION GROUP Mean Score/Group		
VARIABLE	(N=42) Negative	(N=12) Colonized	(N=15) Pneumonia
Age in years	60.95	61.33	55.33
APACHE II score	21.60	19.50	25.53
Hospital days prior to study	8.83	2.58	13.40

(ii) endogenous risk factors - there were very few differences noted between infection levels in the distribution of endogenous risk factors (Table 14). More men were in the pneumonia infection level than in any other level, but none of the factors were found to be significantly different using Chi-square tests.

Table 14.

Endogenous Risk Factors by Infection Level (Time A)

	SUBJECTS IN EACH GROUP		
RISK FACTOR	(n=42) Negative n (%)	(n=12) Colonized n (%)	(n=15) Pneumonia n (%)
Gender - male	22 (52.4)	6 (50.0)	11 (73.3)
- female	20 (47.6)	6 (50.0)	4 (26.7)
Aspiration	4 (9.5)	2 (16.7)	4 (26.7)
Coma	15 (35.7)	5 (41.7)	8 (53.3)
Tube feedings	6 (14.3)	2 (16.7)	1 (7.1)

(iii) exogenous risk factors - there were more frequent breaks in aseptic technique and accidental disconnections from the ventilator (Table 15), as well as in the number of modifications made to the suctioning protocol in the pneumonia group. None of the exogenous risk factors were found to be statistically different between infection levels, using oneway analysis of variance.

Table 15.

Exogenous Risk factors by Infection Levels (Time A)

	MEAN # TIMES/GROUP		
RISK FACTOR	(n=42) Negative	(n=12) Colonized	(n=15) Pneumonia
Breaks in asepsis	.02	.00	.07
Bronchoscopies	.09	.20	.11
Reintubations	.19	.07	.00
Accidental disconnects	.53	.46	.75
Protocol modification	2.10	1.44	3.36
Parameters measured	3.17	5.02	3.28
Endotracheal lidocaine	3.17	.92	3.28
Aerosol medications	5.20	3.67	1.67

Differences in Pathogen Growth

The types of organisms cultured from each subject were also examined. Of interest were subjects who had heavy growth (either 3+ or 4+ growth) of potential pathogens in their sputum. None of the subjects negative for pneumonia or colonization had more than 2+ levels of any potential pathogen. All colonized subjects had at least 3+ growth of potential pathogens, as that was a necessary

criterion for colonization (Table 16). Relatively few of the pneumonia subjects demonstrated heavy pathogen growth. The low levels of growth in the pneumonia group most likely resulted from the masking effects of antibiotic use. By Time A, at least 87% of the pneumonia subjects were on antibiotics, as were 75% of the colonized group and 81% of the negative group.

Table 16.

Heavy Pathogen Growth by Infection Levels (Time A)

		INFECTION GROUP	
		(N=12) Colonized	(N=15) Pneumonia
PATHOGENS		n (%)	n (%)
Gram negatives:	Escherischia coli	1* (8.3)	0 (0)
	Serratia marcesens	1* (8.3)	0 (0)
	Haemophilus species	3* (25.0)	0 (0)
	Neisseria species	1 (8.3)	0 (0)
	Pseudomonas species	1* (8.3)	2 (50.0)
	Citrobacter species	1 (8.3)	0 (0)
	Klebsiella species	0 (0)	1 (25.0)
Gram positives:	Staphylococcus aureus	3 (25.0)	1 (25.0)
	Group B Streptococcus	1 (8.3)	0 (0)
	Totals:	12/12	4/15

(*) = another subject had pathogen but is listed elsewhere

There was a higher percentage of heavy gram-negative growth in the colonized group than the pneumonia group (Table 16), likely due to the definition of colonization requiring at least 3+ growth, whereas the pneumonia definition relied on other factors.

Both groups demonstrated the predominance of gram-negative organisms noted in the ICU literature regarding nosocomial infections.

There was very little difference in the heavy growth of organisms between the two suctioning groups (Table 17). Over 20% of subjects demonstrated heavy growth of potential pathogens in both suctioning groups. There was a slightly lower percentage of heavy growth with gram-negative organisms in the Trach Care group. By Time A, 82% of the Gentle-Flo group, and 81% of the Trach Care group were on antibiotics.

Table 17.

Potential Pathogens by Suctioning Groups (Time A)

NUMBERS OF SUBJECTS

SUCTION GROUP	At least 3+ growth of any pathogen n/group (%)		At least 3+ growth of gram-negative pathogens n/subgroup (%)	
Gentle-Flo group	7/33	(21.2)	5/7	(71.4)
Trach Care group	9/36	(25.0)	6/9	(66.7)

Unusual Occurences During the Study

Two events occured during the study which could have potentially influenced the study results. One was the use of disposable catheters in subjects assigned to the Trach Care group, and the other was a change by the hospital in the types of trays supplied for suctioning with the Gentle-Flo catheters.

Disposable Catheter Use on Trach Care Subjects

It was expected that each subject would have Gentle-Flo catheters used to collect their sputum specimens, as outlined in the suctioning protocol. This procedure involved breaking the Trach Care system once every 72 hours, or a maximum of three times per subject, although two nurses were to be present to allow one nurse to maintain sterile technique while obtaining the sputum specimens. The nurses were asked to record how often they used a disposable catheter (Gentle-Flo) for subjects in the Trach Care group other than for sputum collection. Disposable catheters were used at least one to three times for 17 (47.2%) of the Trach Care subjects by Time A, in addition to those catheters used for the sputum specimens.

Change of Suctioning Trays

After approximately four months of data collection, the hospital introduced a new sterile disposable tray system to be used for suctioning with the Gentle-Flo catheters. It was desirable to test the distribution between suctioning groups of subjects in the study after the introduction of the new trays. A Chi-square analysis did not reveal any significant differences between the numbers of subjects in each suctioning group before and after the introduction of the new trays.

The effect of changing the Gentle-Flo suction trays on the the level of infection was also examined. A 2 x 3 Chi-square analysis was performed to compare the presence or absence of the new trays

by the three levels of infection. No significant differences were found to indicate that the introduction of the new trays had any effect on the levels of infection or the suctioning groups.

Reliability and Validity

Two of the major tools used in the study were the suctioning data checklist and the diagnostic criteria to determine the presence of nosocomial pneumonia. Measures were taken to assess the reliability and validity of these tools.

Suctioning Checklists

During the data collection, a series of sixty observations were made of suctioning procedures being performed on subjects. Thirty suction episodes were observed for each cath[illegible]. Within 24 hours after the suctioning episode, the [illegible]ta checklist was examined to compare the nurse's record[illegible] that suction episode with the observed episode.

It was noted that 50 out of 60 times (83%), the nurses did record the episode. For some of the episodes not recorded, a few nurses were noted to fill in the episode on the checklist when they next came on, relying on their abilities to recall and the continued presence of the subject or checklist.

Suction episodes were categorized as either "full" or "partial" based on whether or not the full GICU suctioning protocol was used for the episode, or if it was modified. During the suctioning observations, the investigator recorded which

column the episode should be recorded in. This was compared to what column the nurses recorded the episode in. An interrater reliability of 82% was obtained between the investigator and the nurses, excluding observations with missing recordings. All but one error in recording columns occured in the Trach Care group, with most due to misinterpretation of the meaning of "full" protocol. Only one of these nurses had not received the orientation to the study.

Diagnostic Criteria

Unfortunately, reliability and validity estimates have not been established for most of the diagnostic criteria in use for nosocomial pneumonia. Face validity of the criteria adapted from Salata et al (1985) for the study was established with the two physician consultants for the study. Although it was decided not to use the diagnostic criteria from the Canadian Nosocomial Infection Surveillance Study, or CNISS, (Bureau of Infection Control, 1982) the subjects were still ranked according to these criteria in addition to the diagnostic criteria used for the final analysis. The two sets of infection levels were then used to calculate a correlation between the two diagnostic methods.

All 171 subjects, across all three infection levels, were used to calculate the correlation between the two sets of criteria. A Spearman's rho of .64 was obtained ($p = < .01$). There were 21 of 78 subjects (25.6%) diagnosed as having pneumonia at Time A, using the study criteria, although six of these pneumonias were also

present on admission. Using the CNISS critieria, 31 of the 78 subjects (39.7%) were identified as having pneumonia. The greater percentage of pneumonias using the CNISS criteria may reflect an ability to overestimate the presence of pneumonia due to the subjectivity noted with use of the criteria. Of the 21 subjects with pneumonia at Time A according to the study criteria, 16 (76.2%) were ranked as having pneumonia with both criteria. It was therefore assumed that most subjects identified as having pneumonia with the study criteria likely did have pneumonia.

DISCUSSION

Major Findings and Conclusions

Using the data mainly from Time A (the time with the largest sample), no statistically significant differences were found in the distribution of subjects at the three levels of infection between suctioning groups. There were also no significant differences in the frequency of suctioning between the three levels of infection.

Although the differences in the distribution of subjects with infection were not significant, there was a tendency toward more pneumonias in the Trach Care suctioning group as a whole. The greater number of pneumonias could be the result of a non-representative distribution of cases, secondary to having a small sample size, or the unequal distribution of cases due to attrition. There was a significant difference between suctioning groups in the number of subjects who had aspirated and the in frequencies of suctioning, which both occurred more frequently in the Trach Care group. It is possible that if the frequency of aspiration and suctioning were evenly distributed between suctioning groups, that no observable differences in the frequency of pneumonia would have existed between the suctioning groups. Alternatively, the increased frequency of suctioning in the Trach Care group may reflect the ease of suctioning with the catheter or the effects of aspiration in that group. As no significant differences were found in the distribution of infections between groups, there is potentially no added risk of pneumonia with the

use of either catheter type or technique. The lack of a significant difference in the frequency of suctioning between infection levels also suggests that suctioning may not be a primary concern in the development of ICU pneumonias.

There was some evidence that hand contamination or manipulation of the endotracheal tube may play an important role in the development of nosocomial pneumonias. The Trach Care group subjects experienced more frequent accidental disconnections (significantly more at Time B), more frequent reintubations, more aerosol medications, and more [redacted] arameter measurements than the Gentle-Flo group, at both time periods. Each of these events afford opportunities for hand contamination of the endotracheal tube. The role of exogenous factors in the development of nosocomial pneumonias could not be eliminated as these factors were not controlled for in the study design.

There were greater numbers of subjects who had aspirated, had extrapulmonary infections or had a Glasgow coma score less than 8 in the group with pneumonia. None of these endogenous factors were significantly different between the infection levels.

A total of 15 out of 69 eligible subjects (21.7%) had developed nosocomial pneumonia in GICU by Time A - 48 to 72 hours. Respiratory colonization developed in 12 of the 69 subjects (17.4%) and 42 subjects (50.9%) were negative for both colonization and pneumonia.

Study Limitations

Sample Size

There were a number of problems related to research in clinical settings which were encountered in this study. One of the largest problems is obtaining a large enough sample from one area with which to test hypotheses. Different clinical areas utilize different procedures and pose difficulties with the numbers of staff to be oriented to the study. For this reason, only one ICU was chosen for the study. Although a large number of subjects were entered into the study from the one ICU, the final sample at Time A was relatively small due to attrition. The size of the sample left by Time B was too small for most analyses to be meaningful.

At Time A, there were 33 subjects in the Gentle-Flo group, and 36 in the Trach Care group. Due to the different sizes of suctioning groups, an harmonic "n" of 34 was computed for the t-tests comparing suctioning groups across different variables. T-tests comparing suctioning groups at Time A had a power of .13 to .51 if the size of the difference between groups was of a small to medium magnitude. The probability of missing a true difference using the Time A sample is anywhere from as high as 87% to a minimum of 49% (Cohen, 1977). If the effect size, or difference between groups, is large, it can usually be noted by the naked eye and research would not always be needed. For this reason it was assumed that the differences between suctioning groups and those

between levels of infection were likely of a small to medium magnitude, if there were differences. With such a high probability of missing a true difference, the significant difference noted in suctioning frequency between the two suctioning groups was likely of at least a medium effect size or larger. Otherwise the difference would not have been noted with such a low power and small sample size.

The power of the two-tailed Chi-square analyses at Time A was slightly better. It ranged from .11 with a small effect size, to as high as .61 with a medium effect size, based on a sample size of 69. The failure to detect significant differences between levels of infection for the two suctioning groups may have been a result of either limited power, or the true absence of a difference.

The oneway analysis of variance used to compare variables between levels of infection also required an adjustment to the sample size for "unequal 'n's" between groups. An adjusted sample size of 23 yielded a power from .10 to .43, thus the probability of failing to detect a true difference was at least 57%, and could be as high as 90% depending on the effect size. A difference was not detected between suctioning frequencies for the levels of infection. There may not have been a difference, but the probability of missing the difference was high.

Unfortunately, the final sample size cannot always be predicted. It was hoped that the attrition rate would not be as

great as it was, based on previous GICU data, but patient populations and trends in ICU are not constant.

Design

The use of a convenience sample prevents generalizing the results to other ICU populations unless they are composed in the same manner as the study population. The probabilities of a similar composition are unlikely. As studies are replicated using similar instruments, diagnostic criteria and a variety of populations, it will be easier to generalize clinical research results across units.

One of the other difficulties in conducting clinical research is the relatively small amount of control in the hands of the investigator. It would have been ideal to have a group of subjects who were not suctioned, but this was not possible. An alternative may have been the comparison of the Trach Care technique with a standard catheter sterile technique in which only one person performs the procedure. This technique is utilized in some ICU's and may maximize the variance between suctioning techniques in order to allow the detection of any existing differences. The frequent use of disposable catheters in the Trach Care group was an added factor which may have affected the ability to detect differences between the suctioning groups, by making both open systems.

Another problem was the number of staff performing suctioning. This also made control of procedures very difficult. ICU staff

generally have their own preferred way of performing procedures and it was observed that the unit protocols were not always followed for the suctioning. The periodic observations of suction episodes, however, indicated that approximately 82% of the time, nurses were accurately recording any modifications of protocols which occured.

The timing of data collection periods may have been a limitation of the study design as well. It is possible, that, due to this timing, there were some subjects who had infections which were not noted in the study. For example, if a subject was suspected to have an infection immediately after Time A, and the physicians decided to begin treatment with antibiotics, the subject could present as "negative" at Time B. This type of error would have only occured between the third and fifth days of the subject's data collection. It was most likely that the majority of subjects would still demonstrate some symptoms at either the end of Time A or the beginning of Time B, thus being classed as either "infected" or "colonized".

Study Instruments

There were limitations associated with the use of both the suctioning data checklist and the diagnostic criteria. The reliability of the checklist depended on accurate completion. It was not often possible for the nurses to complete the checklist immediately, and the checklist was usually completed at the end of their shift. This factor introduced the element of recall into the

reliability of the recordings. At least 83% of the time, the checklist was completed, with an interrater reliability of 82% for the suction classifications.

The diagnostic criteria used may have provided an inaccurate estimate of the number of subjects with nosocomial pneumonia. It is likely that this inaccuracy would be in the form of an underestimate, based on the comparison with the CNISS criteria. Larger numbers of subjects with pneumonia would have perhaps demonstrated more differences between groups, but it was preferable to use more stringent and less subjective criteria for diagnosing pneumonias. The diagnostic criteria are heavily based on the presence or absence of opacities compatible with pneumonia on the chest x-ray. The value of the radiological interpretations was strengthened by the use of three radiologists, and a criterion of consensus between two of the three radiologists.

Other data were extracted from the subjects' charts, such as the number of aerosol medications given and respiratory parameters measured. There may have been omissions by staff in recording these variables.

Implications of the Study

If there are no significant differences in the risk of respiratory infection with either catheter, the choice of suction catheter can then be based on other factors. Examples of other factors are the potential physiologic benefits, efficiency and cost-effectiveness of particular suctioning techniques. A cost-

effectiveness study at University of Alberta Hospitals (1984) between standard disposable catheters and Trach Care catheters demonstrated a 50% cost saving in a 24 hour period with the use of the Trach Care catheter, without including the added costs of the trays necessary for suctioning with the standard catheters. The Trach Care catheters are also reported to be more convenient and are designed for patients receiving high levels of oxygen or positive end expiratory pressure.

Aspiration and frequency of suctioning may still be factors in the development of pneumonia, as both factors occured significantly more often in the suctioning group with more pneumonias. Further, the probability of missing a significant difference in the frequency of suctioning between the levels of infection was high. For these reasons, it is recommended that further study be conducted on the role of suctioning in the development of nosocomial pneumonias, using a larger sample and comparing different types of suctioning techniques.

Due to the known trauma created by endotracheal suctioning, ICU staff have been urged to only suction as needed rather than on the regular basis often practiced in the past (Young, 1984). The increased frequency of suctioning in the group with more pneumonias would suggest that limiting suctioning activities is important, until further research results can demonstrate otherwise.

Patients in ICU are exposed to many risks, of which ICU nosocomial pneumonia is only one. Through continued research into nursing and medical practices, we may be able to provide safer care for this high risk population.

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