University of Alberta

Caring for the radial artery post-angiogram:

A pilot study on a comparison of three methods of compression

by

Jennifer C. Fech

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

Master of Nursing

Faculty of Nursing

Fall 2010
Edmonton, Alberta

Examining Committee

Dr. Colleen Norris, Faculty of Nursing

Dr. Kathleen Hegadoren, Faculty of Nursing

Dr. Robert Welsh, Faculty of Medicine & Dentistry

Abstract

Background:

A coronary angiogram (CATH) is the diagnostic tool used to visualize the coronary arteries of a person's heart. The heart has traditionally been accessed through the femoral artery. However, in the last 20 years, the radial artery has gained more popularity among physicians and patients, thereby offering an alternative to the femoral approach. Various methods of applying compression to the radial puncture site have been used, but no research has been done to show what best practice is. In this case, best practice would be the most effective way of getting hemostasis while limiting complications and ensuring the efficient use of nursing and medical resources.

Objective:

The purposes of this pilot study was to compare two devices and three methods for achieving hemostasis after a transradial angiogram while assessing vascular complications and time endpoints.

Design & Methods:

A mechanical device (Terumo TR wristband) and a hydrophilic wound dressing (Clo-Sur P.A.D.) were used. The Terumo band was studied twice, using the current method and a fast-release method.

Results: Taking into account the small sample size of this pilot study, statistically significant differences are seen in time to discharge in the fast-release Terumo and Clo-Sur P.A.D. groups, as compared with the control Terumo group, without increasing vascular complications.

Acknowledgement

I am very thankful for the support and guidance of Dr. Colleen Norris as she helped me complete this research. I would also like to thank Drs. Robert Welsh and Kathleen Hegadoren for their insights and questions, which I believe substantially improved the outcomes of this study. I am indebted to the nurses and physicians at the Mazankowski Alberta Heart Institute who allowed me to work with them and made my life easier.

I am also indebted to numerous family members and friends, most of all my husband David, for their support and encouragement in making this dream a reality.

Now all glory to God, who is able, through His mighty power at work within us, to accomplish infinitely more than we might ask or think. Ephesians 3:20, The Bible

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Chapter 1

Introduction

This particular research question, regarding the care of the radial artery after a coronary angiogram, arose from personal experiences in the recovery area of a cardiac catheterization lab. A switch in mechanical compression devices had been made from an older mechanical device to the Terumo TR wristband, a unilateral mechanical compression device. The method of pressure release for the Terumo wristband had been transferred from another hospital. There were no manufacturer's instructions regarding compression time or the safe removal of the device post-hemostasis. Wiper, A., Kumar, S., MacDonald, J. and Roberts, D. H. (2006) were among the few authors that published on compression release methods, recommended gradually releasing the air pressure of the Terumo band over four hours. The Radistop, another mechanical compression device, was also removed at 4 hours. The cases all involved patients with elective percutaneous coronary intervention (PCI), not diagnostic cases, which could have affected outcomes because of the amount of anticoagulation given during a PCI. The practice at this particular hospital, for diagnostic cases, was to release and remove the Terumo band by the 2-hour mark. Patients then stayed about another hour for observation (during which they got dressed and reviewed their discharge instructions) before they were officially discharged. Based on this, it appeared that the removal time of the Terumo band for diagnostic cases could be shortened.

Purpose of the Pilot Study

The purpose of this pilot study was to demonstrate the need for a large randomized control study, and to compare two devices and three methods of achieving post-angiogram hemostasis while assessing vascular complications and time endpoints.

Significance of the Pilot Study

Various other methods of compression, such as tourniquets, manual pressure, pressure dressing, hydrophilic wound dressing, and other mechanical devices (commercial, or made at the hospital) have been used since the development of the transradial approach. However, in a review of the literature, no evidence of research regarding best practice in the post-angiogram care of the radial artery was found. This begged the question, what exactly is best practice in this scenario?

Chapter 2

Literature Review

A literature review was conducted to locate studies comparing different methods of achieving hemostasis at the radial puncture site. There was an abundance of medical literature on care of post-CATH patients. Literature was found on best practice for femoral arterial sites (17, 20, 37) and on the usability and analysis of the radial artery post-CATH (6, 25, 23, 18, 8). Articles comparing radial and femoral approaches were also found (5, 7, 30, 1, 28). However, only one article (12) compared two methods of radial compression in a randomized control trial post-CATH. These authors concluded that a hydrophilic wound dressing may achieve hemostasis faster than a unilateral compression device without increasing vascular complications. Since this was the only randomized control trial found, the literature review identified a gap in knowledge about achieving hemostasis at the radial artery puncture following a CATH.

Nursing literature includes published research on the care of the femoral artery after the completion of an angiogram (26, 10, 33). From an anatomical perspective, care for the radial artery is different than that of the femoral artery. The radial artery is directly in front of the radius bone, against which it is easily compressed. However, what is the best method of applying pressure? Which is the fastest, safest and most cost-effective way? What duration of compression limits vascular complications? Many questions remained unanswered, leaving each hospital or area of care to create its own policies and procedures.

Transradial Complications

Complications of the transradial approach were often discussed. These complications included local bleeding, puncture-site hematomas, radial artery occlusion or injury and access failure. Radial artery occlusion was rare and relatively minor (34), but an undesired complication, which could limit future transradial access (29). Choussat et. al. (2000) found that asymptomatic radial occlusion occurred in around 5% of patients. Researchers had not concluded what the predictors of post-CATH occlusion are, but suggest the amount of heparin, the type and duration of compression, and sheath size as potential predictors (4, 9, 32). A unilateral mechanical device, which allowed for venous blood flow, distal flow and dedicated radial compression has been suggested as ideal for hemostasis and preservation of the radial artery (9, 16, 32). These studies were not randomized control trials, which would be needed to confirm their hypothesis.

Methods of Compression

Five main methods of applying pressure to the radial site were identified. Most frequently cited in literature were the tourniquet, mechanical compression device, the hydrophilic wound dressing, pressure dressing, and manual pressure. Little rationale was given in most articles as to the reason for the method(s) of choice. This is important in nursing practice because of the lack of knowledge of best practice, and minimal experimental or evidence-based data. Furthermore, these articles did not look at extraneous or confounding variables, such as the duration of compression that could interfere with a method's effectiveness. These studies also included topics other than transradial angiography, such as peri-operative radial cannulation.

Tourniquet. First described in 1995, this was the first documented method of achieving hemostasis at the transradial site. This method was subsequently studied by multiple authors using a similar application method (14, 20, 21, 22, 34, 35). This procedure required two tourniquets, one at and one proximal to the puncture site on the wrist, over some gauze. Over 30 minutes both tourniquets were gradually loosened until they could be removed, at which time a pressure dressing was applied. There was no information provided on when the releases started, e.g. number of minutes after post-procedure. This seemed to be a very labour-intensive, time-consuming process, and the potential for complete loss of tourniquet pressure at some point seemed high. The most serious drawbacks noted were non-selective pressure and venous congestion that is caused by a tourniquet.

Mechanical Compression. The most common method documented in the last 10 years for hemostasis was the wristband with dedicated radial compression. Mechanical compression was favoured over manual compression due to convenience and ease of application. It increased the turnover rate of the CATH lab, and freed up nurses' time and resources (9). New mechanical devices have often been studied individually, or compared to a previously used device (9, 32). The most common devices studied were the Radi-Stop® and the Terumo TR Band. Concerns specifically arose regarding hematoma development of improperly placed mechanical devices (4). Only one study compared mechanical compression with a different method of achieving hemostasis post-CATH (12**)**. It compared the compression device, the Radi-Stop®, with a hydrophilic wound dressing, and concluded that the hydrophilic wound dressing had two advantages over a compression device: an even lower vascular complication rate, and a shorter time

to hemostasis. This study was limited in that both devices were completely released from the wrist after 30 minutes of compression to check for hemostasis, which could have affected clot development and integrity.

Hydrophilic Wound Dressing. The hemostatic device used in one randomized control trial for the transradial approach is a hydrophilic dressing called the Clo-Sur P.A.D (12). A hydrophilic dressing has a high affinity for water, and absorbs and controls body fluid. Clotting of the blood is determined by the combination of the polymeric structure (linear positive charges) and the molecular weight of the pad. The positively charged 4x4 centimetre pad reacts with the neuraminic acid residue on red blood cells causing agglutination of the cells. The Clo-Sur P.A.D. works outside of the clotting cascade (2, 3, 27). Choi et. al. (12) concluded that this dressing had a faster time to hemostasis (58.7 $\pm$ 32.6 minutes) than the mechanical compression device, Radi-Stop® (131.3 $\pm$ 59.1 minutes) . They released both devices 30-minutes after application to check for hemostasis. This protocol was continued until hemostasis occurred and no bleeding was visible from the puncture site. This protocol could have affected time to hemostasis, clot integrity after hemostasis and discharge time for both devices.

Pressure Dressing. Pressure dressings were studied in various forms, and pressure bandages (gauze and tape) without manual compression were favoured (13, 15, 36). In one study, hemostasis at the radial puncture site was achieved by applying the Stepty-P, a simple sponge applied to the puncture with elastic tape and left in place for 2-3 hours. If bleeding was observed on release of the Stepty-P, gauze and a tourniquet was applied to the wrist until hemostasis occurred (31).

Manual Compression. Manual compression was determine by randomized control trials to be the best method for attaining hemostasis after the transfemoral approach (26). Two articles were found which mentioned applying manual pressure to a radial site, however only one was post-CATH. Tuncali et. al. (2005) studied patients who required an arterial line for hemodynamic monitoring during surgery. Manual pressure was applied for three to five minutes or until hemostasis was achieved. This is not completely generalizable to transradial angiograms because the catheter inserted was smaller than the one inserted during an angiogram. One editorial article, Cheng, 1997, discussed mechanical and manual compression of the radial artery but concluded that there was a need for a randomized control study comparing mechanical with manual compression of the radial artery after an angiogram. A study of this description was not found in the literature review.

Literature Conclusion

Studies describing different methods for achieving hemostasis at the post-CATH transradial site were found, but only one was a randomized control trial comparing two methods. The radial approach has certain advantages, as well as disadvantages, over the femoral approach. Complications associated with femoral punctures, such as a hematoma or bleeding (22, 15), are not as common with the radial approach. A tourniquet causes the most vascular complications, as it is not selective in applying pressure to the radial puncture site. Of note, Campeau (1989) specifically mentioned not obliterating the radial pulse during compression. Clinical practice regarding the radial site has been based on experience of the operators, and available commercial compression devices, not on results of research. Therefore the leading question in designing this pilot study was what

method of achieving hemostasis at the transradial puncture site results in successful, effective hemostasis with the least amount of vascular complications.

Chapter Three

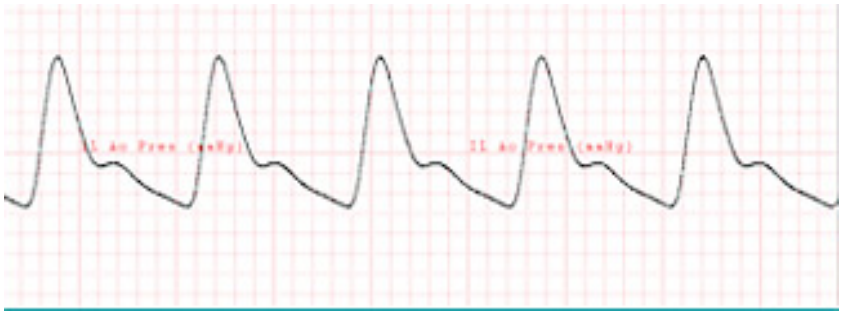
Operational Definitions

An angiogram (CATH) is a picture of what the lumen (inside) of the arteries of the heart looks like. This is the definitive test (gold standard) of diagnosing coronary artery disease. This pilot study will focus on angiograms done via the radial artery, which runs along the thumb-side of the forearm.

The modified Allen's test subjectively measures ulnar artery flow. The patient is instructed to clench his/her fist tightly. Occlusive pressure is applied to both radial and ulnar arteries. The patient is then instructed to relax his hand which, should be blanched. Pressure on the ulnar artery is released and flushing of the hand should occur in 5-15 seconds for a positive result. This test determines if the ulna artery can perfuse the hand adequately while the radial artery is occluded during the angiogram.

Plethysmography (distal flow monitoring) monitors the waveform observed on the computer after the pulse oximeter (sensor) has been applied to the thumb of the affected hand. Flow will be determined by a well-shaped waveform (as below) concurrent with ECG (electrocardiogram) monitoring.

Figure 1. Waveform



After the angiogram, the nurse is responsible for removing the sheath (tube through which angiogram catheters are passed into the artery) and applying a method of compression to the wrist, monitoring the site until the patient is discharged.

Hemostasis occurs when the bleeding has stopped completely (32) after the sheath has been pulled. A hematoma (bruise) is evidence of blood outside of the artery, in the soft tissue. It is a visible and measurable ($\geq$1 cm diameter) mass, which can be measured with a standard ruler. If the hematoma visibly expands (bleeding continues into soft tissue) on inspection, pressure is reapplied immediately for 10 minutes or until bleeding stops. Re-bleeding is visible external bleeding requiring intervention (manual pressure until bleeding stops) after initial hemostasis. Radial artery occlusion (RO) is the absence of a palpable pulse together with the absence of a plethysmography waveform during ulnar artery compression (31).

The Terumo TR wristband is like a watch that wraps around the wrist and applies pressure to the radial artery via an oval-shaped balloon. This balloon is inflated, after the sheath is pulled, until bleeding stops, or to a maximum of 18 millilitres (ml) of air.

The hydrophilic wound dressing is described in the previous section.

Methods

Research Design and Purpose

The nature of a pilot study was to gather enough information to show that a large randomized trial is feasible and necessary (24). This was the first time that two devices and three methods of compressing the radial artery had been studied together, and therefore warranted a pilot study. Lancaster et. al. (2004) quoted the number 30 as a

general sample size for a pilot study. Each arm of this study had 25 people, giving a total of 75 people in this pilot study.

This study compared two devices and three methods of achieving hemostasis post transradial angiogram. The primary outcome was bleeding requiring intervention after initial hemostasis and at day one follow-up. The secondary outcomes were the amount of vascular complications (hematoma and radial artery occlusion) that occurred, and time to discharge.

Setting

The pilot study was set in the Cardiac Cath Lab and Recovery room at the University of Alberta Hospital and subsequently, the Mazankowski Alberta Heart Institute.

Sample and Demographics

The sample was one of convenience. The goal was for 75 people to participate, 25 per group. In this CATH lab, there were approximately 20-25 non-emergent outpatients per week that were transradial angiogram candidates. A research team member was present 2-3 days per week to obtain consent from eligible patients. Of those who consented to participate, only 25-50% were able to complete the study since patients with transfemoral angiograms or angioplasties were subsequently excluded from the study.

Inclusion and Exclusion Criteria

The individuals targeted were those having an angiogram done on a non-emergent, outpatient basis. Inclusion criteria included men and women over 18 years of age who needed an angiogram due to symptoms such as shortness of breath, angina,

heartburn, positive cardiac tests such as an exercise stress test, or as heart transplant follow-up. Other potential medical history included smoking, diabetes, hypertension, obesity, a history of strokes, renal failure, and a family history of heart disease.

Those excluded were inpatients, emergency patients, and booked angioplasty patients. Due to the limited sample size, those with a complete language barrier (who needed a translator) or those with cognitive impairment (who needed a dual physician or guardian consent) were excluded. Those patients in whom the transradial approach was initiated but aborted due to inability to puncture the radial artery were not included in the study. However, if the radial artery was punctured but the approach was abandoned, patients remained a part of the pilot study. Anticoagulation is not considered important in determining the angiogram approach, and therefore patients on these medications were not excluded from the pilot study. No exclusions were made based on physical characteristics or demographics.

Consent and Confidentiality

The physician performing the angiogram explained the risks and benefits of transradial angiography to the patient.

The research team member obtained consent for the study. A consent form and script explaining the pilot study was developed, and a copy of this was given to the patient. The research team member gave information as to the risks and benefits of the three methods of achieving hemostasis at the wrist. The patient was asked to sign the consent form for the pilot study, and their signature was witnessed. It was explained to the patient that they could withdraw at any time. No patient withdrew from the study after consent. To ensure confidentiality, study labels were applied to paperwork and the

patient's name and identifying data were crossed out with a black felt pen. Once the patient consented to the pilot study, a green flag was placed on the front of the chart. Once the transradial angiogram was complete, the next study number (1-75) on a spreadsheet was assigned to that patient. At discharge, all paperwork was placed in a labeled study envelope. The patient received a card (labeled with their study ID) detailing the date and time of their follow-up visit.

Randomization

The numbers 1-75 were entered into a spreadsheet. The 3 methods of compression were each assigned a number from 0 to 2. The control group (Terumo band, current practice) was assigned 0. The Terumo study group (Terumo band, fast release protocol) was assigned 1. The Clo-Sur P.A.D. was assigned 2. A random number table was created online and these random numbers were then entered into the spreadsheet, one method of compression to each study number (appendix 1). For example, study number 1 (the first patient) was given the method number 2 (Clo-Sur P.A.D.). This table was printed and kept in the Recovery Room as reference. Envelopes were labeled 1-75 and contained study labels and plethysmography sheets. The study labels were initially applied to the yellow triplicate copies of the chart, two arrhythmia records, and printed CATH lab record. However, once the move to the Mazankowski Alberta Heart Institute was completed, the paperwork was done electronically. Therefore, an extra copy of the paperwork was printed, the patient's name and identifying data was blacked out and study labels applied.

Reliability and Validity

To ensure recorder reliability, a research team member completed the majority of the Recovery Room paperwork. The CATH lab nurses continued their documentation. The nurses in both areas participated in inservices on operational definitions, methods, complications and the types of measurements to be recorded. The research team members were not blinded during the study, during the follow-up analysis of the radial site, or during analysis of the data. For example, the Clo-Sur P.A.D. remained on the site until the day one follow-up visit and was easily visualized by the research team member during their analysis of the site.

Data Collection

Procedural data was collected from the paperwork in the Recovery Room and CATH lab (Appendix 2). The procedural data collected from each set of paperwork is summarized in table 1.

Table 1: Data Collection on Paperwork

Type of Paperwork	Pre-procedure	Intra-procedure	Post-procedure
Recovery Room (triplicates – yellow copy used for pilot study; or a computer-generated report)	Demographics Vital Signs Medical History (including previous angiograms and access) Medications	-	Vital Signs Nursing Notes: Duration of Pressure Pressure releases per method Time of patient discharge Complications: description, measurements, time of occurrence
CATH lab (computer printed)	-	Time of patient entry and exit Sheath size Types of catheter insertions (through sheath) Anticoagulation (type, admin time, amount) Time of sheath pull Method of compression	-
Arrhythmia Worksheet	Plethysmography (x1) Oxygen saturation (x1)	-	Plethysmography (x3) Oxygen Saturation (x3)

Control and Intervention Methods

The groups are summarized here and in table 2. The control group (0) method was conducted as follows: the Terumo band was applied over the radial puncture site before the sheath was pulled. The balloon was inflated as the sheath was pulled out. Inflation continued until bleeding stopped, to a maximum of 18 millilitres of air. One hour after the application of the band, the balloon was deflated by 3 millilitres of air every 15 minutes until all the air was released. The band remained on the wrist for one more hour after which it was removed and the site covered with gauze and a translucent dressing.

The group 1 method (fast-release) was conducted as follows: application of the Terumo band was the same as in group 0. After 15 minutes of pressure, 3 millilitres of air was released. After another 15 minutes (30 minutes total time of pressure), 3 ml of air was released again. At this point, 3 ml were to be released every 10 minutes until completed in an attempt to decrease compression time. However, the research team more easily managed 15-minute releases as per practice routine. The band was removed from the wrist 15 minutes after the final release, and then the site was covered with gauze and a translucent dressing.

Group 2 was the hydrophilic wound dressing, the Clo-Sur P.A.D. In the angiogram suite, the research team member applied occlusive pressure proximal to the radial artery puncture site as the sheath was removed by a CATH Lab nurse. The pad was placed over the puncture and enough pressure released to allow minimal blood flow. Occlusive manual pressure was re-applied over the Clo-Sur P.A.D. In the proposal, this occlusive pressure was to last for 30 seconds. Once hemostasis was achieved, manual pressure was completely released and a transparent dressing applied to cover the hydrophilic dressing. This was similar to the procedure that Choi et. al. (2005) used.

Table 2: Groups Types, Compression, Release, and Device Removal

Group	Compression Application	Compression Release	Device Removal
Control Terumo TR Band slow-release (0)	Apply band over puncture site. Pull sheath. Inflate balloon until bleeding stops or maximum of 18 ml air.	After 1 hour, release 3 ml of air every 15 minutes.	Remove band 1 hour after final air release, cover site with gauze and transparent dressing.
Terumo TR Band fast-release (1)	Apply band over puncture site. Pull sheath. Inflate balloon until bleeding stops or maximum of 18 ml air.	After 15 minutes, release 3 ml of air. After 15 minutes (30 minutes total time), release 3 ml of air Continue releasing 3ml air every 15 minutes.	Remove band 15 minutes after final air release, cover site with gauze and transparent dressing.
Hydrophilic Wound Dressing (Clo-Sur P.A.D.) (2)	Apply manual pressure proximal to puncture site. Pull sheath. Apply occlusive manual pressure. Apply dressing over puncture. Release manual pressure until blood flow starts and connects with dressing. Re-apply occlusive manual pressure for 30 seconds over dressing, or until hemostasis.	Release pressure once hemostasis achieved. Cover Clo-Sur P.A.D. with transparent dressing.	Remove transparent dressing 24 hours after application. Wash Clo-Sur P.A.D. off with water.

Assessing Endpoints

The primary endpoint, bleeding requiring intervention, was assessed in each group after initial hemostasis was achieved. This was assessed post-CATH and at the 1-day follow-up. The Terumo band is a transparent material, and the site was easily visualized for bleeding. The Clo-Sur P.A.D. covered the site, but bleeding was visible

through the dressing. The Clo-Sur P.A.D. was not removed from the site to maintain clot integrity. The sites were assessed every 15 minutes post-CATH after hemostasis.

If bleeding occurred in groups 0 or 1, pressure was reapplied via the balloon in the terumo band. The balloon was reinflated until bleeding visibly stopped. Air withdrawal of 3 millilitres was attempted 30 minutes later in group 0, and 15 minutes later in group 1. Regular releases (3 ml every 15 minutes) were resumed if there was hemostasis. For cases where hemostasis was not achieved after the second attempt at withdrawing air, the band was to be removed and 10 minutes of manual pressure applied. The 10-minute manual pressure method is not from transradial research, but from transfemoral research, which mentions 10 minutes as the minimum to achieve hemostasis (Walker et al, 2001). Manual pressure was reapplied if bleeding occurred after initial hemostasis in group 2, the Clo-Sur P.A.D. group. In one case, hemostasis was not achieved with >30 minutes of manual pressure. The Cardiologist was consulted and the patient was admitted to hospital overnight for sustained compression via a mechanical compression device. The bleeding was likely due to radial artery dissection. The primary endpoint is summarized for all groups in Table 3.

Table 3: Primary Endpoint

Endpoint	Terumo Control (0)	Terumo Fast-Release (1)	Clo-Sur P.A.D. (2)
Bleeding Requiring Intervention	Reinflate balloon until bleeding stops. Attempt release after 30 minutes. Repeat above procedure if bleeding continues. If hemostasis occurs after 1st or 2nd attempt, continue with pressure releases per method. After 2nd attempt, if bleeding continues, remove band and apply manual pressure x 10 minutes or until hemostasis.	Reinflate balloon until bleeding stops. Attempt release after 15 minutes. Repeat above procedure if bleeding continues. If hemostasis occurs after 1st or 2nd attempt, continue with pressure releases per method. After 2nd attempt, if bleeding continues, remove band and apply manual pressure x 10 minutes or until hemostasis.	Apply manual pressure for 10 minutes or until hemostasis.
Bleeding-1 day post-CATH	1 day post-CATH	1 day post-CATH	1 day post-CATH

The secondary endpoints relating to the radial artery were radial artery occlusion (RAO) and hematoma post-CATH and at one day follow-up. To assess the patency of the radial artery pre-CATH, the modified Allen's test, plethysmography and pulse oximetry were used. The objectivity of plethysmography and pulse oximetry was previously confirmed (19). Post-CATH plethysmography and pulse oximetry were monitored and recorded three times: during initial compression or immediately after manual pressure released, upon discharge, and at the 1 day post-CATH. The presence of the radial artery was to be palpated pre-CATH and at day 1 follow-up. The pulse was not recorded at discharge because the Clo-Sur P.A.D. was not removed and a research team member was not always present at discharge. The secondary endpoint assessments are summarized in table 4.

Table 4: Secondary Endpoints

Group	RAO* (via plethysmography, pulse oximeter)	RAO* (via palpation)	Hematoma
Terumo Control (0)	Pre-procedure During initial pressure application At discharge 1 day post-CATH	Pre-CATH+ 1 day Post-CATH	Once hemostasis established With every deflation At discharge 1 day post-CATH
Terumo Fast-Release (1)	Pre-procedure During initial pressure application At discharge 1 day post-CATH	Pre-CATH 1 day Post-CATH	Once hemostasis established With every deflation At discharge 1 day post-CATH
Clo-Sur P.A.D. (2)	Pre-procedure During initial pressure application At discharge 1 day post-CATH	Pre-CATH 1 day Post-CATH	Once hemostasis established At discharge 1 day post-CATH

*RAO= radial artery occlusion
+CATH= catheterization

Data Analysis

A research team member analyzed the patient charts. A descriptive method summarizing patient characteristics was utilized. All recorded data in this pilot study were summarized in chart format. Tables were used to display data. The data were analyzed using t-tests for equality of means, a two-way analysis of variance (ANOVA), and chi-square. Significance was set at $p \leq 0.05$. SPSS was utilized to create tables and to assist in analysis.

For the primary outcome, bleeding requiring intervention, bleeding was defined as any visible bleeding following initial hemostasis. This categorical data was analyzed using a chi-square test. The secondary outcome, time to discharge, was defined as time in minutes from sheath pull at case end, in the CATH Lab, to time of discharge from the

recovery room. Time to discharge was analyzed using an ANOVA, instead of a t-test, since there were 3 groups. Hematoma formation, the next secondary outcome studied, was defined as evidence of blood in the soft tissue surrounding the puncture site, a visible and measurable (≥1 cm diameter) mass. The site was visually assessed for the presence of a hematoma and monitored for expansion of hematoma (past the marked outline) post-CATH and on day 1. Results were analyzed using a chi-sqaure test. The last secondary outcome, RAO, was defined as a change to the radial artery and pulse, using a visual assessment of the plethysmography waveform and by palpating the radial pulse. The waveform was printed pre-CATH, and 3 post-CATH waveforms were subsequently printed and visually compared. A waveform that was visually dampened or obliterated with or without ulna artery compression was recorded as an occlusion. Palpation, to determine strength and presence of the radial pulse and to correlate with the recorded waveform, was performed on day 1. These were analyzed using a chi-square test.

Ethics

Approval for the pilot study came through the University Hospital's Research Ethics Board. Approval was also granted from the Director of the Adult Cardiac Catherization and Interventional Cardiology Program, the Patient Care Manager, and the Clinical Nurse Educator.

Chapter 4

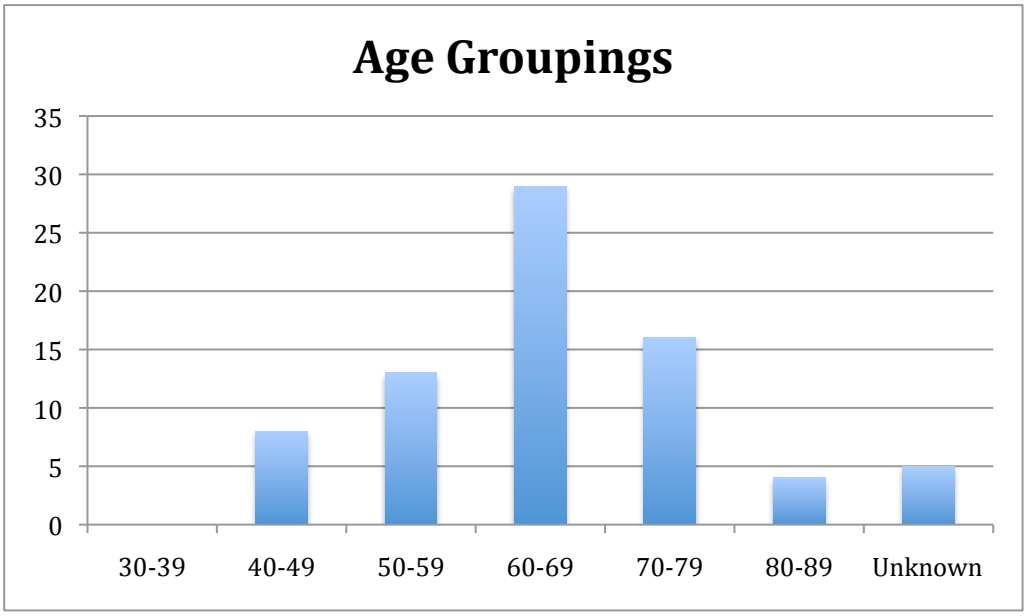
Presentation of Findings

The purpose of this pilot study is to demonstrate the need for a large randomized control study, and to compare two devices and three methods of achieving post-angiogram hemostasis while assessing vascular complications and time endpoints.

Description of Subjects

A total of 75 patients, 64 males (85.3%) and 11 females (14.7%) met the inclusion criteria, and were recruited between May 4, 2009 and March 15, 2010. They ranged in age from 42 to 85 years, with a large majority in their 60s, as shown in Figure 1. Unfortunately, due to the labeling system on the original triplicate paperwork, the ages of 5 patients are unknown since they were only recorded on the patient's hospital label and not written down on the chart

Figure 2. Age groupings



Pre-CATH characteristics are displayed in Table 5. An Allen's test was performed by the physician and only patients whose Allen's result was ≤ 5 seconds had a transradial angiogram. Medication use and cardiac risk factors were collected. Cardiac medications were specifically recorded, and non-cardiac medications were recorded under "other," due to the wide range of potential non-cardiac co-morbidities. For example, post-heart transplant patients who are on anti-rejection medications or patients having a pre-operative (general surgery) assessment. Cardiac co-morbidities were prevalent with 76% of all patients having both dyslipidemia and hypertension. A substantial number, 73.3%, were treated with warfarin, aspirin (ASA), or clopidogrel, or a combination.

Table 5. Pre-CATH characteristics by study group

Variable	Terumo Control (0) N=25	Terumo Fast-Release (1) N=25	Clo-Sur P.A.D. (2) N=25	P-value
Female n(% of group)	4(16%)	4(16%)	3(12%)	
Age: mean (SD)	63.4 (11.2)	62.1 (8.3)	64.1 (10.6)	0.802
Drugs: n(% of group)				
Warfarin	4 (16%)	1 (4%)	1 (4%)	0.241
Aspiring	17 (68%)	13 (54%)	16 (64%)	0.904
Plavix	2 (8%)	4 (16%)	7 (28%)	0.163
ACEi*	9 (36%)	8 (32%)	10 (40%)	0.919
Angiotension receptor blocker	4 (16%)	3 (12%)	8 (32%)	0.213
Beta-blocker	15 (60%)	13 (52%)	14 (56%)	0.971
Calcium Chanel Blocker	4 (16%)	2 (8%)	5 (20%)	0.582
Thiazide Diuretic	4 (16%)	3 (12%)	6 (24%)	0.600
Other	24 (96%)	22 (88%)	25 (100%)	0.385
PMHX				
Previous PCI	4 (16%)	2 (8%)	1 (4%)	0.341
Diabetes	5 (20%)	7 (28%)	5 (20%)	0.762
Dyslipidemia	22 (88%)	18 (72%)	22 (88%)	0.236
Hypertension	21 (84%)	18 (72%)	23 (92%)	0.204
Smoking	10 (40%)	11 (44%)	15 (60%)	0.425
Renal Insufficiency	1 (4%)	3 (12%)	0	0.166

*ACEi= angiotension-converting enzyme inhibitor

Bleeding Requiring Intervention

The primary outcome, bleeding requiring intervention, was studied twice: post-CATH (between initial hemostasis and discharge), and again at the day-1 follow-up visit, if the patient returned. Bleeding was defined as any visible bleeding following initial hemostasis

As evidenced in Table 6, every group experienced bleeding requiring intervention. In both Terumo groups, bleeding occurred in close relation to the time air was withdrawn from the balloon in the Terumo band. To stop the bleeding, the balloon was reinflated until bleeding stopped. At most, it was the same amount of air that was just withdrawn, 1-3 millilitres. Only one patient bled twice, all other patients with the Terumo band only bled once. When bleeding occurred in the Clo-Sur P.A.D. group, manual compression was applied until the blood seen on the gauze dressing stopped expanding. The greatest difference in post-CATH bleeding rates appears to be between the control group (control Terumo band) and the fast-release group (fast-release Terumo band). However, the differences were not statistically significant.

Table 6. Bleeding Requiring Intervention

Primary Outcome	Terumo Control (0)	Terumo Fast-Release (1)	Clo-Sur P.A.D. (2)	P-Value
N	25	25	25	
Bleeding Requiring Intervention n (% of group)	2 (8%)	6 (24%)	3 (12%)	0.25
% within bleeding requiring intervention	18.20%	54.50%	27.30%	
Day 1: Bleeding requiring intervention n (those who returned)	0 (15)	1 (20)	0 (18)	0.47

To assess bleeding requiring intervention during the day 1 follow-up visit, a valid 'n' had to be taken into account, as only 73% of patients returned for that visit (Table 7). Only one patient experienced bleeding on day 1. Bleeding was observed only when the research team member removed the dressing. Pressure was applied for 2 minutes until hemostasis was achieved. The bleeding was likely not arterial, but related to skin adhesion to the gauze dressing.

Hematomas

Few hematomas were seen post-CATH. The words hematoma and bruise were used interchangeably by those participating in data collection to mean any discoloured lump or flat discoloured area. The staff in this particular recovery room used the words interchangeably in practice, which carried over into the pilot study. This would need to be defined better in practice in a large trial. The Clo-Sur P.A.D. was not removed from the radial site until 24 hours (day 1 follow-up), so hematomas/bruises around the puncture site were not seen until the next day. However, this also means that no hematomas/bruises were seen extending past the 4x4 cm pad. During the day 1 follow-up, more hematomas/bruises were seen in all groups. Half of the hematomas/bruises were measured, ranging in size from 1-5.5cm in diameter, with one larger outlier. If not measured, they were described using words like "slight" or "small" bruising. Table 7 shows hematoma/bruise occurrence and significance pre-discharge on follow-up day 1. There were no statistically significant results in this category.

Table 7. Hematoma

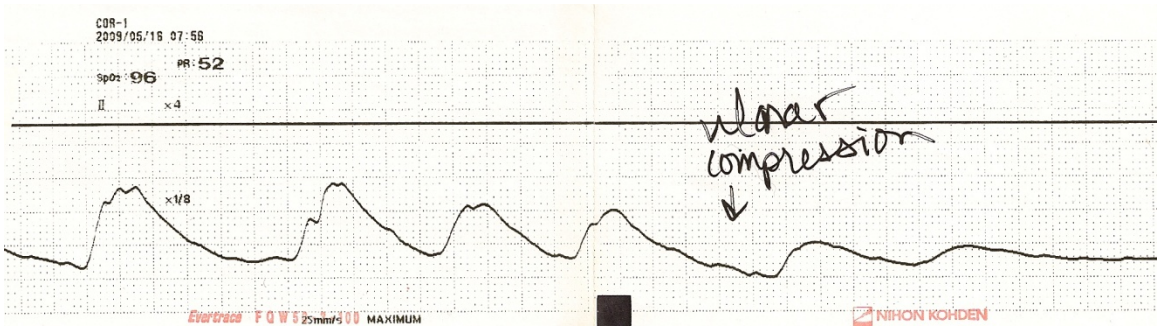
Secondary Outcome	Terumo Control (0)	Terumo Fast-Release (1)	Clo-Sur P.A.D. (2)	P-Value
Hematoma post-CATH+ (n)	1	2	0	0.372
Day 1: Hematoma N (N who returned)	4 (14)	4 (18)	7 (17)	0.468
% within Day 1: Hematoma	26.70%	26.70%	46.70%	

+CATH= catheterization

Radial Artery Occlusion (RAO)

No radial artery occlusions post-CATH were noted via plethysmography in any of these patient groups. An example of one patient's dampened radial waveform is shown in Figure 3.

Figure 3. Dampened waveform



Pulses were not palpated and recorded at discharge in the Clo-Sur P.A.D. group, as the pad was left on and a site assessment was not possible. On day 1, waveform changes during ulna artery compression were noted in both Terumo groups, but not in the Clo-Sur P.A.D. group (group 2) (Table 8). The pulse was palpated distally and proximally to the puncture site. The pulse was documented as not palpable distally on one patient. However, this patient did not have a radial artery waveform change during ulna artery compression, leading to the possibility of an assessment error. None of the

patients were symptomatic (cold hand, numbness, or hand discomfort) with waveform or pulse changes. No statistical significance was noted regarding any radial artery occlusion assessments.

Table 8. RAO (via plethysmography and palpation)

Secondary Outcome	Terumo Control (0)	Terumo Fast-Release (1)	Clo-Sur P.A.D. (2)	P-Value
RAO* post-CATH+ (waveform) (n)	0	0	0	
Day 1: RAO (waveform) N (N who returned)	1 (15)	1 (20)	1 (18)	0.536
Day 1: RAO (palpation) N (N who returned)	0 (15)	1 (20)	0 (18)	0.634

*RAO= radial artery occlusion
+CATH= catheterization

Time to Discharge

The greatest difference between the groups was noted, as expected, in time to discharge. For safety reasons due to arterial puncture, patients were asked to stay a minimum of 90 minutes post-CATH regardless of method of compression. The fastest time to discharge was approximately 90 minutes, in the Clo-Sur P.A.D. group. The longest time to discharge was, as expected, in the control (0) group. These differences were expected due to compression method and duration. The control (0) Terumo group started pressure releases approximately 60 minutes after the sheath pull, whereas the fast-release (1) Terumo group started releases within 15 minutes of the sheath pull, 45 minutes sooner. Also, in current practice, control group (0) patients stayed 30-60 minutes after the last balloon deflation, versus 15-30 minutes in the fast-release (1) Terumo group. These times were statistically significant between control (0) and fast-release (1) Terumo ($p=0.002$), and between control (0) and Clo-Sur P.A.D. (2) ($p<0.001$) as seen in Table 9.

The time to discharge was not significant between fast-release (1) Terumo and Clo-Sur P.A.D. (2) group (p = 0.114), however, patients stayed an average of 20 minutes longer in the fast-release Terumo group.

Table 9. Time to Discharge in minutes

Secondary Outcome	Terumo Control (0)	Terumo Fast-Release (1)	Clo-Sur P.A.D. (2)	P-value
Mean time to discharge in total minutes (standard deviation)	178.2 (50.4)	134.0 (45.8)	113.7 (48.0)	-
Terumo Control (0) & Terumo Fast-Release (1)	178.2	134.0	-	p=0.002
Terumo Control (0) & Clo-Sur P.A.D. (2)	178.2	-	113.7	p<0.001
Terumo Fast-Release (1)& Clo-Sur P.A.D. (2)	-	134.0	113.7	p=0.144

Extraneous Variables

During the analysis of the data, certain variables were observed to widely range, potentially indicating extraneous variables that could influence results. The differences among groups in these variables were assessed by an ANOVA. There were no statistically significant differences between groups in these select variables.

Table 10. Post-CATH variable analysis

Variables	Terumo Control (0)	Terumo Fast-Release (1)	Clo-Sur P.A.D. (2)	P-value
Heparin in mean units (range)	2765.8 (1500-5000)	2512.5 (1000-4500)	2977.3 (1600-6800)	0.195
Systolic BP in mean mmHG* (range)	120.9 (100-158)	124.8 (88-150)	118.2 (95-146)	0.265
Diastolic BP in mean mmHG (range)	67.4 (48-90)	71.8 (60-95)	69.4 (55-85)	0.312
Balloon Inflation in mean milliliters (range)	13.4 (9-18)	13.2 (8-15)	-	0.85

*mmHg= millimeters of mercury

Heparin is used during the angiogram as anticoagulation. The amount of heparin given varied between almost every case. Heparin is administered pre-CATH at approximately 30 units/kilogram, although not all pre-CATH doses were given according to this calculation. The pre-CATH heparin administered ranged from 1000 units to 6800 units in these diagnostic cases. Analysis confirmed the wide range of units of heparin administered but also showed no statistical significance between the groups. The range of units of heparin administered in group 2 (Clo-Sur P.A.D.), is higher than the other groups although the highest amount, 6800 units, was only given once. This patient did not experience any bleeding requiring intervention but, unfortunately, did not return for follow-up. Blood pressure can affect time to hemostasis. High pressure in the artery can delay clot formation and integrity of the clot. There was no statistical significance in mean blood pressure between groups in this pilot study. The lowest systolic (88 mmHg) which was in group 1 (fast-release Terumo) occurred only once and could be considered an outlier. The final extraneous variable that had great potential to affect results was the amount of air used to inflate the balloon of the Terumo band in groups 0 & 1. There was no protocol regarding amount of air used, to a maximum of 18 mL. Certain nurses

preferred a certain volume of air whereas others inflated the balloon only until bleeding stopped. The maximum, 18 mL, was only used to inflate the balloon once and could be considered an outlier, which then would make the ranges of groups 0 & 1 almost exactly the same. Again, no statistical significance was noted with this variable.

The variables not directly assessed, that could cause delayed discharge, included the need to wait for family/friends, waiting for a physician (i.e. to discuss the results of angiogram) or a delay in nursing attention (i.e. if the unit was busy). If a patient was required to wait for family or a physician (as noted in the charting), the discharge time was adjusted to *potential* discharge time, i.e. when the patient was ready to leave. Delays in nursing attention (i.e. scheduled releases delayed) were not assessed.

Chapter 5

Discussion of Findings

Patients were recruited for a randomized controlled pilot study to identify vascular and time endpoints related to 2 devices and 3 methods of compression. Patient characteristics were typical of patients with cardiac risk, as the majority of the patients were males in their 60s.

Outcomes were recorded between sheath pull and discharge, and on day 1 follow-up visit. ANOVA was used to determine significance of results for each numerical endpoint and a chi-square was used for categorical data.

Synopsis of Key Findings

Statistically significant differences in endpoints assessed were noted only in time to discharge. The fastest time to discharge was noted in the Clo-Sur P.A.D. (2) group. A potential reason for this, is the amount of active nursing time required to treat groups 0 (control) and 1 (fast-release Terumo). The Clo-Sur P.A.D. group was labour-intensive for the first 10 minutes, after which the site was merely observed every 15 minutes for bleeding. Discharge in groups 0 and 1 was dependent on the time of last balloon deflation, not time of sheath pull, as in group 2. A delay in the schedule of balloon deflations caused a delay in discharge time. Although time to discharge was not statistically significant between groups 1 (fast-release Terumo) and 2 (Clo-Sur. P.A.D.), the time may be clinically relevant, especially in a fast-paced CATH lab and recovery room. If 3 patients each stayed 20 minutes less, on average, 1-2 more people could benefit from a diagnostic angiogram. The fast-release Terumo group could be as time-

sensitive as the Clo-Sur P.A.D. group if balloon deflations were always done every 15 minutes, per protocol.

There were no statistically significant differences between the groups for the primary outcome, bleeding requiring intervention, and the secondary outcomes, hematoma and RAO. However, the data analysis revealed some trends in this pilot study, which, although not statistically significant, could be clinically significant. More than half of the patients who had bleeding requiring intervention were in group 1, the fast-release Terumo group. This did not increase nursing workload, since any bleeding required re-assessment in 15 minutes, the same time the next deflation was due. It did increase the number of deflations required, and lengthened the time to discharge by 15-30 minutes. Another trend was noted with the analysis of day 1: hematoma, as 41% of the patients with hematomas on day 1 were from group 2, the Clo-Sur P.A.D. group. This group had no observed hematomas pre-discharge as the site could not be assessed for hematoma until day 1, when the 4 x 4 cm P.A.D. was removed. After the sheath was pulled in the CATH lab, the puncture site was not directly visible as with the Terumo band. Therefore, a greater amount of bleeding (and hematoma formation) could occur before it became visible on or around the gauze. This may be clinically significant if larger amounts of heparin are used during the angiogram. At times, after the initial 5 minutes of pressure, the patient was asked to apply pressure with their opposite hand for a few minutes, i.e. during patient transfers. This strategy could be utilized in future studies, or device application, to maintain clot integrity and hemostasis and possibly to reduce the amount of hematomas. The number of hematomas could also be related to the learning curve of the research team member, and with more frequent application, this number

could potentially be reduced. This is difficult to analyze in this study since only 18 patients returned for follow-up and since the duration of data collection was 10 months, some applications of the Clo-Sur P.A.D. were 1 month apart. Only one person was responsible for applying the Clo-Sur P.A.D., which was a way of limiting variables associated with multiple people applying a new device. Although the research team member had been educated in Clo-Sur P.A.D. application, this was the first time the procedure was actually performed. A learning curve was associated with the application of this pad. The first four applications averaged 10.62 minutes. Subsequent applications were significantly reduced, averaging 5.77 minutes with a mode of five minutes.

Extraneous Variables in Findings

Potential confounds were identified during analysis that would need to be addressed in any future study. One key variable, which has the potential to affect bleeding requiring intervention post-CATH in a larger study, was the amount of air (ml) used to inflate the Terumo band balloon. The amount of air used to inflate the balloon in this study was between 9ml and 18ml. Many nurses favoured 12ml to 15ml of air as a general guideline. The manufacturer's instructions mention 13ml as nominal air inflation. Some nurses only inflated enough air to visibly stop the bleeding. No statistical significance between groups 0 & 1 was seen during analysis in this pilot study.

Another key extraneous variable not controlled in this study was the amount of heparin used during the angiogram. Heparin was given in 70 (93.3%) cases, but ranged between 1000 to 6800 units. The majority of heparin boluses were given at the onset of the case. This, combined with a low volume of air in the Terumo band has the potential

to affect the primary outcome, bleeding requiring intervention, as well as the secondary outcome, hematoma

Comparison to a Previous Clo-Sur P.A.D. Study

A comparison can be made to the results of Choi et. al. (2005). Inclusion and exclusion criteria were similar. In both studies, patients were included that took ASA. Other similarities included the use of heparin, verapamil and nitroglycerin as a radial cocktail, and arterial catheter size. Patients were assigned a method, in a randomized fashion, post-CATH. Sheath removal and Clo-Sur P.A.D. application were performed in a similar method. Changes between the studies occurred with how the sites were assessed and how the dressings were removed. In this pilot study, the Clo-Sur P.A.D. was not removed from the site before discharge to maintain clot integrity. Also, the balloon pressure in the Terumo band was released gradually post-CATH to ensure clot stability and integrity. However, in both studies, statistically significant differences were seen between the Clo-Sur P.A.D. group and the compression device in time to hemostasis. Time to hemostasis (complete balloon deflation) in the control (0) group of this pilot study was about 60 minutes before time to discharge, and about 30 minutes before time to discharge in the fast-release Terumo (1) group. Taking those changes into account makes it possible to compare these two studies. The conclusions are similar in both studies: the Clo-Sur P.A.D. significantly reduces time to hemostasis or discharge.

Limitations

The sample size was appropriate to performing a pilot study, but results are not completely generalizable to a larger population. A power analysis should be performed to calculate the required sample size in a larger randomized control trial. Due to the lack

of previous research, controlling for all extraneous variables was difficult because not all variables have been identified. The trial took place at a single-centre with a select number of interventional cardiologists and nurses (those who worked at the centre). Only 73% of the patients returned for the day 1 follow-up visit, so all vascular outcomes after discharge are not accounted for.

Barriers to completion of the study included patient's wrist size, availability of supplies, communication between the research team member and the CATH Lab staff, and a location change. One patient could not be part of the study because the Terumo band was too small for his wrist. Due to an unforeseen increase in transradial angiograms, Terumo band supplies were reduced. To resolve this, a supply of bands was dedicated to study use. Despite attempts to ensure CATH Lab staff knowledge of the presence of a research team member, on three occasions, a band that was not part of the study was applied to the wrist. The research team member attempted to resolve this by informing CATH Lab staff for each patient's involvement and also by spending time in the CATH Lab suites. The CATH Lab and Recovery Room also moved into the Mazankowski Alberta Heart Institute during the study, which caused a dramatic reduction of outpatients, and a change in nursing care strategy and the number of nurses. The majority of the time, a research team member was dedicated to caring for study patients, but recovery room nurses cared for a few patients. Once the situation was settled, about two months later, outpatient bookings increased and the study was able to proceed again.

Implications

A randomized control trial is necessary to continue to assess vascular and time endpoints of these devices. A significant difference is already seen with regards to time

to discharge. However, these differences may continue to change as identified extraneous variables, as mentioned in the synopsis, are controlled.

The Terumo band and the Clo-Sur P.A.D. are effective devices for transradial post-CATH care. A clear benefit of the Terumo band is its transparency and the ability of the nurse or physician to see the puncture site. The site is easy to keep clean and the band does not absorb blood. The Terumo band allows for graduated releases and hemostasis is easy to achieve. The Terumo band can be removed at the end of compression without disrupting a formed clot, thereby maintaining clot and site integrity. In retrospect, one drawback mentioned most often by the patients is the discomfort of the sustained compression of the Terumo band in group 0 (control group). Another drawback noted in this pilot study was that it did not fit the wrist of any man with a BMI greater than 42. Theoretically, if 12 ml of air was consistently used to inflate the Terumo balloon in group 1 (provided bleeding stopped with this initial amount), and deflations were done in a timely manner, discharge time could be the same as with the Clo-Sur P.A.D. group. The Clo-Sur P.A.D. is the most time-reducing device. Hemostasis is achieved in the CATH lab within 5- 10 minutes. The patient can assist in applying pressure on the gauze pads. Once the P.A.D. is on, however, the site cannot be visualized and if bleeding occurs post-hemostasis, it is not easily seen until the blood soaks the gauze. There is a learning curve associated with its use, however, which must continue to be taken into consideration. The device is clearly effective, however, the cost ($100/unit) and lack of ease of initial use of this device must also be taken into consideration. The Clo-Sur P.A.D. and the Terumo band, fast-release method, reduce the intensity of post-CATH care and allow for significantly reduced recovery time.

Conclusion

Research regarding caring for the radial artery, post-sheath removal after an angiogram, is limited. The radial artery is cared for on a near-daily basis by nurses, without much evidence-based practice to support the methods of compression being used. This pilot study supports the need for a large randomized control trial so this data can be expanded and generalized to a larger population. Taking into account the small sample size, statistically significant differences are seen in time to discharge in the fast-release Terumo and Clo-Sur P.A.D. groups, as compared with the control Terumo group, without statistically increasing vascular complications. Based on this pilot study and the clinical experience in this particular CATH lab and recovery room, a recommendation can be made to adopt the fast-release Terumo protocol as standard of practice and to consider the use of the Clo-Sur P.A.D. for transradial angiograms at this location.

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Appendix 1 – Randomization Table

Study ID	Compression Method
1	2
2	0
3	1
4	2
5	0
6	1
7	1
8	0
9	1
10	2
11	2
12	2
13	1
14	2
15	1
16	2
17	1
18	0
19	0
20	2
21	1
22	2
23	0
24	1
25	2
26	2
27	1
28	0
29	0
30	1
31	0
32	1
33	0
34	0
35	0
36	2
37	2
38	1
39	0
40	0
41	2
42	2
43	0
44	2

Study ID	Compression Method
45	2
46	1
47	2
48	0
49	1
50	0
51	2
52	1
53	0
54	2
55	2
56	0
57	0
58	1
59	1
60	0
61	0
62	0
63	2
64	1
65	1
66	0
67	1
68	2
69	0
70	1
71	2
72	2
73	1
74	1
75	1

0= Terumo Control Group
1= Terumo Study Group #1
2= Clo-Sur P.A.D. study Group #2