INCREASING PATIENT COMFORT DURING CARDIAC CATHETERIZATION OR ANGIOPLASTY:
A COMPARISON OF THE USE OF A COLLAGEN PLUG, MANUAL PRESSURE OR THE TRANSRADIAL APPROACH

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A clinical research project submitted in partial fulfillment of the requirements for the degree of MASTER OF NURSING

WASHINGTON STATE UNIVERSITY
Intercollegiate Center for Nursing Education
May 1999
Increasing Patient Comfort During Cardiac Catheterization or Angioplasty:

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or the Transradial Approach

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Acknowledgments

The nursing faculty of Washington State University-Vancouver and The Intercollegiate Center for Nursing Education-Spokane, and most especially the members of my committee, have made my journey into the field of nursing a most wonderful educational adventure. I extend my heartfelt gratitude to all.

There has been one individual, however, who without her unflagging encouragement and friendship, I would not be a master’s prepared nurse. That person is Dr. Renee Hoeksel, my committee chair, mentor and friend. When I was unsure, she offered guidance, when I was discouraged, she lavished praise, and when I needed a friend with a understanding ear, she was there to listen and console. I am now and shall ever be in her debt for prodding me, guiding me, and shaping me into the nurse and person I am today. She has my unfailing respect, admiration, and gratitude.

Finally, I must thank my husband, Al, and my children Clarice, A.J., and Katie. They have shared my joys and sorrows, my frustration and accomplishments, and my growth as a nurse, wife, and mother. They have been understanding, patient, and remarkably encouraging during some very difficult times these past few years. Thank you, my wonderful family, for your incredible patience, understanding, and tolerance. I don’t deserve you, but am eternally grateful I have you.
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Abstract  
In the United States alone, over 1,000,000 people per year enter the hospital for the purpose of having a cardiac catheterization or an angioplasty. Currently, the chosen approach for this procedure is to insert a sheath and catheter through the right femoral artery. Following the procedure, the patient, who has already been lying on their back for 1 to 3 hours, must continue to lie in a supine position waiting for the effects of anticoagulation to diminish and subsequent sheath removal. Following sheath removal, manual pressure is applied for 30 to 60 minutes in order to achieve hemostasis at the insertion site. The patient must then remain in a supine position for as long as 24 hours to ensure adequate sealing of the femoral artery puncture. During this time patients suffer groin pain, back pain, and many of the associated problems that come with immobilization. This paper is a review of the literature regarding a new device and a new approach that can, ultimately, serve to shorten the time of immobilization. The Angio-Seal™ is a bioabsorbable collagen device designed to seal the femoral artery puncture site. It is designed to create rapid hemostasis. Rapid hemostasis may lead to early ambulation and less discomfort suffered by the patient. The new approach reviewed is through the radial artery. Both of these new technologies may serve to lessen patient discomfort and the effects of immobilization.
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Introduction

In 1977, cardiologists around the world witnessed the advent of a new diagnostic
procedure and treatment called respectively, cardiac catheterization (CC) and
percutaneous transluminal coronary angioplasty (PTCA). Prior to 1977 the only treatment
for patients with severe coronary artery disease was intensive drug therapy and coronary
artery bypass and grafting (CABG) surgery (Markakis, 1990). Since that time, patients
requiring PTCA and/or CC worldwide, number in the millions on a yearly basis. In the
United States alone more than 958,000 CCs (Simon, 1994) and over 500,000 PTCA
procedures (Juran, Smith, Rouse, DeLuca and Rund, 1996) are performed annually.
Locally, at the Southwest Washington Medical Center (SWMC), 483 CCs and PTCAs
combined were performed in the fiscal year 1996-1997 (Nuala Farrington, personal
communication, February 27, 1998). These numbers, both nationwide and locally,
represent a large patient population and consequently, this population significantly impacts
both the medical and financial aspects of the health care industry.

Throughout the United States generally, and in our community specifically,
patients receiving either a CC and/or a PTCA enter the hospital as an inpatient. There are
some free standing clinics in the United States that perform ambulatory cardiac
catheterization and angioplasties, but these are not currently approved by The American
College of Cardiology and The American Heart Association (American Heart Association,
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1997). In order to fully understand the impact of new products and new techniques related to these procedures, it’s important to view these procedures from the perspectives of those individuals and organizations who are directly impacted by their performance.

The scope of this paper is not to educate the reader as to the specifics of the CC and PTCA procedures, but rather how certain procedural components impact the major participants. The major participants are considered to be the patient, the nurses involved in the care of the patient, the primary care provider, and the administration of the hospital where the procedure is performed. The procedural components to be discussed are pertinent that they not only effect the outcome of cardiac function, but also, concurrently effect the outcome of patient comfort. Those procedural components are the chosen site of sheath/catheter insertion and the chosen means of providing arterial hemostasis upon sheath removal. First will be a discussion of how these two choices impact the primary participants, beginning with the patient.

The Problem and Who is Effected

The Patient

A patient entering the hospital for the purpose of having a diagnostic CC has most likely already been one of the 57,490,000 Americans diagnosed with having one or more forms of cardiovascular disease (American Heart Association, 1997). The CC procedure is used as a diagnostic tool to discover the origin of cardiac symptoms from which the patient may be suffering. If, during that procedure a stenosed vessel is discovered, an angioplasty may also be performed. Although individual hospitals may vary some parts of their CC and PTCA procedures, overall the procedures remain the same. More than
ninety percent of the time, the chosen site for insertion of the sheath and catheter is the right femoral artery (Juran et al., 1996). This artery is large and provides an avenue for the insertion of introducer sheaths from size 6F (French) up to 11F. During the procedure, and in many institutions, after the procedure is completed, heparin is administered to provide anticoagulation (Juran et al., 1996). These two factors combined lead to the difficulty encountered in attempting to perform the second aspect of this discussion and that is the hemostasis of the arterial puncture.

By the time the procedure is completed, which can be anywhere from 1 to 3 hours depending on the amount of complications and whether or not stent implantation was necessary (Sukin, Baim, Caputo, Ho, Laham, Flatley, Carrozza & Cohen, 1997), the patient has been lying on their back and suffering not only cardiac discomfort, but also musculoskeletal discomfort. However, the time this patient must spend in a supine position is just beginning. In order to achieve optimal hemostasis after the procedure, bed rest and leg immobilization has been, and continues to be, the traditional method of care (Pooler-Lunse, Barkman, & Bock, 1996).

A review of the literature demonstrates the number of hours utilized by primary providers for hemostasis is fairly arbitrary and ranges anywhere from 3 to 12 hours and longer. The patient may have a shorter time in bed if the only procedure performed was a CC whereas with a PTCA with or without the insertion of a stent, the time in bed may easily be greater than 24 hours (Fowlow, Price & Fung, 1995). During this extended immobilization period patients become extremely uncomfortable reporting back pain as the major discomfort (Coyne, Baier, Perra & Sherer, 1994). Other complaints made on a
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frequent basis are leg and groin pain, inability to eat and drink, nausea due to impaired gastric motility, and the inability to void and defecate (Keeling, Taylor, Nordt, Powers, & Fisher, 1996). It’s not uncommon for CC and PTCA patients to receive high doses of narcotics in attempts to alleviate the excruciating back pain. This leads to further difficulty with urination and constipation which then leads to urinary catheterization and the administration of laxatives (Keeling, Knight, Taylor & Nordt, 1994). Along with all the physical manifestations of this forced immobilization, patients often become frustrated, bored, depressed and angry which can lead to noncompliance of the enforced therapeutic measures. Cardiac nurses have many anecdotal stories about patients pulling arterial lines following a PTCA just so they could stand for a few minutes. It’s clear the best solution to prevent patient discomfort related to these very necessary cardiac procedures is early mobilization.

The Nurse

Early mobilization is not only the best solution for the patient, but the best solution for the nursing staff as well. The policies and care protocols may be established by well meaning and learned medical personnel, but it’s the nurse assigned to care for that post-PTCA patient who has to enforce those policies. Of course the first concern of the primary care nurse is the continuation of optimal cardiac function. Nurses continually monitor vital signs to be on the alert for hypotension, hypertension, and cardiac dysrhythmias. Continuous monitoring of the arterial line is of utmost importance in assuring continued vascular patency. Nurses perform frequent groin checks looking for bleeding from the insertion site and for the formation of hematomas. Circulation checks
are performed regularly on the foot and leg on the affected side being alert for distal ischemia (Markakis, 1990). Complications following CC and PTCA are not uncommon and many research studies describe these complications, but with varying reports of occurrence. Koch, et al. (1997) report the incidence of access site complications to be as high as 18% (Koch, Piek, de Winter, Mulder, David & Lie, 1997) whereas Kussmaul, et al. (1996) state these complications can range anywhere from 3% to 40% (Kussmaul, Buchbinder, Whitlow, Aker, Heuser, King, Kent, Leon, Kolansky & Sandza, 1996).

Along with this vigilant cardiac monitoring, nurses also monitor for patient comfort. Needless to say, with the amount of forced immobilization involved with these procedures, a great deal of nursing time is spent in trying to make patients comfortable. Providing comfort measures for a patient who has undergone a CC and has had the sheath removed in the cath lab is difficult. Providing comfort measures for a patient who returns to the floor with the sheath still in place is an even greater challenge. Not only must this patient remain immobile for a greater length of time, but must also suffer the removal of the sheath.

Nurses are responsible for determining the optimal time for sheath removal by monitoring activated coagulation time (ACT) or partial thromboplastin time (PTT) through regular blood draws. Once that time is determined, the nurse is responsible for educating the patient as to the upcoming removal procedure, providing pre-medication, performing the removal of the sheath, and monitoring the status of the patient throughout the process. The literature regarding safe and comfortable sheath removal is quite extensive. Topics range from who should be removing the sheath (Peet, McGrath, Brun...
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& Hilton, 1995) to whether or not lidocaine should be used in conjunction with the removal process (Bowden & Worrey, 1995). Further literature regarding sheath removal and obtaining hemostasis is discussed extensively later in this document, however, whomever removes the sheath, and by whatever means, using the current methodology requires from one to two hours of primary care nursing time. During this time frame, the nurse removing the sheath is unavailable to provide care for additional patients. Care of those patients must be assumed by fellow nurses who also have a full patient load, or care must simply be delayed until the nurse is once again available. This problem affects all participants in the CC and PTCA procedure and other patients as well.

A review of the literature also reveals a general feeling of frustration on the part of nursing in attempting to find solutions to the continued discomfort expressed by patients. Studies have ranged from attempting to modify patient position by changing the degrees of elevation of the head of the bed (Coyne et al., 1994) to log rolling patients gently from side to side with pillows provided for support (Pooler-Lunse et al., 1996) to simply decreasing the length of time a patient needs to spend in bed to achieve hemostasis (Fowlow et al., 1995). The general consensus of all the studies, however, is that decreased time in bed and early ambulation is the solution to patient discomfort.

The Primary Care Provider

The lack of comfort on the part of the patient following a CC and/or a PTCA is not only a problem for the patient and the nurse, but also for the primary care provider (PCP). Of course the main concern for the PCP is to return the patient to optimal cardiac function while also obtaining diagnostic information through the CC process. Patients often
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require pharmacologic and other comfort measures during the angioplasty procedure (Hall-Garcia Cardiology Associates, 1997), but concern for comfort cannot and does not stop there. The PCP sees the patient through the initial recovery period in the cath lab, but must then provide orders for the nursing staff that will allow for adequate pain relief when the patient returns to the floor. Further orders and problem solving must occur when the patient develops difficulty eating and drinking with subsequent nausea and vomiting. The PCP must be available to provide further orders regarding elimination problems and other concerns the patient may have with inability to tolerate immobilization.

If the patient returns to the floor with the introducer sheath still in the access artery, the PCP may be the person responsible for the removal of that sheath. In a survey conducted by Barbiere (1995), 91% of sheaths were removed by nurses after CC and 83% of sheaths were removed by nurses following PTCA (Barbiere, 1995), but as Peet, et al. (1995) reported in a study conducted in Canada, 76.7% of the reporting hospitals stated that interns, residents, and cardiologists were the individuals responsible for sheath removal (Peet et al., 1995). Regardless of who is responsible for the removal of sheaths, this can be a very uncomfortable procedure for the patient and measures should and must be taken to decrease that discomfort. It's also important to note that following sheath removal the patient is still required to maintain bed rest in order to obtain hemostasis of the puncture site. Regardless of who removes the sheath, comfort measures must continue, for the patient still has an extended period of immobilization to follow.

The Hospital Administration

The extended period of care involved in CC and PTCA procedures is also a
problem for hospital administration. They may not be directly concerned with alleviating patient discomfort, but they are concerned with the nursing hours needed to provide direct care and other hospital costs incurred associated with these procedures. Cohen, et al. (1995) reported the average total cost of a PTCA without stenting in 1993 as $7,505.00 and with stenting as $9,738.00. In breaking down the cost, the bill for the cath lab alone was $3,643.00 for the PTCA without stenting and $4,705.00 with stenting, while the expenditures for the room and nursing were the second highest at $1,512.00 for the PTCA without stenting and $2,232.00 with stenting. These costs were based on a length of stay in days of 3.5 and 5.5 respectively (Cohen, Krumholz, Sukin, Ho, Siegrist, Cleman, Heuser, Brinker, Moses, Savage, Detre, Leon, & Baim, 1995).

Total hospital charges for CC and PTCA locally at SWMC in Vancouver are considerably higher with the average charge for a CC totaling $9,382.61 and the average charge for a PTCA being billed at $16,720.52 (Nuala Farrington, personal communication, February 27, 1998). These are charges to the consumer, but with managed care and capitation, there can be no doubt that hospitals would very much like to reduce their overall operating costs while maintaining current hospitalization charges. If time in cath lab can be minimized, nursing hours required for patient care reduced, and overall length of stay for the patient shortened, hospital costs would definitely be decreased. This would seem to be a highly desirable scenario for members of hospital administration.

Summary of the Problem

To achieve the desired outcomes for all participants is the driving force behind the search for the solution to these stated problems. To reiterate those problems, I will restate
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them in the form of questions. For the patient, how can optimal cardiac and vascular function be achieved and maintained while increasing patient comfort and decreasing length of stay? For the nursing staff, how can time at the bedside providing direct patient care to CC and PTCA patients be reduced and still achieve maximal patient outcomes? For the PCP, how can CC and PTCA with or without stenting be performed to achieve the desired diagnostic and therapeutic results while decreasing patient discomfort and the negative effects of immobilization? For the hospital administration, how can time for procedures in the cath lab be lessened, nursing hours required for direct patient care be decreased, length of stay for the patient shortened, and the cost/benefit ratio be improved without compromising positive patient outcomes?

These are provocative and dynamic questions, but questions that may be answered with some modifications made in cath lab procedures and products. The majority of patient discomfort is due to extended immobilization. A review of the literature reveals a general consensus that the reason for the lengthy bed rest is to ensure hemostasis of the femoral artery puncture access site (Keeling, Taylor, Nordt, & Powers 1996). It stands to reason then, that if hemostasis could be achieved in a relatively short amount of time, the length of time patients would have to be immobilized with the affected leg extended could be greatly reduced. Furthermore, if CC and PTCA with or without stenting, could be performed through an artery that wouldn’t be compromised by ambulation, the patient could be allowed limited ambulation while hemostasis is taking place. Currently there is a device that has been extensively tested in Europe and is currently undergoing further research and testing in the United States which reportedly allows for rapid hemostasis
Increasing patient comfort without the extensive application of manual or device pressure that is now widely used. If this new device should prove to perform as well as the manufacturers report, this could go a long way toward answering the needs of those attempting to increase patient comfort. Further, a change in procedure regarding the access site may be the answer. Even though the radial artery approach to CC and PTCA was introduced many years ago, it was not widely accepted due to the small size of the artery and the relatively large size of the instruments used to perform the procedure. However, with the advent of smaller instrumentation, this approach is coming back into use. Using this approach could also provide an opportunity for early ambulation. A closer examination of this new product and fresh look at an older procedure is in order.

**Literature Review**

**Manual Pressure and Device Pressure**

As recently as 1992 O’Brien and Recker instructed nurses on the correct method of removing the arterial sheath from the femoral artery following a PTCA. Their instruction included the use of firm manual pressure directly above the puncture site. This pressure was to be held for 20 minutes, gradually released to assess for bleeding and to be renewed for another 20 minutes if bleeding occurred. This pattern was to continue until hemostasis was achieved or until the doctor arrived. Following hemostasis, a pressure dressing of gauze and tape was to be applied along with a 5 to 10 lb. sandbag (O’Brien & Recker, 1992). Actually, not much has changed since then. Many nurses still prefer to use manual pressure even though other devices for applying pressure have been developed. In 1994, Simon researched the efficacy of using a mechanical clamp
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(ClampEase: Freund Medical Products, Dayton, Ohio) versus manual pressure to obtain hemostasis. Research results noted little significant difference in using the mechanical clamp or manual digital pressure. Further, with the use of the clamp, nurses were free to perform more frequent and detailed assessments and were able to intervene immediately if any difficulty occurred (Simon, 1994). In 1995, Barbiere reported on the use of the FemoStop™ for control of bleeding following procedures requiring femoral puncture (Barbiere, 1995). The device operates differently than the ClampEase, but both devices still require the use of pressure for at least 20 minutes. And finally, in 1997, Rudisill, Williams, Craig and Schoop reported on yet two more mechanical compression devices, the Clampase® and the Compressar®. Again, these devices were compared to the use of manual pressure and again, there were no significant differences of groin complications. The only variant in recommendations to come from this study was that compression time for sheath removal should be between 40 and 80 minutes (Rudisill, Williams, Craig & Schoop, 1997).

In reviewing the literature regarding methods of providing sheath removal and femoral artery hemostasis, it’s clear there has been little advancement in reducing the time and effort needed to achieve positive hemostatic results. Moreover, little advancement has been made in decreasing patient discomfort and immobilization time. Those statements, however, may not hold true if the new hemostatic puncture closure device, the Angio-Seal™ is included in the discussion.

The Angio-Seal™ Device

The Angio-Seal™ (AS) is a hemostatic puncture closure device that was developed
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by the Kensey Nash Corporation. It is currently marketed in the United States by Quinton Instrument Company of Bothell, Washington, and in other countries by Sherwood Medical Company of St. Louis, Missouri (Lowrie, 1995). The device was created specifically to be used as a vascular closure device following CC and PTCA (Kussmaul, Buchbinder, Whitlow, Aker, Heuser, King, Kent, Leon, Kolansky, & Sandza, 1995). It is a bioabsorbable device used to seal the femoral artery access puncture site. It is designed to provide a quick seal at the site and create rapid hemostasis (Lowrie, 1995).

The device consists of several parts, but is marketed as one unit. The AS device is deployed at the conclusion of the CC or PTCA procedure. When the procedure is completed, the sheath used for introducing the catheter is exchanged for an 8F sheath that is designed to fit with the other portions of the AS system. The device carrier is then inserted into the sheath and into the artery. When the anchor at the end of the device carrier is exposed to the arterial flow, it turns perpendicular to the sheath. The sheath and carrier are then gently retracted from the site and the anchor is pulled up flat against the inner arterial wall and covers the puncture site. As the sheath and carrier are further retracted, a collagen plug is deposited on the outer wall of the artery, also covering the puncture site. The arterial puncture site is now essentially sandwiched between the bioabsorbable anchor on the inner wall and the collagen deposition on the outer wall. The sheath and carrier device are then completely removed, leaving behind a long suture that is exposed through a plastic tube. The plastic tube is now used as a tamping device against the collagen plug. This tamping assures the collagen is well seated against the arterial wall. A spring device is then attached to the suture line, applying tension to the suture.
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This is left in place for 15 to 30 minutes and then the suture line is cut to below skin level. Finally, a light occlusive dressing is applied. The entire deployment procedure is designed to take place in less than one minute (Kussmaul et al., 1995).

Clinical Trials

Although this device was designed in the United States, some of the first clinical trials were performed in Europe. One of the first was in the Academic Hospital Maastricht in the Netherlands. In 1993 de Swart et al. used the AS, which at that time had not been given a name and was simply referred to as the new hemostatic puncture closure device (HPCD), to perform a study on a small group of patients. The study enlisted 20 participants of which 13 were men and 7 were women with a mean age of 55. Only four of the patients had just a CC, whereas 16 of the patients had PTCA. The patients having just the CC were given weight based heparin at 100 U/Kg of body weight and the patients having the PTCA were given 10,000 U of heparin after the introduction of the sheath and another 5,000 U of heparin and 150 mg of aspirin toward the end of the procedure. Consequently, all participants were well anticoagulated. Prior to the deployment of the HPCD, a PTT was determined and the mean PTT was 297 seconds (normal 24-34 seconds); however, none of the patients had their heparin reversed. In 19 of the patients, the device deployed without difficulty. In one patient, the suture broke. This didn’t affect deployment, but it did inhibit the placement of the spring on the tamping tube. A pressure dressing was applied on this patient as a precautionary device. The mean time to hemostasis for all 20 patients was 1.2 minutes. None of the patients had any clinically significant complications and only six of the patients had slight bruising at the site.
Duplex ultrasound was performed on all the patients at 1 week, 1 month, and 3 month intervals. At the 3 month check, 5 patients were found to have blood flow patterns that were not completely normal, but they were found to be clinically insignificant as their peak flow velocity was normal. In this initial study patients were not mobilized any earlier than 6 hours because that had been the norm for this procedure in this particular hospital. None of the patients had any difficulty with ambulation. No oozing and no hematoma formation occurred (de Swart, Dijkman, Hofstra, Bar, VanOmmen, Tordoir & Wellens, 1993). Suggestions for slight changes were made to the company manufacturing the device, but generally speaking the physicians conducting the study seemed well pleased with the results.

Following the introduction of the device in Europe and subsequently making some changes to the device (Elizabeth Galie, personal communication, February 27, 1998), a clinical trial was performed in the United States. Other European trials were also performed concurrently. To discuss these trials individually would be too cumbersome and is not warranted for this forum. Rather, the studies will be discussed in comparison with each other. In this way certain areas of the studies can be reviewed and results can be more meaningfully interpreted. It must be noted that each study was conducted from a differing point of view. One study simply reported on the testing of the AS device, whereas others studied its use in CC and PTCA alone, and together. Although the approaches to the studies were different, the items reported on from the results of the studies are fairly comparable, i.e., time to hemostasis, numbers of complications, and time to ambulation. The four studies considered for analysis were reported in various journals.
between 1995 and 1997. Two of the studies were performed in the United States and the other two were performed in France and Germany. The two studies in the United States were performed by the same group of researchers in subsequent years. There have been more trials and studies in the United States, however, the only reports of those studies currently are in a report of the Symposium of Transcatheter Cardiovascular Therapeutics in October of 1997. These studies will be touched upon briefly toward the end of the full study analysis.

Study Design

All studies used an experimental design, although not all had a control group concurrent with their research. In some cases the control group was understood to be those patients who had manual pressure used to achieve hemostasis prior to the research study. Further, all studies used a convenience sample and when a control group was used, randomization to groups was also employed.

Comparison of Studies

The Angio-Seal™ Device

Hemostasis

Henry, Amor, Allaoui, and Trioche (1995) were among some of the first to report on the usage of the AS. A good deal of their reporting is taken up in a description of the device, however, they did report using the device not only for cardiac procedures, but also peripheral angioplasty, even though this was not recommended by the manufacturer. Their study included 80 participants who received PTCA, CC, and peripheral angioplasty. This study was performed without a control group. There were no exclusionary diagnoses
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They reported immediate hemostasis in 78 of the cases, however, the time frame constituting immediate was not stated. The only device-related complication noted was deployment failure in 2 instances. In a multicenter trial reported by Kussmaul, et al. (1995) 435 patients were included in a randomized trial of the AS. Of the 435 participants, 218 patients (group I) received the AS device and 217 (group II) received manual pressure to achieve hemostasis. The determination of achieving bleeding cessation was most often broken into three categories; hemostasis, oozing, or brisk bleeding. The patients in group I achieved hemostasis much faster than those in group II. Seventy-six percent of group I achieved hemostasis in less than one minute and all patients (100%) in group I achieved hemostasis within ten minutes. In Group II, only 25% had achieved hemostasis at the five minute mark and total hemostasis was not achieved for all members until 50 minutes. Additionally, the members of group I had, overall, received a greater amount of anticoagulants throughout the procedures. There were eight deployment failures in group I in the early part of the study.

Following these failures, a new device, with modifications made to the anchor and collagen releasing device, was used. After this change was made only one deployment failure was reported which was a breakage of the intravascular anchor (Kussmaul et al., 1995). In a subsequent study performed by Kussmaul, et al. in 1996, 68 patients receiving PTCA and rotational atherectomy procedures were included in an experimental study without a stated control group. In this sample, complete hemostasis was achieved in an average of 4.4 minutes on all participants. The device did not deploy in 5 cases. In all 5 cases manual pressure was applied and hemostasis was achieved without further
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complication or sequelae (Kussmaul, et al., 1996). Silber, Dorr, Muhling and Konig (1997) from Germany reported on a study using 140 patients. In their study, they focused on attempting two different deployment times. They either left the spring in place for 5 minutes (group I) or for 30 minutes (group II). Seventy patients were assigned, randomly, to each group. At the end of five minutes 74% of the patients in group I had achieved complete hemostasis, whereas 26% of this group had slight oozing. No members of this group were bleeding briskly at the end of five minutes. In group II, at the end of thirty minutes, 71% of the patients demonstrated no bleeding, whereas 29% had slight oozing. Again, none had brisk bleeding. There were no reports of deployment failures in this study. In reviewing the results of time to hemostasis in these limited studies, it seems clear the AS device does produce hemostasis more quickly than that produced by manual pressure.

Complications

As a whole, the complications addressed in the studies were excessive bleeding, hematoma formation, loss of the ability to detect a pulse, ischemia, aneurysm formation, thrombus formation, fistula formation and non-deployment. Henry et al. (1995) noted that non-deployment had occurred in 3 instances, but didn’t consider this a complication, but rather an “annoyance for the user” as manual pressure was able to resolve the situation. No other complications were cited in this study (Henry et al., 1995). Kussmaul et al. (1995) noted out of 218 patients (group I) receiving the AS device, only 27 suffered notable complications. Fifteen of the patients suffered some late bleeding greater than 30 minutes after initial hemostasis was achieved. This bleeding may or may not have been
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significant in nature as the research report doesn't provide that information. In the manual pressure group bleeding of the same nature occurred in 33 of the 217 participants (group II). Hematomas that were palpable were noted to have occurred in 5 patients in group I and in 12 patients in group II. Vascular complications which were considered to be the formation of pseudoaneurysm or arteriovenous fistula formation had an incidence of 7 in group I and 5 in group II. This difference was not considered significant. Ischemia, infection, or loss of pulse did not occur to any participant in either group in this study.

Overall, group I had a complication rate of 12% and group II a rate of 18%. The 6 percentage points of difference may not seem significant, however these percentage points do represent 13 individuals. This is only significant when considering the fact that the 8 non-deployments which occurred in group I were not considered as complications (Kussmaul et al., 1995). If these were added to the number of complications in group I, the numbers of complications in both groups would be more equivalent.

In the 1996 study conducted by Kussmaul et al., there were 11 (16%) complications out of 68 participants. Significant bleeding occurred in nine participants. Primary bleeding at the time of device deployment occurred in six of the nine patients and the other three suffered delayed bleeding when the tamper was removed or when they ambulated for the first time. The other two participants who had complications had hematoma formation of an unstated size. Again, the 5 non-deployments in this study were not considered complications (Kussmaul et al., 1996). If these were to be added to the 11 that were considered, this would change the number of complications to 16 (23.5%), which is actually a considerable increase. Silber et al. (1997) described complications as
either major or minor. Major complications were considered to be thrombus formation, loss of peripheral pulses, pseudoaneurysm formation, fistula formation, and bleeding which required transfusion or vascular surgery. Minor complications were considered to be bleeding from the puncture site which did not need transfusion or vascular surgery. There were neither major or minor complications reported. Each group did report, however bruising at the site the day after the procedure. Group I, which was the group who had the tamper spring removed after five minutes, reported ecchymosis of 6.2 cm$^2$. Group II, who had the tamper spring removed after 30 minutes, reported ecchymosis of 6.8 cm$^2$ (Silber et al., 1997). These figures did not indicate a significant difference. Silber et al. (1997) also followed up with the participants two weeks after they were initially studied. Ninety-six percent of those who participated responded to the contact at the two week mark and none indicated any further bleeding or complication (Silber et al., 1997).

Although the non-deployment numbers are low in comparison to the overall number of participants in most studies, this issue must be of concern due to the possible embolization of the device within the vascular system. However, even though non-deployment complications are not calculated with other vascular and circulatory complications in the literature reviewed, the incidence of complications with the use of the AS device does not seem to be greatly significant. In fact, the number of overall complications with the AS device, even with the non-deployment complications included, is fewer than with the application of manual compression. It is important to note that sheath size proved to be an important factor in the rate of complications in the multicenter study conducted by Kussmaul et al. (1995). The patients receiving the AS device (group
I) all had an 8F device used with the rate of complications at 27 (12%). Those patients receiving manual pressure to control hemostasis (group II) had sheaths of 6F, 7F, and 8F used. Forty eight of the patients in group II had a 6F sheath used with a complication rate of 5 (6%), while the 7F and 8F rates were 14 (25%) and 20 (20%) respectively (Kussmaul et al., 1995). Although these rates are generated by only one study, the results would indicate this as a practice issue which would warrant further research.

Time to hemostasis and the rate and kinds of complications encountered, both have considerable bearing on patient immobilization and comfort level. Unfortunately, none of the research studies reviewed addressed early ambulation as a desirable outcome related to the use of the AS device. However, Silber et al. (1997) and Kussmaul et al. (1995;1996) all cited early ambulation as a very possible outcome of the use of the AS device and suggested further studies relating to that aspect of its use (Silber et al., 1997; Kussmaul et al., 1995,1996). Further studies must also be developed to investigate the use of the AS in a more varied population. Kussmaul et al. (1995) excluded patients who had been on warfarin therapy, thrombolytic therapy within 24 hours of catheterization, acute myocardial infarction, uncontrolled hypertension and obesity (Kussmaul et al., 1995). In the 1996 study, Kussmaul et al. again excluded those with hypertension, an acute myocardial infarction, and obesity along with those who had marked peripheral vascular disease and age greater than 80 years (Kussmaul et al., 1996). Silber et al. (1997) disqualified patients with previous myocardial infarctions, severe hypertension, and those on coagulation therapy. Further, patients were not excluded due to obesity or age and yet none of the patients in the study was greater than 76 years of age or weighed more
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than 113 kg (Silber et al., 1997). Excluding patients from these studies because of their high risk factors is understandable, but it makes the results somewhat less generalizable to the population of individuals who would be the most likely candidates for CC and PTCA procedures and subsequent use of the AS device. Many of the exclusionary diagnoses are typical of those with cardiovascular disease and consequently these individuals need to be included in the populations of further studies. Further research also needs to be conducted regarding the decrease in hospital length of stay and possible cost savings due to the use of the AS device. In the literature, both of these items are alluded to, but neither are specifically addressed. It stands to reason that if hemostasis can be achieved immediately and ambulation started within one to two hours following the procedure without clinical complications, then patient length of stay and costs should both be reduced. This has yet to be demonstrated, however. For a brief comparison of the above studies, see Table I.

Comparison of Studies

The Radial Arm Approach

As exciting as the new AS device may prove to be, further research and testing is necessary to see if it will really help increase patient comfort through early ambulation. In the meantime, another approach to CC and PTCA with or without stent placement may not be through the femoral artery at all, but rather through the radial artery. Once again, the early studies regarding this approach come from Europe. Studies from the Netherlands, France and Switzerland have addressed not only the radial artery approach, but using that approach with PTCA alone, PTCA with stent placement using the left radial artery, and a new radial artery compression device.
Some basic differences between the femoral approach and the radial approach to CC and PTCA need to be stated prior to the discussion of the literature. The radial artery approach requires preliminary examination of circulation to the affected hand. The examination is performed using the Allen test. Briefly, the Allen test requires the examiner, using the thumbs of both hands, to occlude both the radial and ulnar arteries at the wrist of the patient. The patient is then asked to repeatedly clench and open the hand causing exsanguination and a blanched appearance. Then pressure to the artery which will not be cannulated is released. Blood and normal color should return to the hand within 10 seconds (Ewald & McKenzie, 1995). If blood does not return to the hand within the specified amount of time, another approach is considered.

Another universal difference noted in the literature is the size of the equipment used to perform the cardiac procedures. When using the femoral approach, the 8F and 9F sheaths and catheters are commonly used. When using the radial arm approach, sheath and catheter size must be reduced to 4F, 5F, or 6F. This reduction is due to the size of the radial artery in comparison with the femoral artery. Using these smaller catheters at the radial artery site also necessitates acquiring further equipment that current cath labs may not have on hand. This specialized equipment involves a fairly extensive assortment of catheters and guide wires. These are necessary because occasionally some special manipulation is necessary to cause the catheters to make the twists and turns required within the coronary vasculature and some catheters turn certain ways better than others (Kiemeneij, Laarman & de Melker, 1995).

Kiemeneij, Laarman, and de Melker (1995) produced one of the most recent
clinical investigations regarding the radial arm approach to PTCA. Between August of 1992 and April of 1993, out of 660 patients who presented for PTCA, 100 were selected for the transradial approach. The authors state in the early part of the trial, they selected only highly suitable candidates, but as the trial went into the later stages and the practitioners became more familiar with the approach, they selected individuals with multivessel problems, complex problems, and those with stenosed venous grafts from previous CABG surgery. Exclusionary criteria were patients who were hemodynamically unstable and who might be expected to deteriorate during balloon inflation, those who may need intraaortic balloon pumping, and those who had chronic total occlusions of the affected coronary vessel. The 100 participants who were selected to receive the radial arm approach did not have their assessment for suitability completed until they arrived at the cath lab for the procedure (Kiemeneij, Laarman & de Melker, 1995). In a subsequent study performed by Kiemeneij and Laarman (1995) while determining the feasibility of implanting stents via the radial route, excluded patients were those who were lacking collateral circulation in the hand on the affected arm. In fact, investigators purposely included patients who had less than favorable results with previous radial arm PTCA. This study of 100 participants also lacked a control group (Kiemeneij and Laarman, 1995).

The approaches for these last two studies were from the right arm. However, the question as to the usability of the left arm when an angiogram is the only necessary intervention is the basis for a study performed on 415 patients in France in 1994 and 1995. Of 1,008 prospective patients, 593 were excluded. They were excluded if they had known Raynaud's disease, a Q-wave myocardial infarction within the previous week, or were left
handed. They were also excluded if it was thought they needed any interventional procedure such as right heart catheterization or PTCA (Spaulding, Lefever, Funck, Thebault, Chauveau, Hamda, Chalet, Monsegu, Tsocanakis, Py, Guillard, & Weber, 1996).

Chatelain, Arceo, Rombaut, Verin and Urban (1996) set out to determine the efficacy of the Radistop™ for hemostasis following CC and PTCA using the right radial artery approach. They included 159 patients in their study and excluded no one who had the right radial approach. Overall, patient selection seemed appropriate and exclusionary diagnoses reasonable. It’s interesting to note that when the same investigators were involved in consecutive studies, the criteria for exclusion from the studies became fewer and fewer. Some question may be raised as to the ethical nature of making a final decision regarding patient selection just prior to the start of the procedure in the cath lab. An assumption could be made that these patients were well informed regarding the procedure and the experimental conditions under which it was being performed prior to arriving in the cath lab.

A good portion of each research article reviewed regarding this procedure was taken up with technical descriptions of the procedure itself. These descriptions are beyond the scope of this document and not relevant to the discussion. The complications which occurred due to the procedure and how those complications effected patient outcome are, however, relevant.

Complications

Overall, the majority of the initial complications occurred when the radial artery
could not be punctured or cannulated. Out of 100 participants, Kiemeneij, Laarman, and de Melker (1995) could not puncture the radial artery in 3 patients and in 1 patient the guide wire could not be advanced. The 3 patients with puncture failure had subsequent success with the femoral artery approach. In the patient with guide wire difficulties, the brachial artery was used with successful results (Kiemeneij, Laarman, & de Melker, 1995). This provided a puncture and cannulation success rate of 96%. In the 1995 study conducted by Kiemeneij and Laarman involving stent implantation, they had successful puncture and cannulation in 98 (98%) of their 100 participants. Of the two failures, one was successfully treated via the femoral artery and the other via the brachial artery. Spaulding et al. (1996), who was using the left radial approach, seemed to have greater difficulty achieving initial puncture success. Of the 415 participants, there were 29 failed puncture attempts and 8 instances of inability to pass the guide wire. The puncture and cannulation success rate in this study was 91% (Spaulding et al., 1996).

Puncture and cannulation were not at issue in the Chatelain et al. (1996) study. Although there were some failures to gain initial access via the transradial route, the overall success rate of the three studies reviewed here is 95%. Even though no statistical evidence is provided, Kiemeneij, Laarman, and de Melker (1995) state this rate is commensurate with that for the femoral approach. Puncture and cannulation were not the only complications encountered. Complications of a more serious nature were reported by Kiemeneij, Laarman, and de Melker (1995). Some difficulty with guiding catheters was reported in relation to the kinking of the shaft following frequent manipulations and attempts to maneuver through tortuous coronary vessels. This caused radial artery
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vasospasm in one patient and an inability to pass the catheter past the subclavian in another. Both of these individuals had to have the procedure completed via the femoral artery. Although smaller diameter balloon catheters had to be used, this did not appear to present a problem in obtaining patency of coronary vessels following the procedure.

Ninety six patients had successful puncture and cannulation and two of those had to have their PTCA completed via the femoral route. This left 94 patients upon which to base actual PTCA success. Two of the 94 patients had lesions that could not be managed with the smaller size catheters used via the radial route. These two patients had subsequent attempts with larger sheaths and catheters via the femoral also without success. The remaining 92 participants all had varied levels of success. Some patients suffered some degree of dissection, but no greater percentage than would have been expected via the femoral route. The entire procedure lasted a mean 35 minutes with the longest procedure taking 120 minutes and the shortest lasting 17 minutes (Kiemeneij, Laarman, & de Melker, 1995).

Placing stents within the coronary vessels via the radial artery is a more involved procedure, but can, according to Kiemeneij and Laarman (1995), be done successfully. They do point out that the standard sheath-protected stent technique does not work from this approach. However, other complications related to size of the catheter and stent delivery system were overcome with some trial and error methodology. Upon occasion the catheters used to guide the stents into place did not have the strength to hold and guide the stents into place. This problem was corrected with an exchange of one catheter for another from a different manufacturer. Further, there were occasions when stents
were displaced proximal to the target lesion. These stents were then expanded using a balloon tipped catheter without any difficulty or residual clinical sequela. In one patient, a stenotic lesion in the left anterior descending coronary artery was so tight the balloon could not pass. A rotoblator was inserted and passed through the lesion several times with excellent success. The lesion became passable and a stent was successfully placed. In general, 96 patients, with 122 lesions, had 146 stents successfully implanted and angiography demonstrated all stents as being well deployed (Kiemeneij & Laarman, 1995).

Spaulding et al. (1996) reported fewer extremes of complications. They did report eight (2%) episodes of radial artery spasm, but stated the administration of isosorbide dinitrate through the catheter caused the spasm to resolve. Other difficulties encountered included problems maneuvering through some coronary vessels, however none were so difficult as to prevent success. The researchers rated their success rate at 95% (Spaulding et al., 1996).

Clinical success with average types and numbers of complications seems to be the results achieved in these three studies. But how easily were these patients able to achieve hemostasis and how did they rate their level of comfort? These are important questions for this discussion. Unfortunately, the answers aren’t readily available from these studies. Spaulding et al. (1996) didn’t directly address the comfort of the patient, but he did state that all patients whose procedure resulted in success were ambulated immediately. He went on to state that 113 (30%) were also discharged from the hospital the same day.

Patient comfort was addressed by Chatelain et al. (1996) but in specific relation to the use of the Radistop™ device. Briefly, the device is similar to a wrist splint that is closed with
velcro. It provides a base that allows for the application of a compression pad. The amount of pressure applied to the pad can be adjusted with the device. The device was left in place with pressure applied for 30 to 60 minutes in group I (103 patients) who were only having a CC and up to four hours in group II (56 patients) who had a PTCA. The average time to hemostasis was 151 min with the greater amount of time being necessary in group II. In group I, 12 patients complained of painful discomfort due to the device and in group II that number was 14. Even so, the device was not removed and the amount of pressure applied was not changed. There were 23 complications reported including paresthesia in the right thumb (1), absent radial pulse at discharge (7), recurrent bleeding two hours after device removal (1), and a small hematoma present at discharge (15).

Further, 60 patients in group I and 35 patients in group II were discharged the day of the procedure (Chatelain et al., 1996). For a brief comparison of the above studies see Table II

It's difficult to know whether the discomfort suffered by the patients in this study is equivalent to those who suffer discomfort with manual compression with the femoral artery approach. One could assume equivalency of this discomfort, but those with the femoral approach still suffer the back pain and the complications secondary to immobilization, which the individuals with the radial approach would not necessarily suffer. Unfortunately, it's difficult to know the patient outcomes related to comfort using the transradial approach as the research studies don't address this issue. Here then lies the beginnings of further research related to patient comfort when undergoing a CC or PTCA.
Summary and Future Research

It seems clear from the research reviewed, the AS device does improve the length of time needed to achieve hemostasis following the femoral approach to CC and PTCA with or without the use of stents. The literature also alludes to the fact that this device should lead to early ambulation and therefore an increase in patient comfort. Mention is also made of the greater possibility of early discharge and thus a decrease in hospital cost. Unfortunately, these outcomes have not been researched in relation to this device or procedure. Further research needs to be directed toward these outcomes.

The AS device in its current usage is only applied in the cath lab. However, in speaking with a representative of the Sherwood Davis and Geck Corporation, the marketers of the AS, I was informed that this device could also be applied at the bedside by nurses (Elizabeth Galie, R.N., personal communication, March 2, 1998). This would not only require a great deal of research to determine the feasibility, but if instituted, would have an enormous impact on nursing. I believe nurses would welcome this new challenge, but not without solid research providing the basis for not only the use of the device, but also its efficacy, expected complications, and positive patient outcomes.

The AS device is currently being used with 8F sheaths and catheters. Now in production is the manufacture of AS devices that could be used with smaller and larger equipment. Holly Herriety (personal communication, March 3, 1998), Director of Marketing for the Kensey Nash Corporation, reports that product development is currently underway to make the AS device exchangeable with 5F and 6F catheters for the smaller access sites and in 9F, 10F, and 11F sizes for the larger. It seems feasible the AS
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The AS device could be used in conjunction with the radial arm approach to CC and PTCA. Until research takes us to more technological advances, it seems the combination of the AS device and the radial arm approach would be the ideal marriage of current advanced knowledge. These patients would be afforded the best of both worlds; immediate hemostasis and immediate ambulation. This could not only afford excellent patient outcome, but could likely serve to greatly reduce hospital costs.

Although hospital costs are have not been a major part of this discussion, they certainly cannot be ignored. Further research and subsequent practice changes cannot and will not take place if a positive cost to benefit ratio cannot be demonstrated. If the AS device should prove to provide immediate hemostasis and early ambulation, but not effectively reduce length of stay or hospital costs, it’s very unlikely the hospital administration would furnish monies to obtain the device and train personnel in its use.

Cost of the AS device depends on the quantity ordered, but the estimated cost is approximately $165.00 to $205.00 per kit. This cost, along with training costs would have to be off-set by the savings manifested through not only decreased patient length of stay, but also in decreased nursing time. Currently at SWMC the nursing hours spent in direct patient care for a patient with a femoral arterial sheath in place number in the hundreds per month (Nuala Farrington, personal communication, February 27, 1998). If this time could be reduced, along with time spent providing care to alleviate discomfort, one could surmise that costs would certainly be reduced with the advent of the use of the AS device alone or along with the radial artery approach (see Table III). However, there will also be additional costs incurred when initiating these approaches. If both the new
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product, the AS, and the new procedure, the radial arm approach, were both going to be implemented, extra costs would definitely be incurred by material purchase and training. Determining the cost/benefit ratio is again subject matter for further research.

Although not yet available in the literature at the time this paper was written, at the October 1997 9th Annual Symposium on Transcatheter Cardiovascular Therapeutics, there were several poster presentations regarding the use of the AS device. Most of the presentations were with regards to the use of the device in CC and PTCA and its relation to early ambulation. Ward et al. (1997), using the femoral approach, compared the AS device with manual pressure, but also noted patients ambulated at 1.4 hours after sheath removal as compared with 6.6 hours for those receiving manual pressure (Ward, Silver, Casale, Raymond, Kussmaul & Simpfendorfer, 1997). Rodes et al. (1997) also looked at early ambulation in a study including 100 patients divided into two groups. Group I received the AS device and group II received manual pressure. The average ambulation time for those in group I was 2 hours and 20 minutes, whereas in group II the average time was 17 hours and 38 minutes (Rodes, Cote, Bilodeau, Doucet, Tanguay, Bertrand, Bourassa & Perault, 1997). One of the most interesting studies presented, reported using the AS device with patients who had also received stent placement. Currently, the sheath is left in place for an extended period of time following the stent procedure due to the excessive amount of anticoagulation needed. In this study, the sheath was removed immediately at the end of the procedure. The median hemostasis time for those patients was one minute. For those patients in the control group, with manual pressure and sheath removal at least four hours after the end of the procedure, time to hemostasis was a
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median 30 minutes. Time to ambulation for the AS device group was reported at a median of 4.3 hours while the control group median was 12.0 hours (Szego, Rothbaum, Wong, Krukoff, Knopf, Casale, & Jenkins, 1997). One of the presentations focused on cost. Eisenberg et al. (1997) attempted to look at the cost effectiveness of the device. The basic findings noted that each PTCA had an increased cost of an average of $131.00 with the use of the AS device, but a $119.00 savings in cost due to the reduction in required nursing hours. However, in this study, none of the patients were allowed to discharge the same day of the procedure due to hospital policy. Therefore, calculating savings related to early discharge was not possible (Eisenberg, Rodes, Cote, Bilodeau, Doucet, Perrault, & Tanguay, 1997). All of these studies present compelling and interesting findings. Hopefully, these findings will be published in a more complete form in the near future, allowing for greater review and assimilation of the findings.

Conclusion

The following questions then still need to be answered with subsequent research. Does the Angio-Seal, a hemostatic puncture closure device, allow for ambulation at one hour or maybe even 30 minutes following the CC or PTCA? Can this early ambulation include patients receiving stent placement? Further, does this immediate ambulation serve to decrease patient discomfort following these procedures and is optimal cardiac function maintained with the use of the AS device and immediate ambulation?

Further research needs to be conducted regarding the use of the radial arm approach in relation to the use of the AS device. The radial arm approach appears to be effective in providing early ambulation, but are the clinical cardiac results as optimal as
those achieved with the femoral approach? If the AS device provides early ambulation, decreases patient discomfort, reduces hospital costs, and provides optimal cardiac function with the femoral approach, is the use of the transradial approach necessary? A comparison trial of patients in a particular setting or the same multiple settings may answer that question.

The questions posed here are researchable, but not without the dedication of many. A great deal of time, money and commitment must be given by hospital administrators, cardiologists, nurses, hospital personnel and patients. Not only are the above necessary, but so is the desire to make health care delivery, research-based health care delivery. Research is the only real way we can be sure the care being provided and the education being supplied to our patients is truly the best it can be. Hopefully, the research questions being posed here in this discussion will be worthy of being answered by a dedicated group of health professionals who have the foresight to see the answers will provide an ability to improve future patient care.
### Table I
Results of Studies Using the Angio-Seal™ Device

<table>
<thead>
<tr>
<th>STUDY</th>
<th>N</th>
<th># receiving the AS Device</th>
<th>% of Deploymen t Success</th>
<th>Mean Min. to Hemostasis 1 for AS device Group</th>
<th>Mean Min. to Hemostasis for Control Group</th>
<th>% of Complications 2 (excluding device failure)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Henry (1995)</td>
<td>80</td>
<td>80</td>
<td>97.5 %</td>
<td>‘immediate’</td>
<td></td>
<td>none reported</td>
</tr>
<tr>
<td>Kussmaul (1995)</td>
<td>435</td>
<td>218</td>
<td>96.3 %</td>
<td>&lt;10 min.</td>
<td>≥ 50 min.</td>
<td>12.8 % device gr.</td>
</tr>
<tr>
<td>Kussmaul (1996)</td>
<td>68</td>
<td>68</td>
<td>92.6 %</td>
<td>4.4 min.</td>
<td></td>
<td>18 % control gr.</td>
</tr>
<tr>
<td>Silber (1997)</td>
<td>140</td>
<td>140</td>
<td>100 %</td>
<td>Gr. I &lt; 5 min. 74%</td>
<td></td>
<td>none reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gr. II &lt; 30 min. 71%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Hemostasis is complete cessation of bleeding from puncture site.
2. Minor complications are considered to be hematoma formation, ischemia, aneurysm formation, thrombus formation, fistula formation, and excessive bleeding.
Table II
Results of Studies
Using the Radial Arm Approach

<table>
<thead>
<tr>
<th>STUDY</th>
<th>N</th>
<th># receiving the radial arm approach for CC and PTCA</th>
<th># of puncture site failures</th>
<th>% of success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kiemeneij (1995)</td>
<td>660</td>
<td>100</td>
<td>4</td>
<td>96%</td>
</tr>
<tr>
<td>Kiemeneij &amp; Laarman (1995)</td>
<td>100</td>
<td>100</td>
<td>2</td>
<td>98%</td>
</tr>
<tr>
<td>Spaulding (1996)</td>
<td>1,008</td>
<td>415</td>
<td>37</td>
<td>91%</td>
</tr>
<tr>
<td>Chatelain (1996)</td>
<td>159</td>
<td>159</td>
<td>not reported</td>
<td>not reported</td>
</tr>
</tbody>
</table>

1 Puncture site failures were instances in which the radial artery could not be punctured or the catheter could not be advanced.

Table III
Projected Savings per annum in Room and Nursing Care
By reducing stay by 12 hours
Using the Angio-Seal™ Device

<table>
<thead>
<tr>
<th>PTCA’s per annum</th>
<th>Aver. Cost of Cath Lab.</th>
<th>Aver. Cost of room and nursing care for 3.5 day stay</th>
<th>Other costs</th>
<th>Total cost of PTCA</th>
<th>Cost of 12 hrs. of room and nursing care</th>
<th>Cost of AS device</th>
<th># of PTCA's per annum</th>
<th>Poss $ saved with 12 hr. in length of stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$3,643</td>
<td>$1,515</td>
<td>$2,350</td>
<td>$7,505</td>
<td>$216</td>
<td>$185</td>
<td>500,000</td>
<td>$15,500,000</td>
</tr>
<tr>
<td>SWMC 1</td>
<td>$8,100</td>
<td>$3,344</td>
<td>$5,276</td>
<td>$16,720</td>
<td>$477</td>
<td>$185</td>
<td>483</td>
<td>$141,036</td>
</tr>
</tbody>
</table>

1 Southwest Washington Medical Center, Vancouver, Washington.
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SEAL the puncture

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Precautions: The safety and effectiveness of the Angio-Seal device has not been established in the following patient populations:
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- Patients who have skin allergies to blood products, collagen and/or collagen pro-nk/s, or polyvinyl in polyacrylic acid polymers.
- Patients with known autoimmune diseases.
- Patients undergoing thrombotic therapy.
- Patients who have undergone a procedure either by a licensed physician or other health care professional authorized by, or under the direction of, a physician (or other health care professional authorized to operate in the use of the device, e.g., participation in an Angio-Seal physician instruction program or equivalent).

Use of a single-wall puncture technique. Do not puncture the lesion or the artery. If a patient has had a procedure that exerted a pressure on the artery or if the procedure sheath has not been fully withdrawn from the puncture site.

The Angio-Seal device is to be used only by a licensed physician on whom the physician has specifically been trained to perform the procedure. The procedure includes the following steps:
1. An operator who has been trained in the use of the Angio-Seal device or vascular access site management procedures.
2. An operator who has participated in an Angio-Seal physician instruction program or equivalent.

Use of the Angio-Seal device will result in a puncture of the artery.

Warnings: Use of the Angio-Seal device may result in the following conditions or reactions:
- Collagen may protrude from the skin after lamping has been completed, and lead to symptoms of distal arterial insufficiency.
- Bifurcation or being positioned incorrectly.
- Collagen deposits into collateral or embolism.

Contraindications: The Angio-Seal device is contraindicated in patients who have undergone an interventional procedure or who have had an interventional procedure within the past 14 days. The Angio-Seal device should not be used on the order of a physician.

Finally, the following potential adverse reactions or conditions may be associated with use of the Angio-Seal device or vascular access site management procedures:
- 1) Bleeding or hematoma
- 2) Pseudoaneurysm
- 3) Anastomosis
- 4) Device non-deployment
- 5) Infection
- 6) Anchor migration

Thrombosis at puncture site.
- In addition, experience in the clinical trials has demonstrated that:
  - Collagen may protrude from the skin after lamping has been completed, and lead to symptoms of distal arterial insufficiency.
  - Bifurcation or being positioned incorrectly.
  - Collagen deposits into collateral or embolism.

For complete information on warnings, precautions and adverse events, please refer to the Instructions for Use or call the Angio-Seal Information Service toll-free 1-888-864-7444.