Determining Best Nursing Practice: Effectiveness of Three Groin Compression Methods Following Cardiac Catheterization

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Abstract: Cardiac catheterization is an extremely valuable procedure in diagnosis and treatment. However, few changes have occurred in the techniques used for percutaneous arterial cannulation, and for attaining homeostasis after cardiac interventions. Risks associated with femoral sheath removal include inadequate hemostasis leads to vascular complications. This may be costly, increase hospital time, and increase patient discomfort. Moreover, the process of sheath removal and femoral artery compression can be distressful, and affect patient satisfaction. This study was aimed at comparing the effectiveness of three groin compression methods (manual, bandage, and compressor) on patient vascular complications including (hematoma, ecchymosis and oozing), pain, and patient satisfaction following cardiac catheterization. A randomized clinical trial was conducted in cardiac catheterization and coronary Care Unites at National Institute of Heart. It included a sample of 150 patients admitted for performing cardiac catheterization via femoral artery randomly assigned to 3 equal groups: manual compression, bandage, and compressor. The tools used for data collection included Demographic and Clinical Data Sheet, scales for Hematoma Formation, ecchymosis, oozing, pain intensity and patient satisfaction procedure scale. The study maneuvers were applied according to the group. Groin sites were inspected immediately, at 6 and 12 hours post hemostasis. At 6 hours post hemostasis (70.0%) of patients in the manual group hadn't hematoma formation compared to bandage and compressor groups (36.0% and 58.0% respectively) with statistically significant differences between the three groups. A statistically significant difference was revealed among the three groups at 12 hours post hemostasis, (P=0.001). It is evident that less patients in the manual group (6.0%) had large ecchymosis at 12 hours post hemostasis, compared to the compressor (20.0%) and bandage (24.0%) groups. Also at the same time, noticed that no one of patients in the three groups had severe oozing with no one of patients in the manual group had moderate oozing compared to compressor and bandage groups (2.0% and 12.0% respectively), and the difference was statistically significant, (P= 0.07). The bandage group had longer time for hemostasis (23.5±8.3 minutes) with more time of compression (144.9± 50.5 minutes) compared to the two other groups. The manual group had the lowest duration of bed rest (4.8±1.3 hours), and hospital stay (13.4±9.0 hours), compared to the other two groups, and the differences were statistically significant, (p<0.001). Additionally, manual group had the lowest scores of pain at all three assessment times (5, 10 and 20 minutes), whereas those in the compressor group had the highest scores. Overall, (80.0%) of the patients in the manual group were satisfied, compared to only (38.0%) in the compressor group, and (28.0%) in the bandage group. It is concluded that manual compression method after sheath removal in cardiac catheterization patients is associated with lower times of hemostasis and compression. It also has lower incidence of hematoma, ecchymosis, oozing with less pain.This reduction in vascular complications will in turn decrease time of bed rest and duration of hospitalization resulting in higher levels of patient satisfaction, compared to bandage and compressor device. Therefore, it is recommended to use this method, which does not need any special equipment, and is comfortable to the patient with develop a tool for ongoing measurements of patient outcomes upon post-arterial sheath removal.

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1.Introduction

Coronary heart disease is the leading cause of death in the United States today. Treatment options include medical management, coronary interventions, and cardiac revascularization ***(American Heart Association, 2007and Mosca et al.,2011)***. In Egypt, according to the latest annual statistics of the national heart institute in Cairo (2010), approximately 1.3 million input cardiac cauterizations are performed annually, half of those patients have percutaneous cardiac interventions and about 400,000 undergo coronary artery bypass graft operations ***(National Heart Institute,2010).***

Cardiac catheterization is an extremely valuable diagnostic procedure for obtaining detailed information about the structure and function of the cardiac chambers, valves, and coronary arteries. The procedure may include studies of the right or left sides of the heart, as well as the coronary arteries ***(Botti et al., 2001, and Horton Campus, 2011)***.

Historically the procedure was initially performed in 1929, in Eberswalde, Germany. A 25-year-old surgical trainee named **Warner Forssmann** was the first to pass a catheter into the heart of a living person-his own. In 1947, **Louis Dexter** expanded the clinical use of right heart catheterization with studies on patients with congenital heart diseases ***(Braunwald and Swan, 1968)***. Although the technique and accuracy of noninvasive testing continues to improve, cardiac catheterization remains the standard for evaluation of hemodynamics ***(Grossman and Bain, 2000, and Black, 2008)***.

Cardiac catheterization involves passing a catheter through an artery or a vein to the heart, or into a coronary artery. In addition to defining the site, severity, and morphology of lesions, coronary angiography helps in providing a qualitative assessment of coronary blood flow, and helps in identifying collateral vessels ***(Prinkey, 1999; Arora et al.,2009 and Resnic et al.,2010)***.

Usually, cardiac catheterization is performed through the femoral artery, although the use of the radial artery is a recently developed alternative. When catheterization is performed through either femoral artery, where the catheter is introduced through the femoral or groin artery, the procedure is known as "left heart" catheterization because it goes from the femoral artery to the aorta, coronary arteries, and the left ventricle. This accounts for the majority of procedures. If catheter is also placed in the femoral vein to measure pressures within the right side of the heart, the procedure is called "right heart"' catheterization. This is used when measurements of the heart output or lung pressure are needed ***(Phipps et al., 2003 and Lehmann and Samantha, 2009)***.

Decisions about which catheter diameter to use are based on several factors. These include vascular and heart anatomy, the extent to which the catheter must be manipulated, and the desire to limit vascular injury and complications. Larger diameter catheters (7-10 F) allow for greater catheter manipulation, but they have a higher potential for trauma to the coronary or peripheral vasculature. In contrast, smaller catheters (4-6F) are less traumatic, and permit earlier ambulation after catheterization ***(Grossman and Bain, 2000 and Simon, 2010)***.

To gain access to the coronary arteries and cardiac chambers, a femoral arterial sheath is inserted into the groin. Anticoagulation is required during percutaneous coronary intervention procedure to prevent acute thrombotic closure of coronary vessels that can occur during insertion of interventional devices ***(Kern, 2005).*** Usually the procedure takes 2 to 3 hours to be performed. Once the procedure is over, the catheters and then the sheaths are withdrawn and the nurse or the doctor holds pressure directly over the catheterization site. This pressure needs to be maintained for approximately 20 minutes, and needs to be hard enough to prevent any bleeding ***(American Heart Association, 2004)***. Bed rest is maintained prior to and after femoral sheath removal for 4-6 hours to promote healing of the arterial puncture site ***(Chlan et al.,2010)***.

Several methods for sheath removal have been evaluated, from manual pressure to the development of various types of mechanical compression devices applied at the arteriotomy site. ***Rowe and Jones (1972)*** have reported the first use of mechanical compression device. Over ensuing years, improvements in these devices and related techniques have led to a wide range of practices and recommendations for femoral device removal and subsequent patient monitoring ***(Semler,2006)***.

Actual compression of the artery can be done manually or with mechanical compression devices***(Kaur et al., 2007).***Manual compression at the femoral artery during removal is considered "gold standard "for femoral arterial sheath removal ***(Andersen et al., 2007)***.The femoral artery is compressed with two or three fingers until hemostasis is obtained. Continuous direct pressure is required for fifteen to sixty minutes without obscuring distal pulses ***(Odom, 2008).*** The patient must remain in bed, supine for two to six hours post hemostasis. Hand and arm fatigue is a disadvantage of the manual compression but low cost and no specialized equipment are the main advantages ***(Hamel, 2012).***

Mechanical compression employs several different mechanisms to apply pressure on the artery to obtain hemostasis.The C-Clamp consists of a hand adjustable clamp that applies pressure to the artery. A transparent sterile disc is applied over the femoral artery puncture site until hemostasis is obtained ***(Berry et al., 2006).***

The advantages of mechanical compression devices are hands-free operation, decreased contact with blood, and controlled pressure. The disadvantages are that mechanical compression devices on those have severe peripheral vascular disease or femoral artery venous graft ***(Odom,2008).***

Risks associated with femoral sheath removal include inadequate hemostasis resulting in vascular complications such as oozing, ecchymosis, or hematoma, development of pseudo-aneurysm, arteriovenous fistulas, thrombosis, thromboemboli, and retroperitoneal bleed ***(Apple and Lindsay, 2000 and Chlan et al., 2010)***. Vascular complications arise from compression of the femoral vasculature, and occur at rates from 11% to 65% ***(Kaur et al., 2007)***. Approximately 2-3% requires surgical intervention ***(Simon, 2010)***. The incidence of vascular complications after sheath removal following a

percutaneous coronary intervention procedure varies widely according of the compression method used to achieve femoral artery hemostasis ***(Hamel, 2012)***.

Hematoma, ecchymosis and oozing are considered minor complications post percutaneous coronary intervention. Hematoma is a collection of blood in the soft tissue and is identified by local swelling, hardness, and pain. Management of hematoma requires pressure to the groin, bed rest, and careful monitoring ***(Dressler and Dressler, 2006)***.Ecchymosis is a common complication and is accompanied by pain and minor swelling. During the first twenty-four hours after the procedure, a warm compress may be applied to the site to ease discomfort. Oozing can be resolved through continued manual pressure until the oozing subside ***(Rastan et al., 2008).***

Removal of sheaths after percutaneous coronary intervention procedure, cardiac catheterization, and angioplasty, has predominantly become a routine part of nursing practice. However, although the procedure itself has become standardized, a best nursing practice recommendation for the removal of arterial sheaths after cardiac intervention procedures is yet to emerge ***(Berry et al., 2006).***

Significance of the study

Cardiac interventions are widely accepted as a practical management option for coronary artery diseases. However, few changes have occurred in the techniques used for percutaneous arterial cannulation, and for attaining hemostasis after cardiac interventions. Inadequate hemostasis leads to vascular complications which may be costly, increase hospital time, and increase patient discomfort.Moreover, the process of sheath removal and femoral artery compression can be distressful, and affect patient satisfaction. The most effective method of femoral sheath removal is one that decreases time to hemostasis, decrease bed-rest, decrease the rate of vascular complications, relieve patient discomfort and decrease the amount of time the nurse must spend to obtain hemostasis. Ambiguity exists in determining which method of arterial sheath is the most effective.To begin address these gaps, therefore, the purposes of this study was to compare the effects of Three groin compression methods (manual, bandage, compressor) on occurrence of complications (hematoma, ecchymosis, oozing), pain and on patient satisfaction after femoral sheath removal.

Aim of the study

This study was aimed at comparing the effectiveness of three groin compression methods (manual, bandage, compressor) on patient vascular complications(hematoma, ecchymosis, oozing), pain, and patient satisfaction after femoral sheath removal.

Research Hypothesis:

The researchers have assumed that the manual groin compression method after femoral sheath removal will:

1-Cause fewer vascular complications (hematoma, ecchymosis and oozing), compared to bandage and compressor groin compression methods.

2-Cause less pain intensity in patients compared to bandage and compressor groin compression methods.

3-Lead to more patient satisfaction compared to bandage and compressor groin compression methods.

2. Subjects and Methods

Research design

A randomized clinical trial design was used in the conduction of this study.

Setting

The study was conducted in cardiac catheterization and coronary care units at National Institute of Heart in Embaba-Cairo

Subjects

All patients admitted for performing cardiac catheterization via femoral artery during the time of the study were eligible for inclusion in the sample. The inclusion criteria were being 18 years of age or older, alert, to read and write, and having with normal Prothrombin Time (PT) and Partial Thromboplastin Time (PTT). Only cases of successful single wall puncture of the femoral artery were included. Exclusion criteria were being obese, hemodynamically unstable e.g. bleeding disorders, and patients receiving mechanical ventilation, or thrombolytic therapy within 24 hours before or during the Percutaneous Coronary Intervention Procedure (PCIP) (streptokinase, alteplase recombinant, reteplase recombinant, tenecteplase, or other thrombolytics). Also patients with intraorticballon placement, known groin pathology, previous surgery in the iliac or femoral arteries, low hematocrit level, or with documented mental incompetence in the medical record (e.g., Alzheimer's disease), were excluded from the study sample.

A total number of 150 eligible patients were required for three equal groups: manual compression, bandage and compressor groups. Patients were consecutively recruited, based on the inclusion and exclusion criteria, and randomly assigned to one of the three groups until sample size was achieved.

Tools

The tools used for data collection included the following:

- **Demographic and Clinical Data Sheet**: Constructed by the researchers to record patient's demographics, sheath size as well as use of heparin pre and post the procedure, bed rest and hospital stay of the patients after the procedure.
- **Hematoma Formation Scale*: According*** to ***Simon (2010)*** hematoma was defined as an

accumulation of blood at skin level with bruising or swelling in the area of the artery punctures during the period of sheath insertion through 6-12 hours following sheath removal. The scale designed for measurement of hematoma size. It was adopted from ***Al Sadi et al. (2010)***.It classified hematoma into four categories according to surface area: No hematoma (<2cm^2 in diameter), Small hematoma (2≤ 5cm^2 in diameter),Medium hematoma(5≤ 10 cm^2 in diameter) and Large hematoma (≥ 10 cm^2 in diameter).

- **Ecchymosis Scale*:*** According to ***Bensen et al. (2009)***, it was defined as presence of any skin discoloration without a mass. It designed for measurement of ecchymosis size. It was adopted from ***Hamner et al. (2010)***. It classified ecchymosis into four categories according to surface area: No ecchymosis (< 2cm^2 in diameter), Small ecchymosis (2≤ 5cm^2 in diameter), Medium ecchymosis (5≤ 10 cm^2 in diameter) and Large ecchymosis (≥ 10 cm^2 in diameter).
- **Oozing Scale*:*** The scale designed for measurement any leakage of blood from the puncture site. It was adopted from ***Black (2008)***. It classified oozing into four categories according to surface area soaked with blood : No oozing (dry dressing), Mild oozing ((< 2cm^2 in diameter dressing soaked with blood),Moderate oozing (2≤ 5cm^2 in diameter dressing soaked with blood) and Severe oozing (5≤ 10 cm^2 in diameter dressing soaked with blood).

For hematoma formation, ecchymosis and oozing scales, it was filled by the researchers immediately, at 6 and at 12 hours post hemostasis.

- **Pain Intensity Numeric Scale:** Designed to assess pain intensity. It was adopted from Puntillo ***et al. (2001).***The scale determines the level of pain intensity ranging from no pain (scored = 0), to worst (scored = 10). It was filled by the patient three times 5, 10 and 20 minutes of using the method of compression.
- **Patient satisfaction procedure scale:** Designed to assess patient satisfaction regarding type of compression used. A 12- items short form of the patient satisfaction questionnaire (PSQ) developed by ***Puntillo et al. (2001).*** The patients had to respond to the questions about both positive and negative aspects of the procedure on a 3-point scale: "yes a lot", "yes a little", and "no." These were respectively scored 3, 2, and 1. The higher scores indicate greater satisfaction with the procedure (60% or more), and the lower scores (less than 60%) indicate dissatisfaction with the procedure. It was filled by the researchers once after using the method of compression.

Procedures

A pilot study was carried out on five patients for each of the three methods, fulfilling the study inclusion and exclusion criteria. This was done in order to test the applicability of the tools and to estimate the time required for completing them. Based on the results of pilot study, minor modifications were done.

The collection of data lasted for a period of three months, starting from June to August 2012. Data were collected three days a week from 9.00 am to 10.00 pm.(the researchers share each other between morning and afternoon shift).Approval for carrying out the study was obtained from the director of National Institute of Heart. Written informed consents were obtained from patients for participation in the study.

Patients were recruited and assigned to the three study groups: manual compression, bandage, and compressor (C-Clamp). Demographic and Clinical Data sheet were filled by the researchers, and took about 15 to 20 minutes for each patient. The study maneuvers were applied according to the group:

- Manual pressure group: The researchers using three fingertips, applied direct pressure at the groin puncture site. The time of compression averaged 33.5 minutes. Thrombus usually forms at the access site within minutes after placing the fingers 1-2 cm^2 above the femoral puncture site and continuously exerting pressure for 25 minutes or more to achieve hemostasis ***(Berry et al., 2006)***. While applying pressure, the femoral sheath was withdrawn, and pressure was increased at the groin site until hemostasis was achieved; pressure was kept until bleeding stopped completely.
- Bandage group: a wad of eight squares of gauze was placed over the femoral puncture site. It was held in place by a two-meter elasticized non-adhesive blue line bandage applied in a "figure 8 form" around the leg and across the lower abdomen and back. The bandage remained in place for 4-6 hours. According to ***Simon (2010)***, in order to achieve hemostasis, a significant amount of pressure bandage over the access site is required.
- Compressor group: The C-clamp consists of a flat metal plate placed under the patients' buttocks to stabilize the device, and a C-clamp arm. A disposable translucent pad is attached to the tip of the C-clamp arm. Appropriate placement of the translucent pad was achieved. Pressure was

applied at the puncture site by lowering the arm of the C-clamp so that the pad is centered on the vascular access site. As the femoral sheath is removed, pressure was increased in order to achieve hemostasis. Pressure is applied until bleeding is absent (average 19.5 minutes). According to ***Hamel (2012)*** that C-Clamp is used to compress the artery and can take up to a mean of 20 minutes.

After hemostasis is attained a dressing is applied over the site of puncture through apply 4 folded sterile 4×4 gauze sponges and apply optimal pressure when securing tape without hip abduction. Groin sites were inspected for assessment of vascular complications (hematoma, ecchymosis and oozing) at the catheter puncture site was done immediately after the bleeding was stopped, at 6 and at 12 hours after removal of dressing. The edges of hematoma or ecchymosis were outlined with a making pen and the widest dimension was measured to the nearest centimeter.

A scale was used to measure the size of hematoma and ecchymosis. The measurement was done with a ruler scale in cm^2 i.e., the maximum length and breadth of hematoma and ecchymosis was multiple to get the area of each.

Measurement of oozing was carried out through observing the dressing by using a ruler scale in cm^2 measures the maximum length of oozing on the dressing.

All patients were trained on how to use pain intensity numeric scale before angiography procedure and rated their intensity of site pain compression experience at the observation time.

Ethical Consideration:

The ethical research consideration in this study was included the following:

The research approval was obtained before research implementation.

-The objectives and the aim of the study were cleared to the participants.

-The research maintain on anonymity and confidentiality of the subjects.

-Subjects are allowed to choose to participate or not and they have the right to withdraw from the study any time without penalty.

Statistical analysis

Data entry was done using Epi-Info 6.4 computer software package, while statistical analysis was done using SPSS 11 statistical software package. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations for quantitative variables. Quantitative continuous data were compared using ANOVA test for comparisons among more than two groups. When normal distribution of the data could not be assumed, the non-parametric Kruskal-Wallis test was used instead. Qualitative variables were compared using chi-square test. Statistical significance was considered at *p*-value <0.05.

3. Results

Table 1 describes the personal characteristics of patients in the three study groups. It indicates that most of them were 50 years old or more, with close mean ages in the early fifties. The gender distribution was almost equal between males and females, with slightly higher preponderance of females in the manual and compressor groups. However, no statistically significant differences were revealed among the three groups in any of these characteristics.

The same table illustrates that in the majority of the patients, sheath size 7 was used, with no statistically significant differences among them. Also, the great majority of patients in the three study groups had taken 5000 units of heparin pre-operatively and 500 unites post-operative with no statistically significant differences among them.

Table 2 compares hematoma formation as a vascular complication among patients in the three study groups. As the table shows that the three groups were similar immediately post hemostasis with no differences of statically significance. However, at 6 hours post hemostasis (70%) of patients in the manual group hadn't hematoma formation compared to bandage and compressor groups (36% and 58% respectively) with statistically significant differences between the three groups. At 12 hours post hemostasis (92%) of patients in the compressor group and (90%) in manual group compared with (60%) of patients in the bandage group hadn't hematoma formation with statistically significant differences between them (*P*= 0.001).

A comparison of ecchymosis occurrence as a vascular complication among patients in the three study groups is displayed in Table 3. It can be noticed that the three groups were similar immediately post hemostasis with no differences of statistically significance. The table shows that (40%) of the patients in the manual group had no ecchymosis, compared to (20%) in the compressor group, and (12%) in the bandage group at 6 hours post hemostasis, this differences was statistically significant, (*P*=0.001). Also a statistically significant difference was revealed among the three groups at 12 hours post hemostasis,(*P*=0.02). It is evident that less patients in the manual group (6%) had large ecchymosis, compared to the compressor (20) and bandage (24%) groups.

A comparison of oozing as a vascular complication among patients in the three study groups is illustrated in Table 4. As the table shows, no statistically significant differences were revealed

among the three study groups immediately and at 6 hours post hemostasis. However at 12 hours, (70%) of patients in the manual group had no oozing compared to compressor (68%) and (44%) in bandage groups. It also noticed that no one of patients in the three groups had severe oozing with no one of patients in the manual group had moderate oozing compared to compressor and bandage groups (2% and 12% respectively), and the difference was statistically significant, (***P*= 0.07**).

Figures 1, 2 and 3; summarize vascular complications changes in the mean scores of hematoma, ecchymosis and oozing respectively in the three study groups, immediately, at 6 and at 12 hours post hemostasis.

When the means scores of hematoma formation were compared between the three study groups, the difference were statistically significant starting at 6 hours post hemostasis (*P*=0.002) as shown in Figure 1. It is noticed that the peak mean of hematoma formation was for the bandage group (5.34± 4.09) compared with compressor and manual groups (4.24± 4.06) and (2.75± 2.92) respectively. It then declined down at 12 hours post hemostasis reaching (2.80±2.97) for bandage and (1.07± 0.99), (1.01± 1.62) for compressor and manual groups respectively with statistically significant differences between the three study groups (*P*= 0.001).

As for ecchymosis scale, Figure 2 demonstrates that the means of ecchymosis were lower in the manual groups throughout study phases with statistically significant differences at 6 and 12 hours post hemostasis. On the other hand, the increasing trend continued in the bandage group till 12 hours post hemostasis.

Figure 3 shows that the means scores of oozing in the manual group were lower at 6 hours to 12 hours post hemostasis compared to patients in the bandage and compressor groups with statistically significant differences at 12 hours (*P*=0.07).

Concerning hemostasis and compression times among patients in the three study groups, table 5 points to statistically significant differences in the two parameters, $p<0.01$ and $p<0.001$, respectively. It is obvious that the bandage group had longer time for hemostasis (23.5±8.3 minutes) with more time of compression (144.9± 50.5 minutes) compared to the two other groups. As for time of hemostasis, manual and compressor groups were (18.1± 5.5) and (17.1± 3.8) respectively.For time of compression, manual and compressor groups were (22.4± 6.2) and (15.1± 2.7) respectively. The table also shows that the manual group had the lowest duration of bed rest (4.8±1.3 hours), and hospital stay (13.4±9.0 hours), compared to the other two groups, and the differences were statistically significant, $p<0.001$.

Table 6 presents the scores of post-procedure pain among patients in the three study groups. It is obvious that patients in the manual group had the lowest scores of pain at all three assessment times (5, 10 and 20 minutes), whereas those in the compressor group had the highest scores. All these differences were statistically significant, $p<0.001$.

As regards patients' satisfaction with the procedure, table 7 demonstrates statistically significant differences among the three study groups, $p<0.001$. It was noticed that the highest percentage of patient satisfaction was in the manual group, while it was lowest in the bandage group. Overall, 80.0% of the patients in the manual group were satisfied, compared to 38.0% in the compressor group, and 28.0% only in the bandage group.

4. Discussion

With increasing number of cardiac catheterizations performed and evolving technology, nurses in the front line and play a key role in the prevention of vascular complications following femoral sheath removal, followed by compression of the femoral artery which is a nursing responsibility in many critical care settings***(Chlan et al.,2010).***Nurses can choose among three accepted methods to achieve hemostasis of the femoral artery: manual pressure, manual pressure and bandage, or C-clamp compression devices or compressors. The method chosen for sheath removal may be dependent on the individual performing the sheath removal ***(Hamel, 2012)***.

The aim of this study was to compare the effectiveness of three groin compression methods (manual, bandage, and compressor) on patient vascular complications (hematoma, ecchymosis, oozing), pain, and patient satisfaction after femoral sheath removal. It was hypothesized that the manual compression method after femoral sheath removal will cause fewer vascular complications (hematoma, ecchymosis and oozing), less pain intensity with more patient satisfaction compared to bandage and compressor groin compression methods.

The results have shown that patients in the three present study groups were similar in their age, gender distribution with no statistically significant differences among them. These two parameters were important to be equally distributed among the three study groups because of their possible relations to the occurrence of complications. This is in congruence with ***Hamner et al. (2010)*** who have reported that age, height and weight, as well as sex are known to be predictive of complications.

Table 1. Characteristics of Patients in the Three Study Groups

Items	Group						X^2	*p*-value
	Manual (n=50)		bandage (n=50)		Compressor (n=50)			
	No.	%	No.	%	No.	%		
Age (years):								
<50	18	36.0	16	32.0	20	40.0	0.69	0.71
50+	32	64.0	34	68.0	30	60.0		
Mean±SD	53.5±7.7		53.8 ±7.4		54.6 ±7.5			
Gender:								
Male	24	48.0	29	58.0	23	46.0	1.65	0.43
Female	26	52.0	21	42.0	27	54.0		
Sheath Size (FR)								
7	40	80.0	38	76.0	41	82.0		
8	3	6.0	2	4.0	1	2.0	2.54	0.86
9	2	4.0	3	6.0	1	2.0		
10	5	10.0	7	14.0	7	14.0		
Pre-Procedure Heparin (Units):								
1000	10	20.0	13	26.0	11	22.0		
2500	4	8.0	4	8.0	6	12.0	1.75	0.94
5000	35	70.0	31	62.0	32	64.0		
10000	1	2.0	2	4.0	1	2.0		
Mean± SD	5224.5± 1358.1		5364.6± 1457.7		5102.0± 714.3			
Post-Procedure Heparin (Units):								
500	30	60.0	35	70.0	33	66.0		
1000	20	40.0	15	30.0	17	34.0	1.12	0.57
Mean± SD	700.0± 247.4		650.0± 231.5		670.0± 239.3			

(*) Statistically significant at p<0.05 (F) ANOVA

Table 2.Comparison of Hematoma Formation as a Vascular Complication among Patients in the Three Study Groups throughout Study Period:

Complication	Group						X^2	*p* -value
	Manual (n=50)		bandage (n=50)		Compressor (n=50)			
	No.	%	No.	%	No.	%		
Hematoma Formation *Immediate :								
-None(<2cm^2)	29	58.0	24	48.0	27	54.0		
-Small(2≤ 5cm^2)	12	24.0	10	20.0	10	20.0	3.91	0.69
-Medium(5≤10cm^2)	3	6.0	5	10.0	2	4.0		
-Large(≥10cm^2)	6	12.0	11	22.0	11	22.0		
Hematoma Formation *At 6 Hours :								
-None(<2cm^2)	35	70.0	18	36.0	29	58.0		
-Small(2≤ 5cm^2)	9	18.0	12	24.0	7	14.0	16.38	0.01*
-Medium(5≤10cm^2)	2	4.0	7	14.0	2	4.0		
-Large(≥10cm^2)	4	8.0	13	26.0	12	24.0		
Hematoma Formation *At 12 Hours :								
-None(<2cm^2)	45	90.0	30	60.0	46	92.0	21.68	0.001*
-Small(2≤ 5cm^2)	3	6.0	10	20.0	3	6.0		
-Medium(5≤10cm^2)	1	2.0	5	10.0	1	2.0		
-Large(≥10cm^2)	1	2.0	5	10.0	0	0.0		

(*) Statistically significant at p<0.05

Table 3.Comparison of Ecchymosis as a Vascular Complication among Patients in the Three Study Groups throughout Study Period:

Complication	Group						X^2	*p* -value
	Manual (n=50)		bandage (n=50)		Compressor (n=50)			
	No.	%	No.	%	No.	%		
Ecchymosis *Immediate :								
-None(<2cm^2)	47	94.0	46	92.0	45	90.0		
-Small(2≤ 5cm^2)	2	4.0	3	6.0	3	6.0	0.79	0.93
-Medium(5≤10cm^2)	1	2.0	1	2.0	2	4.0		
-Large(≥10cm^2)	0	0.0	0	0.0	0	0.0		
Ecchymosis *At 6 Hours :								
-None(<2cm^2)	20	40.0	6	12.0	10	20.0		
-Small(2≤ 5cm^2)	21	42.0	16	32.0	20	40.0	20.3	0.001*
-Medium(5≤10cm^2)	5	10.0	14	28.0	13	26.0		
-Large(≥10cm^2)	4	8.0	14	28.0	7	14.0		
Ecchymosis *At 12 Hours :								
-None(<2cm^2)	26	52.0	13	26.0	20	40.0	15.01	0.02*
-Small(2≤ 5cm^2)	18	36.0	15	30.0	16	32.0		
-Medium(5≤10cm^2)	3	6.0	10	20.0	4	8.0		
-Large(≥10cm^2)	3	6.0	12	24.0	10	20.0		

(*) Statistically significant at p<0.05

Table 4.Comparison of Oozing as a Vascular Complication among Patients in the Three Study Groups throughout Study Period:

Complication	Group						X^2	*p* -value
	Manual (n=50)		bandage (n=50)		Compressor (n=50)			
	No.	%	No.	%	No.	%		
Oozing *Immediate :								
-None(Dry Dressing)	21	42.0	18	36.0	20	40.0		
-Mild(<2cm^2)	27	54.0	31	62.0	29	58.0	1.01	0.91
-Moderate(2≤ 5cm^2)	2	4.0	1	2.0	1	2.0		
-Severe(5≤10cm^2)	0	0.0	0	0.0	0	0.0		
Oozing *At 6 Hours :								
-None(Dry Dressing)	26	52.0	20	40.0	26	52.0		
-Mild(<2cm^2)	23	46.0	26	52.0	22	44.0	3.37	0.49
-Moderate(2≤ 5cm^2)	1	2.0	4	8.0	2	4.0		
-Severe(5≤10cm^2)	0	0.0	0	0.0	0	0.0		
Oozing *At 12 Hours :								
-None(Dry Dressing)	35	70.0	22	44.0	34	68.0	14.2	0.07*
-Mild(<2cm^2)	15	30.0	22	44.0	15	30.0		
-Moderate(2≤ 5cm^2)	0	0.0	6	12.0	1	2.0		
-Severe(5≤10cm^2)	0	0.0	0	0.0	0	0.0		

(*) Statistically significant at p<0.05

Table 5. Comparison of Hemostasis and Compression Times among Patients in the Three Study Groups

Items	Mean ±SD			Kruskal Wallis test	*p* -value
	Manual (n=50)	bandage (n=50)	Compressor (n=50)		
Time of hemostasis (min)	18.1±5.5	23.5±8.3	17.1±3.8	19.81	<0.01*
Time of compression (min)	22.4±6.2	144.9±50.5	15.1±2.7	117.83	<0.001*
Bed rest (hours)	4.8±1.3	6.7±1.1	6.7±1.0	62.95	<0.001*
Hospital stay (hours)	13.4±9.0	22.1±13.9	18.6±10.1	16.93	<0.001*

(*) Statistically significant at p<0.05

Table 6. Comparison of Post-Procedure Pain among Patients in the Three Study Groups

Items	Mean±SD	Kruskal	*p* -value

	Manual (n=50)	bandage (n=50)	Compressor (n=50)	Wallis test	
Pain:					
5 minutes	4.6±1.4	6.1±1.0	8.5±1.1	101.38	<0.001*
10 minutes	2.3±0.9	3.7±0.8	5.6±0.8	112.75	<0.001*
20 minutes	0.5±0.6	1.6±0.8	2.6±0.9	86.36	<0.001*

(*) Statistically significant at p<0.05

Table 7. Comparison of satisfaction with procedure among patients in the three study groups

Items	Group						X^2 *p* -value
	Manual (n=50)		bandage (n=50)		Compressor (n=50)		
	No.	%	No.	%	No.	%	
Total							
Satisfied	40	80.0	14	28.0	19	38.0	
Dissatisfied	10	20.0	36	72.0	31	62.0	30.48(<0.001*)

(*) Statistically significant at p<0.05

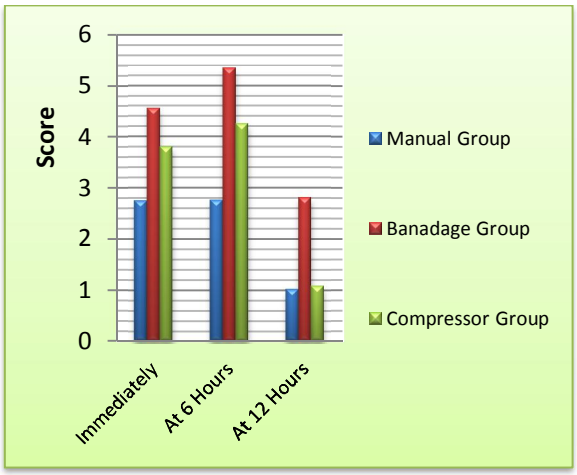

Figure 1. Mean Scores of Hematoma Formation Scale among Patients in the Three Study Groups throughout Study Periods

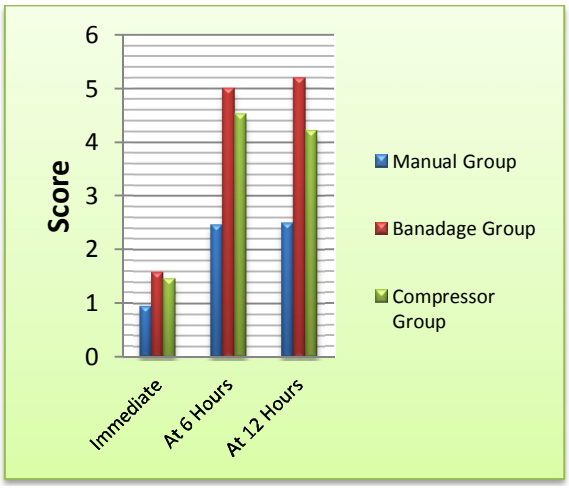

Figure 2. Mean Scores of Ecchymosis Scale among Patients in the Three Study Groups throughout Study Periods

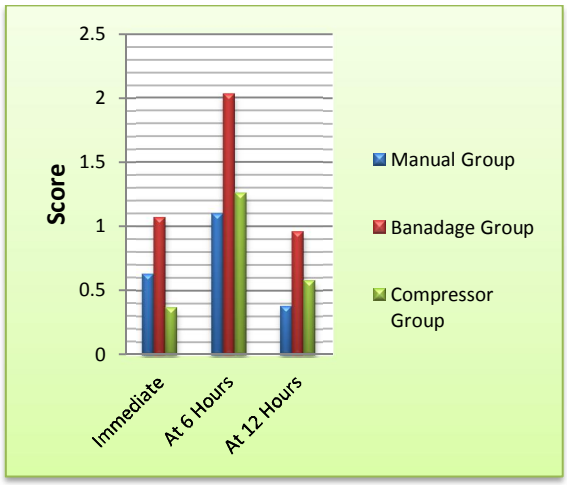

Figure 3. Mean Scores of Oozing Scale among Patients in the Three Study Groups throughout Study Periods

The comparability of the catheterization sheath size among patients in the three groups was also important to be able to compare outcomes with no confounding factors. Thus, in the majority of the patients, sheath size 7 was used, with no statistically significant differences among the three groups. This result is in line with ***Magosaki et al.(1999)*** who have similarly mentioned that A7, 8F sheaths were mostly used among patients undergoing percutaneous coronary procedures.

As regards the use of pre and post-procedure heparin, the present study results have shown that the majority of the patients used 5000 units of heparin pre-operatively, and 500 units post-operatively, with no statistically significant differences among the three groups. These findings are in agreement with ***Amin et al (2001)*** who reported that during the Percutaneous Treansluminal Coronary Angioplasty (PCTA) procedure, patients receive large amounts of heparin. Moreover, most patients receive intravenous heparin for some time after the procedure to prevent clot formation and arterial spasm. Also, nurses need to be

vigilant when caring for patients who have had vascular complications prior to femoral sheath removal and had received antiplatelet medications. This result is incongruent with ***Bergquvist (2002)*** who has mentioned that Heparin 10000 units as an I.V. bolus in coronary surgery should be commenced immediately prior to angioplasty or coronary stent placement, and followed by repeated boluses or continuous infusion of heparin to maintain the activated clotting time greater than 300 seconds.

Concerning hematoma formation as a vascular complication among patients in the three study groups, the current study has revealed that around three – fourth of the patients in the manual group had no hematoma formation at 6 hours. This was statistically significantly higher than the other groups but at 12 hours, the majority of manual and compressor groups had no hematoma formation compared to more than half of patients in the bandage group. These findings are in agreement with ***Magosaki et al. (1999)*** who have reported hematoma formation rates in the device or compressor group, compared to manual compression group, 16% and 10%, respectively. Also, the present study is congruent with the results of the study carried out by ***Benson et al. (2009)***, where patients who underwent manual sheath removal had fewer hematoma formation compared with those who underwent sheath removal using the compressor or bandage pressure. On the same vein, Al ***Sadi et al. (2010)*** revealed that patients with pressure bandages experienced a higher incidence of hematoma formation. ***Hamel (2012)*** added that hematoma increased in C-clamp immediately after femoral sheath removal, and decreased at 12-hour assessment period. These results are in agreement with the present study findings.

Conversely, these present study results are in contradiction with those of ***Jones and McCucheon, 2003 and Jones. 2012)*** who have reported that formation of hematomas occurred significantly more often in the manual compression group than in the group in which a mechanical device was used. Also, in disagreement with the foregoing present study findings, ***Semler (2006)*** have reported that the incidence of hematoma formation using the manual method was higher (6%), compared to using the compressor (2%). Meanwhile, ***AlSadi et al. (2010)*** have claimed that both manual and mechanical compressions are equally effective. However, these authors have also noted a more frequent switch from mechanical to manual compression to obtain post procedure hemostasis.

Concerning ecchymosis, the present study has revealed that less than half of the patients in the manual group had no ecchymosis compared to less than one fourth in the compressor and slightly one eighth for the bandage groups at 6 hours post hemostasis .This finding is in agreement with ***Juran et al.(2008)*** who study the effect of manual pressure and bandage in reducing ecchymosis in patients undergoing coronary angiography and found that patients with bandage had a higher incidence of ecchymosis than patients used manual pressure.

Also the current study revealed that less than only one tenth of the patients in manual group had large ecchymosis compared to less than one fourth for compressor and bandage groups.This findings is in congruence with foregoing present study finding, ***Kaur et al. (2007)*** have highlighted increase in size of ecchymosis among the subjects who were given compression with " C-Clamp" or bandage compared to manual compression after 12 hours was noted. In the same vein, Simon ***(2010)*** have explained that mean size of ecchymosis was (4.68± 9.33cm^2) and (6.76± 154 cm^2) in the manual and compressor respectively after 12 hours of compression.

Concerning oozing, the current study revealed that less than three quarter of patients in the manual group had no oozing compared to more than half in compressor and less than half in bandages groups at 12 hours post hemostasis. Moreover, more than one tenth of patients in bandage group had moderate oozing and less than one tenth in compressor group compared to no one in manual group. These findings are in agreement with **Chlan *et al.* (2010)** who found a higher rate of bleeding in the compressor group (8%), compared to the manual compression group (3%). Furthermore, Resnic ***et al.*** **(2010)** who has reported that the incidence of oozing trended downwards after sheath removal across all groin compression methods.

Conversely, these present study results are in contradiction with those of ***Odom (2008)*** and ***Jones (2012)*** who have reported that bleeding from the femoral puncture site after femoral sheath removal did not differ significantly when either a mechanical compression device or manual compression was used to attain hemostasis.

Concerning hemostasis and compression times, the present study findings pointed to statistically significant differences among patients in the three study groups. Patients in the bandage group had greater time of hemostasis. Meanwhile, patients in the bandage group had the longest time of compression, whereas the compressor group had the shortest time of compression. These results are in congruence with ***Semler (2006)*** who has also demonstrated that the time spent in manual compression of the artery was longer, compared to using the compressor (C-clamp). Moreover, Also ***Benson et al. (2009)*** have shown that the time of hemostasis was statistically significantly longer in the bandage group, compared to the manual group. Additionally, ***Chlan et al. (2010)***have stated that the decrease in time required for manual pressure

application leads to cost saving through decreased equipment use, earlier discharge time, and improved bed utilization. Also, ***Hamel (2012)*** have mentioned that the manual method is a safe and effective method of achieving hemostasis after cardiac catheterization; it can hasten time to hemostasis, ambulation, and discharge.

Conversely, these present study results are in contradiction with ***Magosaki et al. (1999)*** who have reported that the time to hemostasis was significantly shorter in the bandage group, compared to manual and compressor groups.

According to the present study findings, manual group patients had a lowest duration of bed rest and hospital stay than bandage and compressor groups and the differences were statistically significant. These results are in congruence with ***Lehmann and Samantha (2009)*** who have demonstrated that patients with manual pressure bed earlier with early discharge from the hospital than compressor devices.

The present study has also assessed post-procedure pain intensity among patients in the three study groups. It was showed that the patients in the manual group had the lowest scores of pain, while those in the compressor group had the highest scores. These differences were statistically significant at all three times of assessment. These findings are in line with ***Bowden and Worrey (1995)*** and ***Puntillo et al. (2001)*** who have reported that manual compression was the least painful. However, these present study results are in disagreement with ***Massat (2003)*** who has emphasized that the benefits of compressor include the reduction in time to hemostasis, and consequently early ambulation of patients, increased patient comfort, and earlier discharge for some patients. Meanwhile, ***Chlan et al. (2010)*** could not reveal any statistically significant differences among the three compression methods as regards discomfort, pain, and distress.

As for satisfaction with procedure among patients in the three study groups, the present study has also demonstrated statistically significant differences. The findings have elucidated that patients' satisfaction was lowest in the bandage group, and highest in the manual compression group. These findings are congruent with ***Berry et al. (2006)*** who explained that when providing manual compression to the femoral artery, it is easier to release pressure to examine and assess if hemostasis is achieved. This not possible with the C-Clamp or bandage compression as nurses may leave it on longer as it is convenient and without opportunities to assess hemostasis. Additionally, ***Hoke et al.(2010)*** has claimed that the manual pressure is a safe, cost effective alternative with fewer vascular complications and less pain than other devices compression used which will in turn increase patient satisfaction.

However, in disagreement with these findings, ***Rogers et al. (1999)*** compared the traditional methods of compression used to achieve hemostasis, and found that compressor devices have high overall levels of safety and efficacy, and consequent patient satisfaction.

Conclusion and Recommendations

Given the present study findings, it is concluded that manual compression method after sheath removal in cardiac catheterization patients is associated with lower times of hemostasis and compression. It also has lower incidence of hematoma, ecchymosis, oozing with less pain.This reduction in vascular complications will in turn decrease time of bed rest and duration of hospitalization resulting in higher levels of patient satisfaction, compared to bandage and compressor device.

Therefore, it is recommended to use this method, which does not need any special equipment, and is comfortable to the patient. Optimal guidelines for care of patients post-arterial sheath removal need to be develop and implemented to enhance patient outcome. Also develop a tool for ongoing measurements of patient outcomes upon post-arterial sheath removal.

Implications for nursing practice:

This study provides nurses with research findings to support independent decisions to implement interventions during sheath removal.

Future efforts around the care of these patients should focus on forming consistent definitions for parameters defining what constitute complications such as bleeding, hemorrhage, hematoma, so that these can be systemically applied in research studies.

Nurses should continue to use their clinical judgment in selecting the sheath removal method that they believed to be the most appropriate.

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