Comparing the Effects of Two Types of Groin Dressing Securements on Skin Integrity, Hematoma Formation and Bleeding After Arterial Sheath Removal

by
Mary E. Singleton, RN, MSN

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Background

Impaired skin integrity is an adverse complication associated with the use of adhesive tape to secure the groin dressing after angiographic procedures.

Purpose: The purpose of this project was to evaluate the impact of the tape used to secure the post-femoral artery sheath removal dressing on skin integrity, hematoma formation and bleeding, and to develop a tool that could be used for ongoing patient outcome analysis.

Method: In this Quality Improvement project, two groups of adult patients were observed following removal of their femoral artery sheaths. Using current hospital protocols, groin dressings were secured with either 3M™ Medipore™ H Soft Cloth Surgical Tape or Johnson & Johnson Elastikon® Elastic Tape. If the sheath was removed in the cardiac catheter lab, Medipore H tape was used to secure the groin dressing. If the sheath was removed on a nursing unit, Elastikon tape was used to secure the groin dressing.

Measures: Skin integrity, hematoma formation and bleeding were assessed immediately after hemostasis was established (baseline), and 6–8 hours and 12–16 hours post-hemostasis.

Findings: There was no difference in hematoma formation between the groups ($p = .960$); however, there was a statistically significant difference in loss of skin integrity ($p < .001$). Patients with Medipore H tape securing the dressing had significantly lower incidence of loss of skin integrity (6.7%) than patients with Elastikon tape securing the dressing (80%).

Conclusion: The type of tape used to secure the groin dressing post-femoral artery sheath removal has a significant effect of the quality of skin integrity, but for this sample, no difference in hematoma formation or bleeding.

Introduction

Cardiovascular disease (CVD) is the leading cause of death in the United States. Invasive procedures for the diagnosis and treatment of CVD include cardiac catheterization, percutaneous transluminal coronary angioplasty (PTCA), rotoblator, athrectomy, laser and coronary artery stent. All of these procedures involve percutaneous access to the femoral artery.

Promoting hemostasis after femoral artery sheath removal is an essential element of patient care. Manual and mechanical compression devices along with collagen plugs are the initial methods to achieve hemostasis. Subsequent care generally includes a combination of visual monitoring, bed rest, sandbags and pressure dressings. Complications most commonly identified after removal of a femoral sheath include bleeding, hematoma formation, pseudoaneurysm and impaired perfusion to the extremity distal to the site of sheath removal (Lynn-McHale & Carlson, 2001).

The frequency of groin complications, including hematoma formation and bleeding, are difficult to track and are highly variable depending upon procedure, population and measurement tool. Published rates range from .5 to 15% (Silkman, Kim, & Baim, 1988; Simon, Bumgarner, Clark, & Israel, 1998). Loss of skin integrity under the groin dressing was often considered a minor complication or not mentioned in studies; however, one study noted a 7.9% rate of skin injury related to the post-procedural dressing secural (Blankenship, Clegg, & Powell, 1991).

Guidelines for practice must be validated through scientifically based studies. Differences in dressing protocols require investigation of their impact on skin integrity, hematoma formation and bleeding. Although lacking in control and randomization, Quality Improvement projects in clinical practice provide a setting in which interventions may be evaluated for their impact on patient outcomes.

The Problem

When nursing staff at a large Midwestern regional medical center identified significant loss of skin integrity under groin dressings as an adverse outcome after cardiac catheterization, dressing application protocols were changed and a quality improvement project instituted. Forty percent of the patients (n = 4/10) had erythema and/or epithelial stripping after removal of the pressure dressing. The dressing protocol was revised by discontinuing use of the benzoin spray and adding a skin prep before the dressing was applied. Elastikon tape, with bi-directional stretch, remained the securement device, but smaller pieces of tape were applied with less stretch of the tape during application and adhesive remover was used during removal. (See Dressing Protocols, Tables 1 & 2.) This change in practice resulted in an immediate reduction in incidents of patients' impaired skin integrity. During a follow-up, no patients exhibited stripping or blisters, and only one (n = 1/10) had erythema which was minimal. The committee noted that use of the skin prep and adhesive remover were inconsistent and removed them from the dressing protocol. In the following year and a half, intermittent complaints of skin irritation and anecdotal reports of increased hematomas and bleeding were received

Table 1. Original Dressing Protocol

After achieving hemostasis, apply pressure dressing:

1. Cut three 10–12 inch pieces of Elastikon tape
2. Apply 8–10 folded sterile 4x4 gauze sponges
3. Abduct the patient's hip
4. Tightly stretch the tape over the gauze sponges
5. Return the hip to midline
6. Apply 5 lb. sandbag
7. Remove dressing in 24 hours

by the cardiac catheterization lab staff. This project was developed in response to staff requests for assistance in determining optimal care guidelines for patients after removal of femoral arterial sheaths.

The staff of the cardiac catheterization lab selected an alternate adhesive tape, Medipore H tape, a non-woven, polyester "soft cloth" tape with cross and diagonal stretch, (See Dressing Protocols, Table 3) while the nursing care areas continued to use the standard tape (Elastikon tape) to secure the pressure dressings. This project evaluated the two clinical groups post-femoral artery sheath removal for the outcomes of skin integrity, hematoma formation and bleeding.

Methodology

Project Design

This prospective, repeated measure study compared the effects of two types of adhesive tape used to secure post-femoral artery sheath removal dressings on skin integrity, hematoma formation and bleeding in a convenience sample. The use of Medipore H tape or Elastikon tape was based on the standard protocol in the patient care area where the arterial sheath was removed. If the sheath was removed in the Cardiac Catheterization Lab, Medipore H tape was used to secure the groin dressing. If the sheath was removed on a nursing unit, Elastikon tape was used to secure the groin dressing. The dressing protocols were very similar and the post-procedural care was identical except that patients in the Elastikon tape group returned to the nursing unit with the arterial sheath secured by Medipore H tape. The Medipore H tape was replaced with Elastikon tape when the sheath was pulled, so this group had one more "dressing" change. To help control for this effect, patients with impaired skin integrity at baseline (after hemostasis has been obtained) were not included in the project. Skin integrity, hematoma formation and bleeding were measured at three points in time: (a) immediately after hemostasis had been obtained but before application of the groin dressing, (b) 6–8 hours and (c) 12–16 hours post-hemostasis.

Instruments

The outcome variables (skin integrity, hematoma formation and bleeding) were measured by physical assessment of the groin site. Patients with impaired skin integrity or injury at baseline were excluded from the project.

Skin Integrity Scale. Skin integrity was measured by visual inspection of the skin where the dressing was applied using the Skin Integrity Scale (Patrick & Maibach, 1991). The groin site was graded on an ordinal scale, 0 to 4, based on the following categories:

0. Negative, normal skin: no apparent cutaneous involvement
1. Definite erythema: faint but definite erythema, no eruptions or broken skin OR no erythema but definite dryness; may have epidermal fissuring
2. Erythema and induration: moderate erythema, may have a few papules or deep fissures, moderate to severe erythema in cracks
3. Vesiculation: severe erythema (beet redness), may have generalized papules OR moderate to severe erythema with slight edema (edges well defined by raising)
4. Bullous reaction: generalized vesicles or eschar formations OR moderate to severe erythema and/or edema extending beyond the area of the patch (p. 210).

Hematoma Formation and Bleeding Scale. The hemostasis scale for evaluating hematoma formation and bleeding was originally developed by Christenson, Staab, Burko, & Foster (1976). In 1995, it was modified by Hogan-Miller, Rustad, Sendelbach, & Goldenberg by adding measurement of the hematoma in centimeters. Variations of this instrument have been used in several studies (Barkman & Lunse, 1994; Christenson et al., 1976; Eisenberg & Mani, 1977) although these researchers did not discuss the validity or reliability of the tool. Hematomas and bleeding were graded on an ordinal scale, 0 to 4, based on the following categories:

0. Benign: no bleeding, no hematoma
1. Small hematoma, scant oozing: no intervention except application of 4x4 gauze
2. Moderate hematoma or bleeding: application of manual pressure for less than or equal to 15 minutes
3. Large hematoma (> 5 cm) or bleeding: extended pressure application for more than 15 minutes
4. Surgical intervention, hematoma evacuation, pseudoaneurysm repair

Loss of blood was defined as application of additional manual pressure on the puncture site for > 15 minutes to alleviate bleeding. Hematoma was defined as the presence ˆ of a localized mass of blood under the skin. Hematoma formation and bleeding were assessed by palpation, visual inspection and chart review. The RN palpated the femoral arterial puncture site for a hard accumulation of blood

Table 2. Revised J & J Elastikon® Elastic Tape Dressing Protocol

After achieving hemostasis, apply pressure dressing:

1. Cut 1 or 2 pieces, 8–10 inches long, of 3-inch-wide Elastikon tape
2. Apply "Prep-Site" protective wipe to the groin site*
3. Apply 8–10 folded sterile 4x4 gauze sponges
4. Apply optimal pressure when securing tape without hip abduction
5. Apply 5 lb. sandbag
6. Remove dressing in 12–16 hours using adhesive remover and a gentle pulling motion*
7. Apply a small adhesive bandage to puncture site for 24 hours

* The protective wipe and adhesive remover were not used at the time of the study.

Table 3. 3M™ Medipore™ H Soft Cloth Surgical Tape Dressing Protocol

After achieving hemostasis, apply pressure dressing:

1. Cut one 8–10 inch length of 3-inch-wide Medipore H tape
2. Apply 4 folded sterile 4x4 gauze sponges
3. Apply optimal pressure when securing tape without hip abduction
4. Apply 5 lb. sandbag
5. Remove dressing in 12–16 hours
6. Apply a small adhesive bandage to puncture site for 24 hours

Methodology (continued)

under the skin. The edges of the hematoma were outlined with a marking pen and the widest dimension measured to the nearest centimeter. The chart was also reviewed for documentation of bleeding from the site.

Sample Groups

The target population was adult patients undergoing diagnostic or interventional cardiac procedures performed via percutaneous transfemoral arterial approach at an urban Midwestern regional medical center. Following current practice, patients having sheaths removed immediately in the Cardiac Catheterization Recovery Room (following diagnostic procedures) had 3M™ Medipore™ H Soft Cloth Surgical Tape used to secure the groin dressing. Patients having sheaths removed either in the Interventional Cardiology Unit or Coronary Intensive Care Unit (following diagnostic or interventional procedures) had Elastikon tape used to secure the groin dressings. A convenience sample of 30 patients was in each group.

Exclusion criteria included thrombolytic therapy within 48 hours of the time of procedure, known bleeding disorders, intra-aortic balloon placement, injury to the groin from prior invasive procedures, and tape allergy or hypersensitivity.

Procedure

An initial assessment provided a baseline measurement for all participants and was documented on the data collection tool. The edges of the dressing were elevated to make the assessment at 6–8 hours. If no problems were identified, the edges of the dressing were resealed. At 12–16 hours, the dressing was completely removed and the area reassessed. A "small adhesive bandage" was then applied to the puncture site.

Results

Seventy-seven patients were initially assessed for this project. Seventeen were eliminated due to incomplete data sets, early discharge from the hospital, use of a collagen plug resulting in different dressing/post-procedure protocol, patient confusion, groin bruising remaining from prior heart catheterization, extended catheter indwell time and hematoma formation.

Sixty patients were included in the data analysis. Descriptive statistics, two-sample t-tests and Fisher exact tests revealed similarities and differences between the two groups. The groups had similar demographic characteristics. The J & J Elastikon tape group had greater total co-morbidities, but hypertension was not statistically different between groups. As anticipated, the groups were dissimilar with regards to documented diagnosis of coronary artery disease (66.6% Medipore H tape group; 93.3% Elastikon tape group) and procedural characteristics (100% diagnostic heart catheterizations in the Medipore H tape group; more angioplasties, stents, and rotoblators in the Elastikon tape group). However, the length of time pressure was applied to achieve hemostasis was similar despite the larger sizes of arterial sheaths, longer sheath dwell time and higher levels of heparinization in the Elastikon tape group (see Table 4).

The Mann-Whitney U test and Backward Stepwise Multiple Regression were used to analyze the relationship between the variables and the patient outcomes. Statistical significance was not achieved for any of the demographic characteristics or co-morbidities in relation to the outcomes of skin integrity, hematoma formation or bleeding.

Table 4. Comparison of Co-Morbidity and Procedural Factors by Group

Co-Morbidity	3M™ Medipore™ H Soft Cloth Surgical Tape Cath Lab Recovery n (%)	J & J Elastikon® Elastic Tape Interventional/CICU n (%)	Fisher Exact Test Level of Significance (*p* value)
Coronary Artery Disease	21 (69.9%)	28 (93.3%)	.042
Diabetes Mellitus	7 (23.3%)	13 (43.3%)	.170 *(ns)*
Peripheral Vascular Disease	3 (9.9%)	3 (9.9%)	.237 *(ns)*
Chronic Obstructive Lung Disease	5 (16.6%)	9 (29.9%)	.360 *(ns)*
Congestive Heart Failure	27	22	.472 *(ns)*
Obesity	9 (29%)	7 (23.3%)	.771 *(ns)*
Hypertension	22 (73.3%)	20 (66.6%)	.779 *(ns)*
Procedural Factors	**Mean ± SD**	**Mean ± SD**	**Two-sample t-test (*p* value)**
Sheath size (fr)	7.0 ± .9	8.0 ± .5	< .001
Indwell time (min)	29.7 ± 14.5	769.3 ± 525.3	< .001
Maximum Systolic Pressure recorded (mm Hg)	151 ± 19.7	141 ± 14.9	.048
Maximum Diastolic Pressure recorded (mm Hg)	85 ± 9.3	78 ± 9.7	.007
Amount of heparin administered (units)	1400 ± 1522	7016 ± 4706	< .001
Length of time femoral artery compressed to achieve hemostasis (min)	22.6 ± 7.5	27.7 ± 19.4	.180 *(ns)*

Age, height and weight were not significantly different between groups.

Skin Integrity

Although groin skin was intact for all subjects at baseline (immediately after the sheath was pulled and hemostasis achieved), differences in skin integrity became apparent by 6–8 hours (see Figure 1).

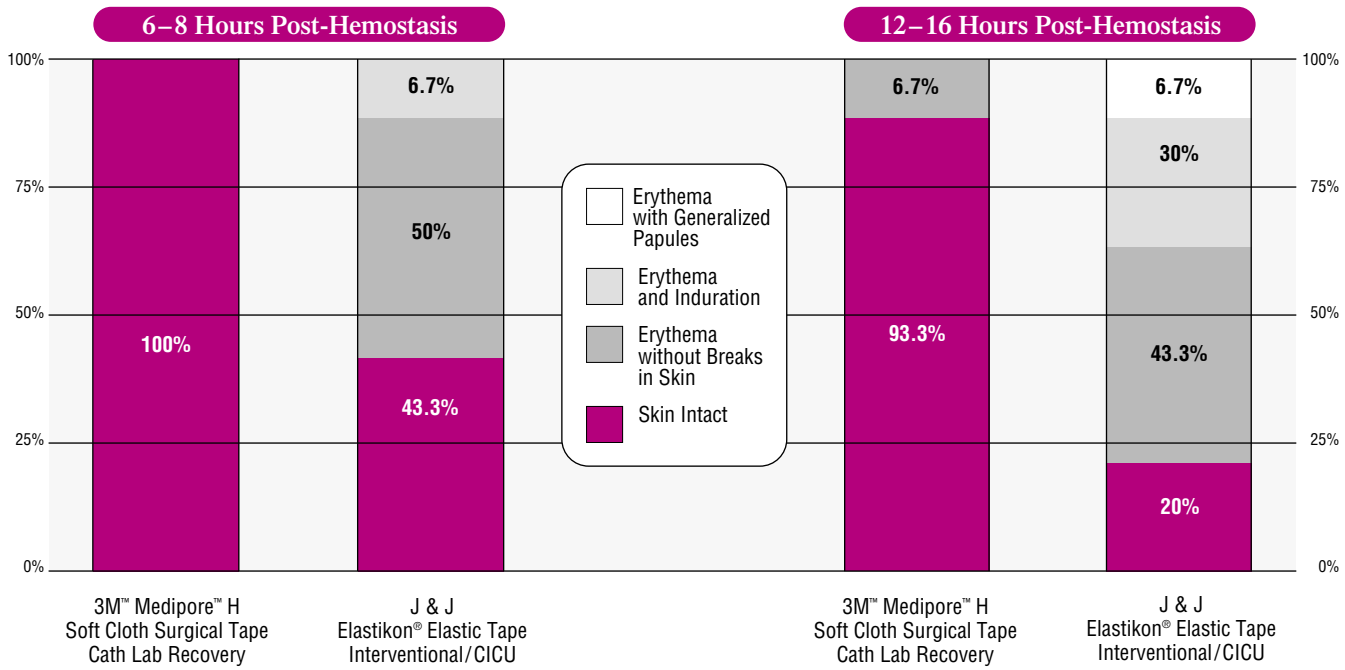
- **At 6–8 hours post-hemostasis**
  100% of the patients in the Medipore H tape group had normal skin, while 56% of those in the Elastikon tape group began to show signs of skin problems; 13 (43.3%) had normal skin; 15 (50%) had definite erythema but no breaks in the skin and 2 (6.7%) had erythema plus induration ($p < .001$).
- **At 12–16 hours post-hemostasis**
  93.3% of the patients in the Medipore H tape group had skin that remained intact. Two Medipore H tape patients (6.7%) developed erythema but no broken skin. 20% of the Elastikon tape patients' skin remained intact; 13 (43.3%) had definite erythema without broken skin; 9 (30%) displayed erythema and induration and 2 (6.7%) developed erythema with generalized papules ($p < .001$).

Thus, there was a statistically significant difference in loss of skin integrity between the groups. Patients who had groin dressings secured with Medipore H tape had significantly lower incidence of loss of skin integrity (6.7%) than patients who had dressings secured with Elastikon tape (80%).

Hematoma Formation and Bleeding

There was no difference in hematoma formation between the groups. At baseline, 86% of the patients who would enter the Medipore H tape group and 79.9% of patients who would enter the J & J Elastikon tape group had no or benign (rated 0) hematomas. At 6–8 hours, 86.6% of patients in both groups were rated 0 ($p = .96$). At 12–16 hours, 89% of patients in both groups were rated 0 ($p = .989$). Of the hematomas/bleeding noted at the final assessment, one patient in the Medipore H tape group had a hematoma that was rated a 1 (small) and two were rated 3 (large); one patient in the Elastikon tape group had a hematoma that was rated a 1 (small), one was rated a 3 (large), one was rated a 4 and subsequently had surgical repair of a pseudoaneurysm.

Figure 1. Impact of Dressing Secural on Incidence of Impaired Skin Integrity After Femoral Sheath Removal



Discussion

Studies examining care of patients after femoral artery sheath removal have frequently described the lack of scientifically tested patient care guidelines. This project provided objective data on the outcomes of skin integrity, hematoma formation and bleeding.

Skin Integrity

In this project, loss of skin integrity was identified at 12–16 hours in 80% of the Elastikon tape group and 6.7% of the 3M Medipore™ H Soft Cloth Surgical Tape. A statistically significant difference ($p < .001$) was noted at both assessments 2 and 3. A Backward Stepwise Logistical Regression identified taping procedure as the only variable implicated in the outcome of skin integrity loss. Loss of skin integrity had been cited in several studies (Blankenship et al., 1991; Blaylock et al., 1995; Bogart, 1995; Bogart et al., 1995; Christenson et al., 1976; Faller, Kantorski, Morgan, & Keller, 1995; Haygood et al., 1993; Wikblad & Anderson, 1995). The common variable implicated in all of the studies was tape. Data from this project support the results of previous research findings.

Hematoma Formation and Bleeding

Dressings secured with Medipore H tape and Elastikon tape had similar incidents of hematoma formation; 3 from each group ($p = .960$), an incident rate of 10%, with one surgical intervention. No single variable was related to hematoma formation. The findings were in contrast to several studies which implicated several factors associated with hematoma formation: higher blood pressure (Christenson et al., 1976; Waksman et al., 1995), larger sheath size (Vignola et al., 1981; Silkman et al., 1988), degree of heparinization (Bowden, Matsco & Worrey, 1998; Waksman et al., 1995), female gender (Blankenship et al., 1991; Hogan-Miller et al., 1995; Waksman et al., 1995; Wikblad & Anderson, 1995), increased age (Blaylock et al., 1995, Waksman et al., 1995) and dressing type (Blankenship et al., 1991; Christenson, 1976; Eisenberg & Mani, 1977).

Limitations

Some limitations of this project were related to sample, environment and project design.

The sample was predominately Caucasian. The two groups differed in procedures much more than expected. Except for the length of time pressure was held to attain hemostasis, differences in all of the procedural characteristics were statistically significant, which made the findings less generalizable. The project design also had limitations. With a sample size of 30, the project had an acceptable power of 0.91, but the lack of randomization for group assignment led to an increased risk of sampling bias. The risk of committing a Type II error with nonparametric tests was recognized, however they were used due to the distribution free assumptions of these tests.

Additional limitation was that the instruments lacked demonstrated validity and reliability. Content validity was confirmed by experts. All of the expert clinicians who evaluated the Hematoma Scale suggested the addition of "bruising" to clarify the Hematoma Scale in future studies.

Finally, the variation in arterial sheath insertion technique between physicians and arterial sheath removal technique and taping technique among practitioners could not be controlled.

Conclusion

Post-procedural care is delivered by nursing staff. Guidelines for care must be revised according to science-based evaluation of patient outcomes. Nursing staff identified and reported the issue of loss of skin integrity with an elastic pressure dressing. Comparisons of an elastic tape and a soft cloth tape provided objective data on the effectiveness and complication rates of each type of dressing secural. Using Medipore H tape to secure the groin dressings resulted in significantly better skin integrity than using Elastikon tape with no increase in incidence of hematoma formation. Potential benefits may also include cost savings since fewer gauze sponges were used in the Medipore H tape protocol.

Clinical staff were in a position to identify issues that impacted patient outcomes and were excited to participate in a meaningful quality improvement project. Optimal guidelines for the care of patients post-arterial sheath removal were developed and implemented resulting in enhanced patient outcomes and a tool for ongoing measurements of patient outcomes upon post-arterial sheath removal.

Data Collection Tool

Procedure: _____ Date: _____ Unit: _____ Hospital #: _____

Data Collection: Enter available data

Demographic Data

1. Age: _____
2. Gender: F or M
3. Height: _____ ft _____ in
4. Weight: _____ kg
5. ASA: Yes or No
6. Chronic steroid use: Yes or No
7. Hormonal therapy: Yes or No
8. Ethnic origin:
9. Co-Morbidities:

Procedure Data

1. Femoral sheath size: _____ fr
2. Time sheath in dwelling: _____ hr
3. PTT at removal time: _____ sec
4. Time pressure held: _____ min
5. BP max post line removal: _____ Sys _____ Dia
6. Amount of heparin during heart cath: _____ U

Clinical Intervention: Circle One

J & J Elastikon Tape or 3M™ Medipore™ H Soft Cloth Tape

Clinical Outcomes:

Enter the score for each scale at the indicated time intervals below.

Skin Integrity Scale

0. Negative, normal skin: no apparent cutaneous involvement
1. Definite erythema: faint but definite erythema, no eruptions or broken skin OR no erythema but definite dryness, may have epidermal fissuring
2. Erythema and induration: moderate erythema; may have a few papules or deep fissures, moderate to severe erythema in cracks
3. Vesiculation: severe erythema (beet redness), may have generalized papules OR moderate to severe erythema with slight edema (edges well defined by raising)
4. Bullous reaction: generalized vesicles or eschar formations OR moderate to severe erythema and/or edema extending beyond the area of the patch

Immediately: Skin Integrity: _____

6–8 hours: Skin Integrity: _____

12–16 hours: Skin Integrity: _____

Hematoma Scale

0. Benign: no bleeding, no hematoma.
1. Small hematoma, scant oozing: no intervention except application of 4x4 gauze.
2. Moderate hematoma or bleeding: application of manual pressure for less than or equal to 15 minutes
3. Large hematoma (> 5 cm) or bleeding: extended pressure application for more than 15 minutes
4. Surgical intervention, hematoma evacuation, pseudoaneurysm repair

Immediately: Hematoma: _____

6–8 hours: Hematoma: _____

12–16 hours: Hematoma: _____

Comments:

Singleton, 1997

Figure 2. Data Collection Tool: Post-Femoral Sheath Removal

This project was submitted to the School of Nursing and the faculty of the Graduate School of Wichita State University in partial fulfillment of the requirements for the Degree of Master of Science in Nursing, Spring 1997.

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