Advances in Nursing Science & Research

doi: 10.39127/ANSR:1000104

Al-Shualah RM. Ad Nurs Sci Resear: ANSR-104.

Research Article

Groin Dressing Post Cardiac Catheterization: Traditional Pressure Vs Transparent Film

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Citation: Al-Shualah RM (2018) Groin Dressing Post Cardiac Catheterization: Traditional Pressure Vs Transparent Film. Ad Nurs Sci Resear: ANSR-104.

Received Date: 15 August, 2018; **Accepted Date:** 23 August, 2018; **Published Date:** 30 August, 2018.

Abstract

Background: *Post cardiac catheterization puncture site care is usually done with a tight pressure dressing in many institutions due to the belief that it should prevent the bleeding. This practice is uncomfortable to the patients. Nurses have also described difficulty in assessing the sheath insertion site in the groin when pressure dressing is in place. A new way of dressing using transparent film dressing (TFD) has approved and rated better with regard to: comfort, less pain, decrease hematoma formation and facilitates nurses' assessment of the puncture wound site after femoral sheath removal.*

Aim: *To determine the efficacy of a small transparent non pressure dressing compared with the traditional controlled pressure dressing applied to the femoral artery puncture wound to maintain hemostasis with respect to 3 outcomes: patient satisfaction, bleeding or hematoma formation, and nurse-reported ease of assessment of the groin site after the procedure.*

Materials and Methods: *Design: An experimental design, randomized study. Patients: 80 post cardiac catheterization patients were randomized to have their groins dressed either with pressure dressing (N = 40) or Transparent Film Dressing (N = 40). Patients ambulated 8 hours after the procedures. Outcome variables were hematoma formation or bleeding, patient discomfort, and nurse-reported ease of observation of the groin puncture site after the procedure. Five instruments were used for data collection: Demographic and medical data sheet, Hematoma Formation and Bleeding Scale, Skin Integrity Scale, Patient Discomfort and Pain Scale and Nurses Ease of Assessment Scale.*

Results: *Results of the study showed that 100% in TFD group vs. 55% in pressure dressing group reported feeling very comfortable (p value of 0.003). Hematoma formation was equal in the two dressing groups with no incidence of bleeding complications. Nurses rated the ease of assessing the groin significantly higher for TFD than for pressure dressings (p value of 0.000).*

Conclusion: *Dressing of the puncture site after cardiac catheterization with TFD was more comfortable than the conventional pressure dressing without any difference in hematoma or bleeding complications. So TFD can be used safely and comfortably after achieving hemostasis.*

Keywords: Groin Dressing; Pressure Dressing; Post Cardiac Catheterization Puncture Site Care; Transparent Film Dressing.

Abbreviations: TFD, transparent film dressing; CAG, coronary angiography; PTCA, percutaneous transluminal coronary angioplasty; ASA, acetylsalicylic acid.

Introduction

Cardiac catheterization with coronary angiography has become a common procedure performed worldwide. It is now considered a safe procedure that can be done on an outpatient basis [1]. These procedures involving arterial puncture carry a risk of access site complications estimated to occur in 1% to 5% of procedures. These complications range from simple hematomas to significant bleeding events requiring transfusion, extended hospital stay and possible surgical repair [2]. Also these procedures may be associated with serious complications, even when performed in a technically flawless fashion [3]. Pressure dressing has been used as the standard following sheath removal after percutaneous transluminal angioplasty (PTCA) in many institutions. Patients complain about discomfort while the dressing is in place, pain when the dressing is removed after discharge, and skin complications afterward. Many patients have experienced skin irritation where tape has been applied. Nurses have also described difficulty in assessing the sheath insertion site in the groin when a pressure dressing is in place [1]. Previous studies examining pressure dressing which was applied to other types of incision have failed to show a decrease in complication such as hematoma formation [4]. New techniques have been developed and used to decrease incidence of such complication. one of these techniques is the application of transparent film dressing (TFD) at puncture site after cardiac catheterization which approved and rated better with regard to: comfort, ease of use, ease of dressing removal, less pain, decrease hematoma formation, also better cosmetic appearance and greater patient acceptance were noted with the use of TFD [5]. Furthermore, this type of dressing will facilitate nurses assessment of the puncture site and enhance early detection of any complication might be encountered since nurses will have the ability to visually assess ongoing bleeding in the subcutaneous tissue immediately post cardiac catheterization [2].

Materials and Methods

Design: Experimental randomized controlled clinical trial.

Setting: This study has been conducted at cardiac catheterization Lab at tertiary teaching hospital in Saudi Arabia.

Study Patients: all patients who had just undergone diagnostic left heart catheterization (angiography) and angioplasty and whose introducer sheath could be removed and hemostasis at the puncture site could be obtained right after the procedure were included to participate. The study protocol was approved by our hospital ethics committee and written informed consent was obtained from all participants.

Random Sample of 80 patients underwent cardiac catheterization (diagnostic-therapeutic) through femoral approach were included in this study.

Exclusion Criteria: we excluded patients with the following features: non- femoral approach for the procedure, usage of the arterial sheath larger than 7-F size, known bleeding disorders, active bleeding in femoral access site before sheath removal, received thrombolytic within 48 hours of the time of procedure, injury to groin area from prior invasive procedure, systolic blood pressure greater than 190 mmHg or diastolic blood pressure greater than 110 mmHg, compression time more than 40 minutes required to obtain hemostasis ,inability to lie flat for at least 8 h after cardiac catheterization, hemodynamic instability requiring invasive blood pressure monitoring through the sheath or intra-aortic pump support , know to be allergic to any of the dressing material , unwilling to participate and no informed consent.

Procedure: Diagnostic cardiac catheterization and angioplasty was carried out traditionally via the right femoral approach using 6 F sheaths and catheter system. After sheath removal, hemostasis was obtained by a groin compressive device or manual compression for at least 20 minutes in each case. Special attention was given to make sure that all hemostasis was completed and stable before the dressing was applied. The person responsible for sheath removal and hemostasis was blind to the type of dressing being applied. In case hemostasis was not achieved in 20 minutes, the puncture site was compressed for another 10 minutes and repeated if necessary until the bleeding stopped. After hemostasis was obtained, the patients were then randomized to either the conventional tight pressure dressing or to a light dressing with transparent tape (Tegaderm).

- Group one assigned to pressure dressing which is made manually by cath. lab nurses and consisted of gauze dressing covered with 2 bulky abdominal gauze pads and tape.
- Group 2 assigned to the Transparent Film Dressing applied over 2x2 inch (5x5 cm) gauze sponge.

All patients were placed on absolute bed rest for at least 8 hours. Patients were allowed to have bed head elevated up to 45 degrees for meals or reading. Both groups were closely monitored for:

- Bleeding or hematoma formation.
- Patient's discomfort or complaint.

All nurses employed on the unit where patients were admitted after CAG or PTCA were trained to participate in the study. The nurses assess the patients every 4 hours for complains of discomfort in addition to the routine checking of vital signs and assessment of the groin site after sheath removal .

Data Collection Tools: Five tools have been used for data collection:

Tool (1)*:* Demographic and medical data sheet

Developed by the researcher for patient and it includes: age, gender, first catheterization, drugs used during angioplasty, type of pressure applied, and duration of bed rest before discharge and presence of any co-morbid conditions: DM, Hypertension, previous MI, COPD, high cholesteremia.

Tool (2)*:* Hematoma Formation and Bleeding Scale.

The hemostasis scale for evaluating hematoma formation and bleeding was originally developed by Christenson et al [6]. In 1995, it was modified by Hogan-Miller et al [7] by adding measurement of the hematoma in centimeters. Hematoma and bleeding were graded on an ordinal scale, 0 to 4, as follow ordinary:

- Benign: no bleeding, no hematoma
- Small hematoma, scant oozing: no intervention except application of 4x4 gauze
- Moderate hematoma or bleeding: application of manual pressure for less than or equal to 15
- Minutes
- Large hematoma (> 5 cm) or bleeding: extended pressure application for more than 15 minutes
- Requires surgical intervention, hematoma evacuation or pseudoaneurysm repair

Tool (3)*:* Skin Integrity Scale

Skin integrity was measured by visual inspection of the skin where the dressing was applied using the Skin Integrity Scale [7]. The groin site was graded on an ordinal scale, 0 to 4, as follow ordinary:

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

Tool (4) Patient Discomfort and Pain Scale

Patients were asked to rate how comfortable it was to remove the dressing and to rate the condition of the groin site when the dressing was removed. In order to rate the pain, patients were asked 'On a scale of 1 (very comfortable) to 10 (the most painful), how comfortable was it for you to remove the dressing?" the scale used was based on the Numeric Scale

Tool (5)*:* Nurses Ease of Assessment Scale

The nurse responsible about the patient is asked "Were you able to observe the groin site directly?" and the answer options are yes or no. Also the responsible nurse is asked to rate ease of groin site assessment for bleeding or hematoma once the dressing is placed on a scale from 1 (difficult to assess), to 5 (easy to assess).

Data Analysis: Data was collected then analyzed using SPSS program for data tabulation, presentation and statistical analysis. Data was coded then fed to the computer and verified before performing the statistical analysis. First descriptive statistics was calculated to determine the characteristics of the sample as well as the frequency and types of complication. Chi square test was used for statistical analysis. The level of significance selected for this study was $P \leq 0.05$.

Results

A total of 80 patients gave consent to be in the study. 40 of them were randomized to conventional tight pressure dressing and the other 40 to TFD. The study sample was 70% women and 30% men, with a mean age of 55 years (SD, 10.7). Time pressure applied to achieve hemostasis after sheath removal was ranged between 30-35 mints in both kinds of dressing. None of the demographic variables differed significantly among the 2 dressing groups (Table 1). The type of drugs received during catheterizations are described in (Table 2). Both dressing groups were balanced regarding the use of ASA, Plavix, Clexane and Warfarin.

All patients in both group had normal skin immediately after arterial sheath removal. The differences and change in skin integrity began to appear in 6-8 hours and 12-16 hours periods. After 6-8 hours, in pressure dressing group 75% had normal skin, 2.5% had definite erythema and 5% developed erythema and induration but in TFD group, all patients had normal negative finding. In 12-16 hours period, for the pressure dressing: 80% maintained normal ski , 10% had definite erythema , 2.5% had erythema or induration and 2.5% developed vesiculation while in TFD group, 90% of the patients maintained normal skin , 2.5% had definite erythema, 2.5% had erythema or induration and 5 % developed vesiculation. Skin integrity was maintained butter, although this difference was not statistically significant, in TFD group than pressure dressing group. **(Figure 1).**

Patients' Profile	Patients had Pressure gauze dressing N = 40		Patients had TFD N = 40		Test	
	No	%	No	%	X^2	P
Age : - 30-40 - 41-50 - 51-60 - 61- 70 - > 70	 3 11 14 10 2	 7.5 27.5 35 25 5	 1 17 15 5 2	 2.5 42.5 37.5 12.5 5	3.572	0.467
M ± SD	**(54.80 ± 10.7)**					
Gender: - Female - Male	 28 12	 70 30	 28 12	 70 30	0.000	0.596
Procedural Factor:						
Time pressure held: - >20 - 20-24 - 20-24 - 30-35 - 35-40	 5 5 17 13 0	 12.5 12.5 42.5 32.5 0	 3 20 14 1 2	 7.5 50 35 2.5 5	3.034	0.55
BMI: (30.50 ± 3.24) - Normal (18.5-24.9) - Overweight(25-29.9) - Obesity (> 30	 13 19 8	 32.5 47.5 20	 14 17 9	 35 42.5 22.5	0.037	0.982

Table 1: Patients' Baseline Characteristics.

Drug use	Patients had Pressure gauze dressing N = 40		Patients had TFD N = 40		Test	
	No	%	No	%	X^2	P
Aspirin: - Yes - No	 38 2	 95 5	 37 3	 92.5 7.5	0.213	1.00
Plavix: - Yes - No	 32 8	 80 20	 30 10	 75 25	0.287	0.790
Warfarin: - yes - No	 2 38	 5 95	 2 38	 5 95	0.000	1.00
Clexane: - Yes - No	 8 32	 20 80	 4 36	 10 30	1.57	0.348
Chronic Steroid use: - yes - No	 1 39	 2.5 97.5	 0 40	 0 40	1.013	1.00

Table 2: The studied Patients according to drugs used and their relations with type of dressing post catheterization.

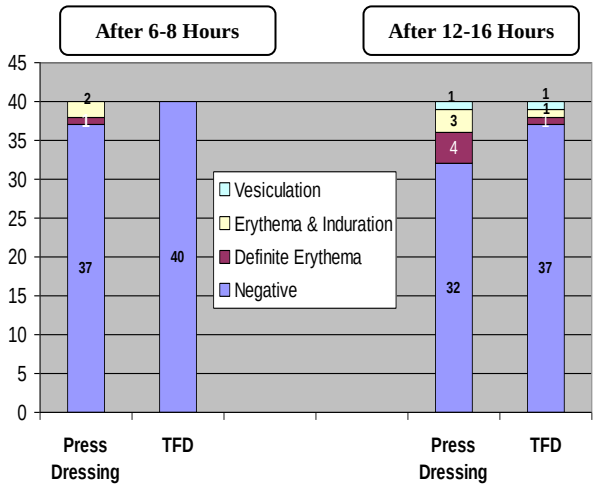

Figure 1: Impact of Type of dressing on skin integrity after femoral sheath removal post catheterization.

Hematoma and bleeding complication began to appear at 6-8hrs and 12-16 hrs. After 6-8 hours, incidence of hematoma was equal in both dressing group (3 patients had hematoma in pressure dressing and 3 patients in TFD). After 12-16 hours, incidence of hematoma was 6 patients in pressure dressing versus 4 patients in TFD. Hematoma formation was equal in the two dressing groups with no incidence of bleeding complications. **(Figure 2).**

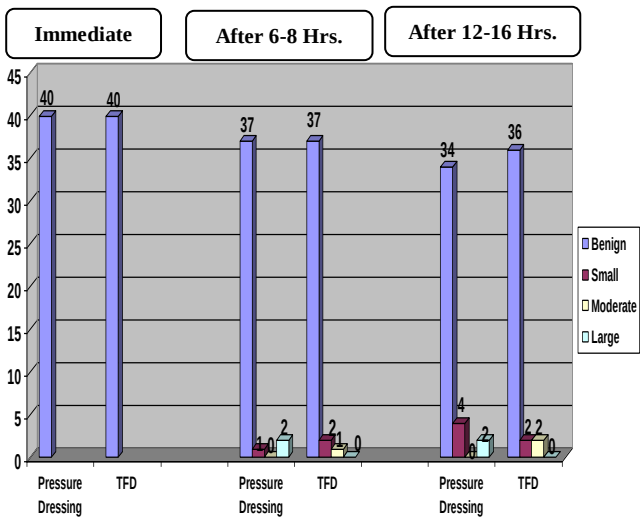

Figure 2: Impact of Type of dressing on incidence of hematoma and bleeding post catheterization.

Level of discomfort was assessed using the numerical pain scale. 40 patients in TFD versus 22 patients in pressure dressing reported feeling very comfortable **(Figure 3)** and this difference was statistically significant with p value of 0.003 **(Table 3)**. None of the patients complained of moderate or severe pain in TFD but 10 patients had moderate pain and 8 patients had severe pain in pressure dressing **(Figure 3).**

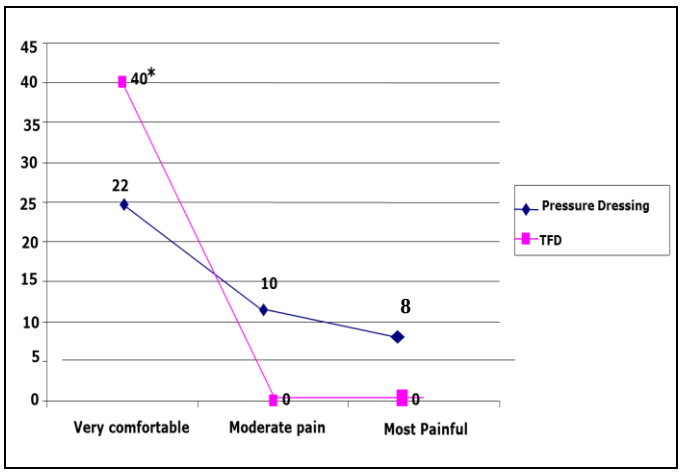

Figure 3: Impact of Type of dressing on patient discomfort and pain post catheterization**.**

Nurses have also participated in assessing groin puncture site area after the procedure in the ward. 32 nurses rated difficult assessment with pressure dressing and none of the nurses in TFD reported difficulty in assessing the groin area **(Table 4).** This difference was statistically significant with P value of 0.001 **(Figure 4).** In contrast, 37 nurses rated easy assessment with TFD versus nil in Pressure dressing group and this difference was statistically significant (P value 0.000).

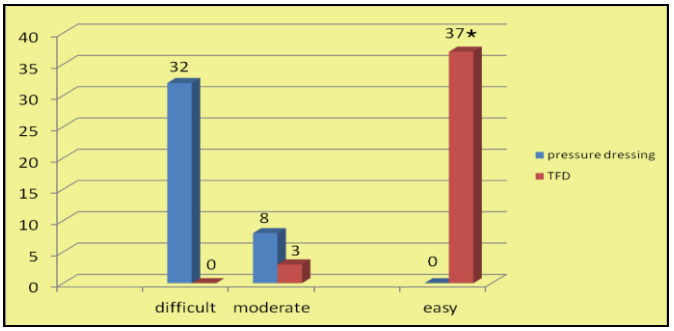

Figure 4: Impact of Type of dressing on nurses' ease of assessment of the groin for bleeding or hematoma.

Discussion

Puncture site care with dressing after cardiac catheterization is still considered a necessity in many cardiac centers. The major function is to keep the wound dry and clean. The application of a tight pressure dressing at the groin after femoral puncture is done with the notion that late bleeding complication can be prevented. An earlier study showed that late recurrent bleeding or hematoma could occur at the rate as high as 8-12 percent [5]. Several factors have contributed to the lower rate of late bleeding complication. Using a smaller sized catheter and abandoning routine heparin are the main factors [6].

We believe the most important step in preventing late recurrent bleeding or hematoma is the initial hemostasis attempt weather it is done manually or by closure device. Our study confirmed the impression that subsequent tight pressure with a sticky material was not necessary and in fact made patients uncomfortable. Our data showed that elastic adhesive tape application to the skin of a sensitive area such as the groin could be very uncomfortable and painful. More than 50 percent of the patients reported pain or discomfort with the adhesive tape in pressure dressing. The most painful or uncomfortable moment was during removal of such dressing due to the sticky nature of the adhesive tape. Hair pulling effect can and usually happens despite the best efforts to shave the groin area. These findings are consistent with the study done by Mcle et al who compared the application of pressure dressing, adhesive bandage and TFD over the puncture site in the groin area on 100 patients. These authors found that application of film dressing is more comfortable and reduce the incidence of puncture site complication [2]. Another study by Lue et al also supported the use of transparent film dressing after femoral sheath removal in which this dressing didn't lead to an increased bleeding or hematoma formation, and has provided greater comfort to patients [7]. Tegaderm is a piece of thin film that seals to the skin and it is very easy to apply and remove. The incidence of late recurrent bleeding and hematoma was slightly more, although not statistically significant, in the pressure dressing group. 6 F catheters were used in all the cases. Using TFD may have other advantages. It is Waterproof film, made of Hypoallergenic materials, provides effective bacterial barrier, reduce infection and easy to apply. The transparent nature of the film dressing allows early detection of bleeding or hematoma. The puncture site can be inspected directly. Theoretically, it should allow patients to take a shower after cardiac catheterization. Lastly, using TFD may be more economical. The cost of the Tegaderm is cheaper than pressure gauze dressing, if not the cheapest of the materials available in the market for wound dressing.

Conclusion

Dressing of the puncture site after cardiac catheterization with TFD was more comfortable than the conventional pressure dressing without any difference in hematoma or bleeding complications. So TFD can be used safely and comfortably after achieving hemostasis for both diagnostic and interventional cardiac catheterization.

Limitations of the study

Some limitations of this study were related to sample size and project design. Study was conducted on a relatively small number of cases. A relatively larger number and multi-center design are needed to confirm these results. Also limited time to finish this project is of big concern.

Conflict of interest

Author has no conflict of interest.

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