Groin Dressing After Cardiac Catheterization. Comparison Between Light Dressing with Thin Transparent Tape (Tegaderm®) and Conventional Tight /Pressure Dressing with an Elastic Adhesive Bandage (Tensoplast®)

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Abstract

Post cardiac catheterization puncture site care is usually done with a tight pressure dressing by an elastic adhesive bandage (Tensoplast®) due to the belief that it should prevent bleeding. The practice is uncomfortable to the patients. The authors compared a new way of dressing using light transparent tape (Tegaderm®) to the conventional tight pressure one. 126 post coronary angiography patients were randomized to have their groins dressed either with Tensoplast® or with Tegaderm®. Patients ambulated 8 hours after the procedures. The groin was evaluated for pain, discomfort and bleeding complications. 49 per cent in the Tensoplast® *vs* 26.9 per cent in the Tegaderm® group experienced pain (p value of 0.01). 55.5 per cent in the Tensoplast® group *vs* 11.1 per cent in the Tegaderm® group reported discomfort. 4.7 per cent in the Tensoplast® *vs* 1.6 per cent in the Tegaderm® group developed bleeding or hematoma. Dressing of the puncture site after cardiac catheterization with Tegaderm® was more comfortable than the conventional Tensoplast® without any difference in bleeding complications.

Key word : Groin Dressing, Post Cardiac Catheterization Puncture Site Care

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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). The procedure involves, puncture of the big artery such as the femoral artery. A catheter ranging from 5F to 8F is inserted through the femoral puncture site with or without the use of an intravascular sheath. After the procedure the hemostasis is obtained by either manual compression or by a compressive device. The puncture site is usually covered tightly with a pressure dressing using an elastic adhesive bandage (Tensoplast®) material(2). Weight such as a sandbag (2-5 Kg) is usually placed over the dressing. This is done because of the fear of recurrent bleeding or hematoma at the puncture site. This practice is cumbersome and can cause discomfort to the patient without the benefit of preventing recurrent bleeding or hematoma. We believe that the most important step to prevent the bleeding complication of the puncture site is the initial hemostasis. A subsequent tight pressure dressing may not be necessary. The 3M Tegaderm® Transparent Dressing is a waterproof, bacterial barrier which consists of a non-adherent absorbent pad bonded to a larger thin film backing coated with a border of hypoallergenic, water-resistant adhesive. It is commercially available and has been used widely for covering surgical wounds. Our hypothesis was that dressing of the puncture site after cardiac catheterization *via* the femoral route with this light thin film material was more comfortable and did not cause any more bleeding complications.

MATERIAL AND METHOD

Study Patients. All patients who had just undergone diagnostic left heart catheterization and angiography (Left Ventricle and Coronary) and whose introducer sheath could be removed and hemostasis at the puncture site could be obtained right after the procedure were invited to participate. The study protocol was approved by our institutional ethic committee and informed consent was obtained from all the participants.

Exclusion criteria. We excluded patients with the following features:

1. Hematoma greater than 2 cm right after the cardiac catheterization procedure or after initial intravascular sheath removal and hemostasis.
2. Compression time more than 40 minutes required to obtain hemostasis.
3. On an active anticoagulation regimen, i.e. IV or sq. heparin.
4. Inability to lie flat for at least 8 h after cardiac catheterization.
5. Hemodynamic Instability requiring invasive blood pressure monitoring through the sheath or intraaortic pump support.
6. Known to be allergic to any of the dressing material.
7. Unwilling to participate and no informed consent

Study Protocol.

Cardiac Catheterization and Angiography.

Diagnostic cardiac catheterization and angiography was carried out traditionally *via* the right femoral approach using 6 F sheaths and catheter system. The inguinal area of both groins were shaped and prepared using an antiseptic for sterile conditions. 1 per cent Lidocaine without epinephrine was used as the local anesthetic agent. A puncture of either the right or left femoral artery was done with an 18 G Cook needle after a small track of tissue overlying the artery was created by a scalpel and arterial forceps. Front wall puncture was encouraged in most cases although Seldinger type of puncture was acceptable. A 6 F sheath was placed over 0.38 short guide-wire. Insertion and exchange of catheters was done through this intravascular sheath. Manipulation of the catheter, mostly Judkins' type and pigtail catheter, was done in standard fashion. Low osmolarity contrast either with Ioxaglate (Hexabrix) or Iopromide (Ultravist) was used in all cases. Contrast media injection in the coronary artery was done by hand and power injector was used for LV injection. Heparin was not used in any of the procedure. Intraaortic pressure, ECG and finger oxymetry were monitored during the procedure. After all necessary information was obtained, the sheath was removed. Approximately 3 ml of blood was aspirated out of the sheath prior to its removal. Hemostasis was obtained by a groin compressive device (COMPRESSAR) 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 with Tensoplast® or to a light dressing with transparent tape Tagaderm®.

Conventional Pressure Dressing.

The elastic adhesive bandage (Tensoplast®) 7.5 cm in width was stretched out and cut into several pieces at lengths that would cover the distance from the anterior superior iliac spine to the inner thigh. 4X4 sterile gauze was placed on top of the puncture site and pre-cut pieces of Tensoplast® were applied on top by stretching one end to the anterior iliac spine and the other end to the inner thigh. In some cases, a figure of eight wrap was done according to physician preference.

Tagaderm® Light Dressing.

3M Tegaderm® dressing with an absorbent pad of 5 cm X 7 cm was applied and sealed to the skin with the absorbent pad on top of the puncture site. (Fig. 1)

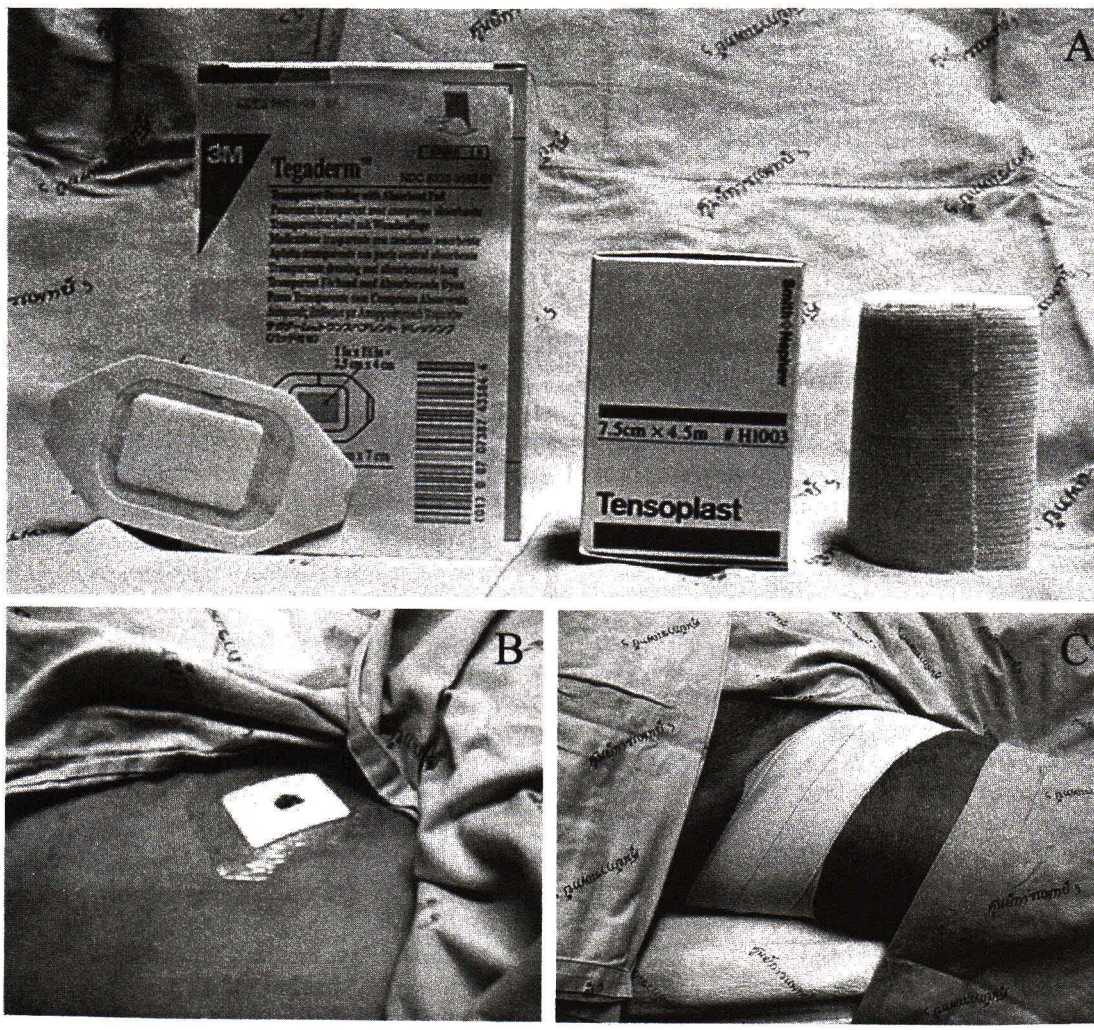

Fig. 1. A, Groin dressing material: 3M Tegaderm® and Tensoplast®. B, Light dressing with Tegaderm®. C, Pressure dressing with Tensoplast®.

Post Dressing Care.

All patients were placed on absolute bed rest for at least 8 hours. A 2-Kg sandbag was placed on top of the dressing in all cases. Patients were allowed to have the bed head elevated up to 45 degrees for meals or reading. The puncture site was checked every 20 minutes for one hour and every one-hour after that by lifting the sandbag up and inspecting for bleeding or hematoma. The patient was asked to ambulate after completing the 8 hours of bedrest and the puncture site was free from bleeding or hematoma. Both types of dressing were left in placed and the patient was discharged home or transferred to the ward or to another hospital. Patients were contacted by telephone 24 hours after they had left the cardiac catheterization laboratory. Upon being contacted by phone, patients were asked to remove the groin dressing themselves. Questions regarding the puncture site condition were answered at this time. Those who remained in the study site were checked the next day for puncture site complications. They were seen again at the cardiology clinic 7-10 days after discharge.

Endpoints.

Primary Endpoints.

Pain and Discomfort were the primary endpoints of the study. Each were separately evaluated and divided into 3 categories i.e. no pain or no discomfort at all; some pain or some discomfort and very painful and much discomfort. Attention was paid during application and removal of the dressing. In view of the analysis, the presence of any level of pain or discomfort was used as the marker of endpoints.

Secondary Endpoints.

Recurrent Bleeding or Hematoma and Skin reaction at the puncture site were the secondary endpoints. Recurrent Bleeding was defined as active reappearance of unclotted blood through the puncture site that was previously compressed and reapplication of the compression either manually or by device was required. Tainting of blood on the gauze overlying the puncture site was not counted as a bleeding complication. Hematoma was counted as the accumulation of blood in the connective tissue at the puncture site of more than 2 cm or larger regardless of blood transfusion status. If the two appeared in the same patient, it was counted as one event. Skin Reaction was described as redness of urticarial type around the puncture site.

Analysis.

From our experience with the elastic adhesive bandage after cardiac catheterization procedure approximately half (50%) experienced pain or discomfort. The rate of such similar untoward subjective complaints of using Tegade™ material in our experience with surgery patients was in the neighborhood of 5-10 per cent. Based on such expected event rate and significant level of 5 per cent and a power of 80 per cent, power calculation revealed that a sample size of 100 patients was required.

Statistical analyses were carried out using SPSS for Windows software. Analyses were done according to the principle of intention to treat, and all p value was two sided. The total number of patients, who developed untoward endpoints (both primary and secondary) in each group at any timeframe, was compared separately using student T-test. Combined endpoints were also compared in the same manner. More than one outcome could appear in the same patient and all events were counted and compared. Categorical data was compared using Fisher Exact Test. Conditional logistic regression was used for pain analysis and correlation. P value of <0.05 was considered statistically significant.

RESULTS

From June 1999 to January 2000, there were 690 patients who underwent diagnostic left heart catheterization and coronary angiography procedures. 140 patients were eligible for this study. 14 patients were excluded, 12 being unable to be contacted by phone and 2 being unable to lie flat after the procedure. Complete data were available in 126 patients, 63 of which were randomized to conventional tight pressure dressing with Tensoplast® material and the other 63 to Tegaderm®. Baseline characteristics did not differ significantly between the two groups. (Table 1) The groups were similar with regard to age, sex, body weight, number of punctures, time to hemostasis and total procedure time.

35 out of 63 patients (55%) in the Tensoplast® group *vs* 7 out of 63 patients (11%) in the Tegaderm® group complained of discomfort during the dressing period. The difference was statistically significant with p value of <0.001. 49 per cent (31 patients out

Table 1. Patients' baseline characteristics.

Characteristic	Group 1 (n=63)	SD	Group 2 (n = 63)	SD	P value
Age (yr)	59.52	9.13	59.22	9.18	0.854
Sex					
Male	30	47.61%	31	49.20%	0.859
Female	33	52.38%	32	50.79%	0.859
body weigh (kg)	59.86	16.96	64.66	19.07	0.138
Heigh (cm)	162.23	5.99	157.94	21.57	0.132
Number of puncture (time)	1.22	0.49	1.16	0.54	0.493
Time to hemostasis (min)	20.32	1.98	19.68	2.52	0.468
Procedure time (min)	32.76	20.75	35.22	18.69	0.119

Mean (SD) for quantitative data; *t*-test used fr comparison

Table 2. Endpoints according to study groups.

Events	Group 1 (n=63)	%	Group 2 (n = 63)	%	P value	RR	95% CI
Bleeding of hematoma							
Yes	3	4.761	1	1.587	0.619*	3.000	0.321-28.069
No	60	95.238	62	98.412			
Allergic reaction							
Yes	14	22.222	9	14.285	0.249	1.556	0.727-3.330
No	49	77.777	54	85.714			
Discomfort							
Yes	35	55.555	7	11.111	< 0.001	5.000	2.403-10.402
No	28	44.444	56	88.888			
Pain							
Yes	31	49.206	17	26.984	0.010	1.824	1.131-2.939
No	32	50.793	46	73.015			
Combined endpoints							
Yes	45	71.4	28	44.4	0.002**	1.607	1.170-2.207
No	18	28.6	35	55.6			

Number (%), * Fisher's Exact Test, ** Pearson chi-square

of 63) in the Tensoplast® group *vs* 26 per cent (17 out of 63) in the Tegaderm® group experienced pain. The p value for the difference was 0.01. (Table 2)

There was a slightly but not statistically significant higher incidence of recurrent bleeding or hematoma in the Tensoplast® group (4.7% *vs* 1.5%, p=0.619). Of the 3 recurrent bleeding in the Tensoplast group, 2 occurred at 8-hours post cardiac catheterization and 1 occurred at 24 hours. The only episode of recurrent bleeding in the Tegaderm® group occurred within the 8-hour period. All of the patients who developed bleeding complications were hospitalized overnight for observation. There was no additional vascular complication and all were discharged the next morning. There was a trend of lower incidence of allergic skin reaction in the Tegaderm® group (22.2% *vs* 14.2%, p = 0.249). (Table 2)

When all endpoints were combined, there was a significant difference between the two groups.

Table 3. Association between pain at application & removal and using Tegaderm® & Tensoplast®.

Factor	Odds ratio	95% CI of OR	P-value
Group			
Tensoplast®	2.786	1.356-5.726	0.005
Tegaderm®	1		
Time			
Removal	4.822	2.583-9.002	<0.001
Application	1		

Conditional logistic regression

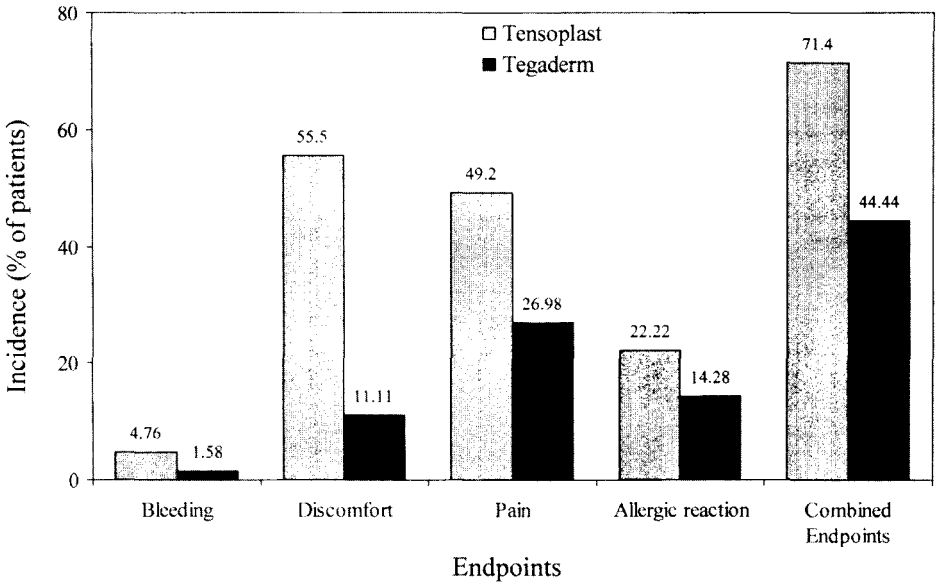

Fig. 2. Individual and combined endpoints comparison between Tensoplast® and Tegaderm® group.

More patients in the Tensoplast® group developed endpoints than the Tegaderm® group (71.4% *vs* 44.4%, p = 0.002). (Table 3, Fig. 2)

Analysis of Pain using conditional logistic regression, there was strong and significant association between the time frame and pain. The odds ratio of pain during removal was 4.82 and was independent of any type of dressing. (Table 3) The odds ratio of pain using Tensoplast® was 2.78 compared to the Tegaderm® group (95%CI 1.35-5.72, p = 0.005).

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 per cent[3]. Absolute bed rest, pressure dressing and application of weight such as a sandbag are the standard measures in most catheterization laboratories to prevent late bleeding. Later registry data revealed the rate to be much lower[4]. 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. We believe the most important step in preventing late recurrent bleeding or

hematoma is the initial hemostasis attempt whether it is done manually or by compressive device. Our study confirmed the impression that subsequent tight pressure with a sticky material such as tensoplast® was not necessary and infact 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 per cent of the patients in our series reported pain or discomfort with the adhesive tape. The most painful or most uncomfortable moment was during removal of such a dressing. It is probably due to the sticky nature of the adhesive tape. Hair pulling effect can and usually happen despite the best efforts to shave the groin area. Subjective endpoints were used in this study and the bias was kept as minimal as possible. The patients were asked to remove the dressing themselves and reported the effect it had immediately after. This would minimize the recall effect that memory can fade with time. 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 conventional Tensoplast® group. Placing a weight such as a sandbag on top of the groin with a tight tensoplast® dressing may not have the desired gravity effect. We believe that when the elastic bandage is stretched between the anterior superior iliac spine and the inner thigh, tension is created. This tension would act as a bridge preventing the intended weight from the sandbag going to the groin. Thin tape such as Tegaderm® would not cause such a tension effect and the intended weight pressure effect can be expected. We did not use heparin routinely and a 6F catheter was used in all the cases. Using a smaller catheter size e.g. 5F without heparin has been shown to reduce the femoral bleeding risk[5]. The practice of using Tegaderm® can be potentially applied to the patients after cardiac catheterization with a 4F-5F system.

Using Tegaderm® may have other advantages. Major Skin reaction, urticarial type in this study, was significantly less in the Tegaderm® group. This may be due to the hypoallergenic border of the film. The transparent nature of the tape allows early detection of bleeding or hematoma. The puncture site can be inspected directly. The film seals to the skin and is waterproof. Theoretically, it should allow patients to take a shower after cardiac catheterization. Lastly, using Tegaderm® may be more economical. The cost of the Tegaderm® is cheaper than Tensoplast®, if not the cheapest of the materials available in the market for wound dressing.

SUMMARY

Groin dressing after cardiac catheterization and angiography with the 6 F catheter system can be done safely and comfortably with 3M Tegaderm® transparent film.

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การปิดแผลหลังทำการสวนหัวใจและฉีดสีเข้าหลอดเลือดหัวใจวิธีใหม่

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หัตถการสวนหัวใจและฉีดสีเพื่อตรวจหลอดเลือดหัวใจเป็นหัตถการที่ทำกันเพิ่มขึ้นในประเทศไทย โดยมักจะทำการสวนหัวใจผ่านทางขาหนีบ งานวิจัยนี้ได้ทำการศึกษาเปรียบเทียบการปิดแผลที่ขาหนีบด้วยวัสดุชนิดใหม่ที่เป็นแผ่นใสบางเบา (กลุ่มเทคะเดิม) กับวัสดุชนิดเก่าที่มีผ้ายางเหนียวทึบ (กลุ่มเทนโซพลาส) โดยคัดเลือกผู้ป่วย 126 รายที่เพิ่งได้รับการทำหัตถการสวนหัวใจและฉีดสีเพื่อตรวจหลอดเลือดหัวใจให้ได้รับการปิดแผลอย่างใดอย่างหนึ่ง และติดตามวัดอาการเจ็ดปวด ความไม่สบาย และอัตราการเกิดภาวะเลือดออกที่ขาหนีบ ในระยะเวลา 8 ชั่วโมงที่นอนพัก และ หลังจากที่ให้ผู้ป่วยลุกเดินก่อนจะกลับบ้านในวันเดียวกัน และ 24 ชั่วโมงหลังจากที่ออกจากโรงพยาบาลไปแล้ว และพบว่า มีจำนวนผู้ป่วยมากกว่าที่ได้รับการปิดแผลด้วยเทนโซพลาส (วิธีเก่า) รายงานความเจ็บปวด (49% เทียบกับ 26.9%) ในช่วงปิดแผลหรือเอาวัสดุที่ปิดแผลออกก่อนจะกลับบ้าน บอกถึงความไม่สบายในระหว่างที่ได้รับการปิดแผล (55.5% เทียบกับ 11.1%) เมื่อเทียบกับในกลุ่มที่ได้รับการปิดแผลด้วยวัสดุใหม่ (เทคะเดิม) และความแตกต่างนี้มีความสำคัญทางสถิติที่ระดับ 0.01 การปิดแผลทั้งสองวิธีไม่มีความแตกต่างกันในอัตราการเกิดภาวะเลือดออกที่แผล ทางผู้วิจัยสรุปว่าการปิดแผลขาหนีบหลังหัตถการสวนหัวใจและฉีดสีด้วยวัสดุเทคะเดิมลดความเจ็บปวดและไม่สบายกว่าวัสดุเทนโซพลาสโดยไม่ได้ทำให้มีภาวะเลือดออกมากขึ้น

คำสำคัญ : การปิดแผล, การทำสวนหัวใจและฉีดสี

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