A Randomized Trial between Different Suture Materials (Polydioxanone vs. Poliglecaprone 25) and Different Suturing Techniques (Running Subcuticular Suture Alone vs. with Running Horizontal Mattress) in Prevention of Hypertrophic Scar Development in Median Sternotomy Wound

Boonlawat Homvises MD*

** Department of Surgery, Faculty of Medicine, Thammasat University, Pathumthani, Thailand*

Background: *Hypertrophic scar development after median sternotomy wound in cardiac surgery patients is quite common in surgical practice and becomes a major concern nowadays.*

Objective: *To compare cosmetic outcome between different suture materials and different suture techniques for skin closure in median sternotomy wound.*

Material and Method: *A randomized clinical trial was conducted in 80 patients who underwent cardiac surgery in Thammasat University Hospital, Thailand. In respect of the materials and the techniques used to suture the skin, the patients were randomly allocated to four groups. In group 1, the skin was closed with subcuticular running 4-0 Poliglecaprone 25 (Monocryl). In group 2, the skin was closed with subcuticular running 4-0 Polydioxanone (PDS). In group 3, the skin was closed with subcuticular running 4-0 Poliglecaprone 25 (Monocryl) and running horizontal mattress 6-0 Nylon. In group 4, the skin was closed with subcuticular running 4-0 Polydioxanone (PDS) and running horizontal mattress 6-0 Nylon. Postoperative evaluation was performed at 2 and 6 weeks, 3 and 6 months follow-up visits. The scar was analyzed in three parts: upper, middle and lower one third of the sternal wound. The outcome measures for surgical wound were width, height and overall appearance of the scar using the Vancouver scar scale (VSS). A linear visual analogue score (VAS) was preformed to assess pain and itch.*

Results: *At 6 months, there were no significant differences between 4 groups of patients in every parameters (width, height, VSS, pain score and itch score) at three different wound sites (upper, middle and lower). There was a statistically significant and progressive increase in scar stretching, height and total VSS from top to bottom of the sternum with the same pattern in all groups of patients ($p<0.05$). At 6 months, scar showed a statistically significant difference in width when compares to 6 weeks and 3 months ($p<0.001$).Female had a statistically significant difference of scar stretching at upper two third of the sternum ($p<0.05$). Female scar width was approximately 2 folds greater than male patient. During follow-up in group 3, two patients died postoperatively due to multi-organ failure and one patient developed wound infection.*

Conclusion: *There were no significant differences in cosmetic outcomes between different suture materials and different suture techniques.*

Keywords: *Polydioxanone, Poligiecaprone 25, Running horizontal mattress, Hypertrophic scar development, Median sternotomy wound*

J Med Assoc Thai 2014; 97 (Suppl. 8): S88-S94
Full text. e-Journal: *http://www.jmatonline.com*

Hypertrophic scar development after median sternotomy wound in cardiac surgery patients is quite common in surgical practice and becomes a major concern nowadays. The incidences are varied from 50-94%[1,2]. The development of hypertrophic scar can occur form multiple risk factors. Wound tension is one of the most important factors[3]. If wound tension is decreased, the development of hypertrophic scar will be decreased.

At Thammasat University Hospital, we routinely use running subcuticular technique with

Correspondence to:
Homvises B, Department of Surgery, Faculty of Medicine, Thammasat University, Pathumthani, 10120, Thailand.
Phone: 0-2926-9523, Fax: 0-2926-9530
E-mail: boonlawat@yahoo.com

Poliglecaprone 25 (Monocryl®) for closing median sternotomy wound. Monocrylis a monofilament absorbable suture which tensile strength at 2nd week is only 30%. At 2nd week, the healing process is not completed. Consequently, the increase of wound tension which overcomes tensile strength can be the cause of hypertrophic scar. Polydioxanone (PDS) is another monofilament absorbable suture, and its tensile strength at 2nd week is higher than 70%. At 6th week, the tensile strength is still maintained up to 35% while a maturation phase of healing process is developing[3,4]. Therefore, Polydioxanone may produce less scarring than Poliglecaprone 25.

Not only wound tension but good wound approximation and wound edge eversion are also important factors that affect the development of hypertrophic scar. Running subcuticular technique alone may not accomplish these goals. Re-approximation suture with running horizontal mattress is the method that may improve wound approximation and wound eversion. It has been shown that the development of hypertrophic scar decreases after using this technique[5].

In the present study, the authors investigated cosmetic outcome between different suture materials and different suture techniques of skin closure in median sternotomy wound and determined the new method to prevent the development of hypertrophic scar.

Material and Method

Patients

Total of 80 consecutive patients in the age group of 18 years or older who underwent cardiac surgery at Thammasat University Hospital, Pathumthani, Thailand from September 2009 to September 2010 were enrolled into this study. One patient who had wound infection and 2 patients who died after surgery were excluded from the present study. The effective study population was therefore 77 patients. The local ethics committee had approved the study protocol and all participants were asked to sign a written informed consent (MTU-SU-1-CR070-070/53).

Operative techniques

All patients underwent cardiac surgery, according to standard hospital practice with or without cardiopulmonary bypass (CPB). Perioperative Cefazolin for 24 hours(h) was given as prophylactic antibiotic. All sternal wounds were closed in layers (presternal fascia and subcutaneous tissue) with a running suture using an absorbable braided synthetic suture to relieve tension, close dead space and appose wound edges. In respect of the material and the techniques used to suture the skin, the patients were randomly allocated to four groups.

Group 1) Subcuticular running 4-0 Monocryl to be left in place (Mono).

Group 2) Subcuticular running 4-0 PDS to be left in place (PDS).

Group 3) Subcuticular dermal running 4-0 Monocryl to be left in place with running horizontal mattress (RHM) 6-0 Nylon to be removed with in 7 days (Mono + Nylon).

Group 4) Subcuticular dermal running 4-0 PDS to be left in place with running horizontal mattress (RHM) 6-0 Nylon to be removed with in 7 days (Mono + Nylon) (All wounds were closed bythe same surgeon, BH).

Outcome measures

The outcomes measures for surgical wound were (1) width of the surgical scar in millimeters, (2) height of the surgical scar in millimeters and (3) overall appearance of the scar measured on the Vancouver scar scale

The Vancouver scar scale (VSS) items measured vascularity, pliability, and height, each on a 3- to 6-point ordinal scale; pigmentation was measured on a 3-point categorical scale (Fig. 1).

A linear visual analogue score (VAS) (where 0 represented no pain/itch and 10 represented unbearable pain/itch) was preformed to assess pain and itch.

Follow-up

The scar was analyzed in three parts, defined respectively as:

1. Upperone-third: that overlying the manubrium of the sternum.

2. Middle one-third: that overlying the body of the sternum and lying between the breasts.

3. Lower one-third: that overlying the xiphisternum and extending onto the abdomen.

Postoperative evaluation of the wounds was performed at 2 and 6 weeks, 3 and 6 months. At 2 weeks, all patients were evaluated for wound infection, dehiscence, erythema or skin irritation. At 6 weeks, 3 and 6 months, a clinical data-blinded surgeon rated each scar on the relevant outcome measures. The surgeon did not see the patient scars with visible sutures in place, photographic, written or verbal for the information about the groups to which the

individual patients had been randomized.

Statistical analysis

Kruskal-Wallis test was used for the assessment of differences among 4 groups of patients. Mann-Whitney test was used for the assessment of differences between each group of patients. Univariate analysis (Linear regression test) was used to identify independent risk factors. The *p*-values less than 0.05 were considered to be statistically significant. All analyses were performed using SPSS software system, version 17 (Chicago, USA).

Results

Baseline characteristics (Table 1)

A total of 80 patients participated in the study (age range 25-81 years, 50 male patients and 30 females). There were no significant differences in most of baseline characteristics except in the group of Mono + Nylon which had significant lower creatinine level and high incidence of valve operation. During follow-up in Mono + Nylon group, two patients died postoperatively due to multi-organs failure andone patient developed wound infection.

Median sternotomy wound outcomes

At 6 months postoperatively, there were no significant differences between 4 groups of patients in every parameters (width, height, VSS, pain score and itch score) at three different wound sites (upper, middle and lower) (Table 2). Therefore, each group of patients was directly compared to each others in four different ways (Mono vs. Mono + Nylon, PDS vs. PDS + Nylon, Mono + Nylon vs. PDS + Nylon and Mono vs. PDS), which revealed nearly no significant differences in all parameters (Table 3).

Fig. 2 showed the results of analysis of the scars in all group of patient. There was a progressive

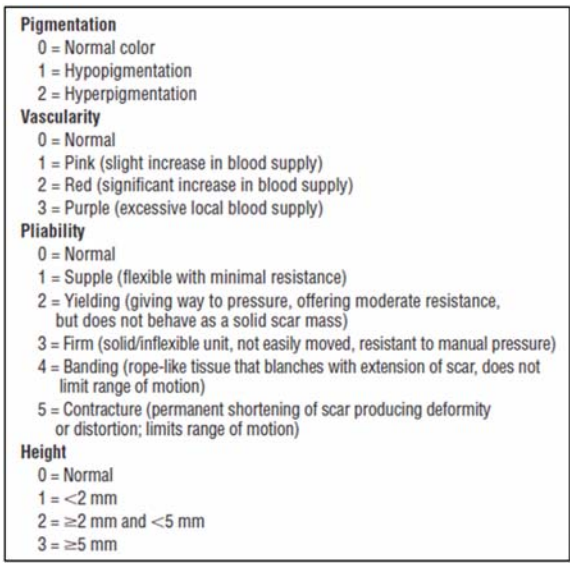


Fig. 1 Vancouver scar scale (VSS).

Table 1. Baseline characteristics

	Mono	Mono nylon	PDS nylon	PDS	Total	*p*-value
n	20	20	20	20	80	
Age (year)	62.2±11.9	59.4±14.1	62.1±11.2	58.9±15.9	60.8±13.2	0.428
Male/female, n	15/5	11/9	11/9	13/7	50/30	0.322
Operation (%)						0.010
CABG	11 (55)	9 (45)	13 (65)	14 (70)	44 (57)	
Valve	2 (10)	10 (50)	2 (10)	3 (15)	17 (22)	
Aorta	0	0	2 (10)	1 (5)	3 (3)	
Combine	6 (30)	1 (5)	2 (10)	1 (5)	10 (12)	
Others	1 (5)	0	1 (5)	1 (5)	3 (3)	
Diabetes (%)	7 (35)	5 (20)	4 (20)	8 (40)	22 (28)	0.377
Creatinine (mg/dl)	1.4±1.0	1.0±0.3	1.7±1.9	1.8±1.7	1.5±1.4	0.000
COPD (%)	1 (5)	1 (5)	1 (5)	0	3 (4)	0.891
Smoking (%)						0.931
Ex-smoker	6 (30)	4 (20)	4 (20)	4 (20)	18 (23)	
Yes	1 (5)	1 (5)	1 (5)	0	3 (4)	
Hypertension (%)	11 (55)	10 (50)	13 (65)	15 (75)	47 (61)	0.322

CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease

increase in scar stretching correlated with the duration after surgery. At 6 months, a statistically difference in width of scar was observed when compared to 6 weeks and 3 months ($p<0.001$).

Fig. 3 showed the results of analysis of the scars at 6 months after surgery. There was a progressive increase in scar stretching, height and total VSS from the top to the bottom of sternum with similar pattern in all groups of patients. The analysis showed a statistically significant difference in all scar parameters between the upper and lower parts of the scar ($p<0.05$).

Risk factors of scar development (Table 4)

Aging was the significant protective factor for scar development based on univariate analysis (Linear regression test), which lead to the conclusion that the older had better scar outcome. Surprisingly, active smokers tend to have better scar outcome too.

Table 2. Outcome measurement at 6 months in all 4 groups of patients

	Mono	Mono nylon	PDS nylon	PDS	Total	*p*-value
n	20	17	20	20	77	
Upper						
Width (mm)	1.10±1.50	1.10±2.10	1.00±1.10	1.60±2.50	1.20±1.90	0.978
Height (mm)	0.29±0.12	0.17±0.35	0.06±0.17	0.15±0.35	0.10±0.27	0.481
Total VSS	0.40±0.50	1.00±1.30	0.40±0.60	1.30±1.30	0.80±1.00	0.063
Middle						
Width (mm)	1.70±1.50	2.00±1.80	1.40±1.40	1.00±1.10	1.50±1.50	0.330
Height (mm)	0.26±0.39	0.55±0.84	0.30±0.45	0.15±0.35	0.32±0.56	0.374
Total VSS	1.10±1.30	1.70±1.80	1.20±1.60	1.30±1.30	1.30±1.50	0.708
Lower						
Width (mm)	2.50±1.80	3.20±2.00	2.20±2.20	2.20±2.20	2.50±2.00	0.344
Height (mm)	0.82±1.31	1.11±0.91	0.93±1.36	0.65±0.87	0.88±1.11	0.339
Total VSS	2.30±2.30	3.20±1.90	2.80±2.60	2.00±1.80	2.60±2.20	0.374
Pain score	0.20±1.20	0.20±1.20	0.30±0.80	0	0.20±0.90	0.531
Itch score	0.20±1.20	0.20±0.80	0.40±1.00	0.10±0.50	0.20±0.90	0.847

VSS = Vancouver scar scale

Table 3. Outcome comparison between each group of patients

	p-value			
	Mono vs. mono + nylon	PDS vs. PDS + nylon	Mono + nylon vs. PDS + nylon	Mono vs. PDS
Upper				
Width (mm)	0.721	1.000	0.668	0.952
Height (mm)	0.131	0.599	0.404	0.239
Total VSS	0.446	0.014	0.247	0.023
Middle				
Width (mm)	0.645	0.426	0.359	0.176
Height (mm)	0.371	0.338	0.441	0.333
Total VSS	0.408	0.397	0.361	0.499
Lower				
Width (mm)	0.295	0.951	0.113	0.559
Height (mm)	0.129	0.706	0.250	0.969
Total VSS	0.148	0.519	0.516	0.842

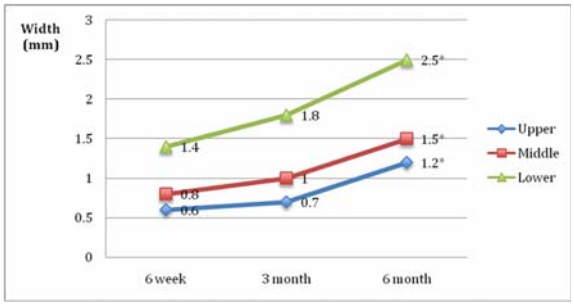
VSS = Vancouver scar scale

On the other hand, aortic and valve surgery had significantly poor outcomes, when compared to CABG.

Fig. 4 showed a difference in scar stretching between female and male patients. In female patients' group, scar width was a statistically significant different at upper and middle parts of sternum.

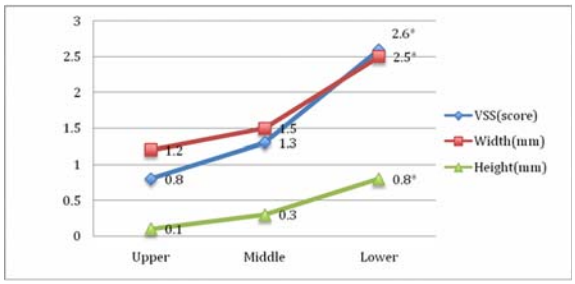
Discussion

There were many ways to assess severity of scar. In this study, we used objective scar measurement including scar width to determine scar stretching and scar height to determine scar hypertrophy. Vancouver scar scale (VSS), wildly used and acceptable method[6], was another method that we used to compare each wound. We found that the lower one third of the sternotomy incision had a greater tendency towards hypertrophic scar formation, regardless of the suture materials and this finding was similar to the previous studies[7,8]. Female predilection was another interesting factor that we found. Female had a statistically significant difference in scar stretching at upper two third of the sternum. Scar width was approximately 2 folds greater than male patient. It was known that hypertrophic scar formation was closely related to skin tension. Increased tension contributed to inferior cosmetic outcome, so the female breast may contributed to lateral force that caused more skin tensions in upper two third of the sternum.



* *p*-value <0.05

Fig. 2 Scar width in different time interval after surgery.



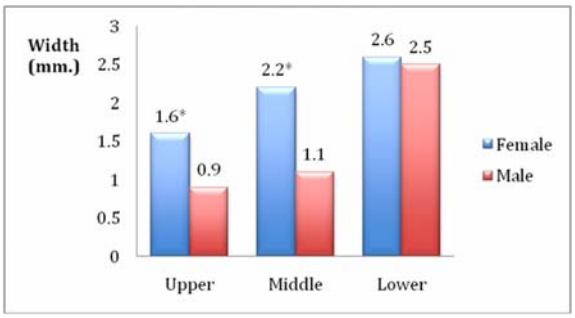
* *p*-value <0.05

Fig. 3 Scar width, height and VSS in different parts of the sternum.

Table 4. Risk factors of scar development in median sternotomy wound patient

	Univariate analysis (linear regression)					
	Width		Height		VSS	
	Coef (95% CI)	*p*-value	Coef (95% CI)	*p*-value	Coef (95% CI)	*p*-value
Age	-0.7 (-0.09, -0.04)	0.000	-0.0 (-0.01, 0.00)	0.081	-0.1 (-0.07, -0.28)	0.000
Female vs. male	-0.6 (-1.40, 0.14)	0.108	-0.1 (-0.33, 0.20)	0.621	-0.2 (-0.94, 0.42)	0.448
Operation (CABG vs.)						
Valve	0.8 (-0.04, 1.77)	0.063	0.2 (-0.02, 0.56)	0.068	0.9 (0.18, 1.63)	0.015
Aorta	1.8 (-0.31, 4.08)	0.092	1.2 (0.57, 1.99)	0.001	2.9 (1.15, 4.64)	0.002
Combine	0.2 (-0.91, 1.34)	0.700	0.1 (-0.25, 0.47)	0.557	-0.1 (-1.04, 0.75)	0.747
Others	0.7 (-1.04, 2.59)	0.398	0.3 (-0.21, 0.95)	0.216	1.0 (-0.37, 2.52)	0.144
D M	-0.2 (-1.02, 0.63)	0.642	-0.2 (-0.30, -0.26)	0.893	-0.4 (-1.12, 0.30)	0.256
Creatinine	-0.2 (-0.60, 0.14)	0.224	-0.6 (-0.18, 0.05)	0.273	-0.2 (-0.48, 0.15)	0.297
COPD	-1.6 (-3.42, 0.14)	0.071	-0.4 (-1.07, 0.16)	0.144	-1.4 (-2.98, 0.09)	0.066
Smoking (non-smoking vs.)						
Ex-smoker	-1.2 (-3.39, 0.90)	0.251	-0.0 (-0.76, 0.75)	0.992	-1.1 (-3.03, 0.75)	0.234
Yes	-0.9 (-1.82, -0.13)	0.023	-0.2 (-0.54, 0.50)	0.101	-0.6 (-13.9, 0.09)	0.087
HT	-0.5 (-1.34, 0.17)	0.128	-0.1 (-0.38, 0.14)	0.376	-0.3 (-0.99, 0.34)	0.332

Coef = coefficient; CI = confidence interval; VSS = Vancouver scar scale



* *p*-value <0.05

Fig. 4 Scar width between male and female in different parts of the sternum.

The two primary concerns with the RHM suture technique were mentioned, firstly wound edge necrosis due to constrictive effect on superficial skin vessels and secondly the risk of suture marks. We found only one patient from Mono + Nylon group who developed wound infection, which had no evidence of wound necrosis. The RHM suture will be removed at post-operative day 7. Therefore, at 6th weeks post-operation, we cannot detect any suture marks or any difference between each group of patients. There were some problems with RHM. Due to length of the sternal wound, RHM was slightly time-consuming procedure, which required approximately 15 minutes additional time. Another problem encountered was the need of stiches removal. It is important not to stich off later than 7 days. The longer the RHM sutures stay in place, the harder for stitches removal.

This study revealed no statistically significant differences in the development of median sternotomy scar (width, height, and VSS) between the 4 groups of patients. Even though comparing each group individually, we still could not detect any difference among the factors studied. Additionally, when postoperative pain and itch scores were compared, there was no significant difference among the four groups of patients. Future studies about new suture material or suture techniques should be performed to improve cosmetic outcome of the patients.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบระหว่างชนิดของไหมเย็บแผลและวิธีการเย็บแผลเพื่อป้องกันการเกิดแผลเป็นของแผลผ่าตัดบริเวณหน้าอก

บุลวัชร์ หอมวิเศษ

ภูมิหลัง: การเกิดแผลเป็น (hypertrophic scar) ตามหลังแผลผ่าตัด median sternotomy ในผู้ป่วยที่ได้รับการผ่าตัดหัวใจถือเป็นปัญหาสำคัญและพบได้บ่อยมากกว่าร้อยละ 50 โดยที่มีบางรายงานพบได้สูงถึงร้อยละ 90 โดยที่การเกิดแผลเป็นดังกล่าวนำมาถึงปัญหาความสวยงามของแผลผ่าตัดบริเวณหน้าอกต่อผู้ป่วยและในบางราย อาจมีอาการต่างๆ เช่น เจ็บหรือคันบริเวณแผลเป็นร่วมด้วย ในปัจจุบันยังไม่มีวิธีใดวิธีหนึ่งที่สามารถป้องกันการเกิดแผลเป็นดังกล่าวได้

วัสดุและวิธีการ: เป็นการศึกษาแบบสุ่มเลือก (randomized clinical trial) ในผู้ป่วย 80 ราย ที่ได้รับการผ่าตัดหัวใจผ่านแผลกลางหน้าอกที่โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ โดยจะแบ่งผู้ป่วยเป็น 4 กลุ่ม ตามวิธีและชนิดของไหมที่ใช้เย็บปิดผิวหนังผู้ป่วย กลุ่มที่ 1 ใช้วิธีเย็บแบบ subcuticular running ด้วยไหม 4-0 Poliglecaprone 25 (Monocryl), กลุ่มที่ 2 ใช้วิธีเย็บแบบ subcuticular running ด้วยไหม 4-0 Polydioxanone (PDS), กลุ่มที่ 3 ใช้วิธีเย็บแบบ subcuticular running ด้วยไหม 4-0 Poliglecaprone 25 (Monocryl) ก่อนแล้วเย็บชั้นบนวิธี running horizontal mattress ด้วยไหม 6-0 nylon, กลุ่มที่ 4 ใช้วิธีเย็บแบบ subcuticular running ด้วยไหม 4-0 Polydioxanone (PDS) ก่อนแล้วเย็บ ชั้นบนวิธี running horizontal mattress ด้วยไหม 6-0 nylon หลังจากนั้นจะประเมินผลหลังผ่าตัด เมื่อเวลาผ่านไป 2 สัปดาห์, 6 สัปดาห์, 3 เดือน และ 6 เดือน โดยจะแบ่งแผลที่ประเมินออกเป็น 3 ส่วน และจะประเมินลักษณะของแผลเป็นทั้งหมดโดยใช้ Vancouver scar scale (VSS) ร่วมกับ ประเมินความคันและเจ็บของแผลเป็นโดยใช้ linear visual analogue score (VAS)

ผลการศึกษา: โดยภาพรวมที่ระยะเวลา 6 เดือนหลังการผ่าตัด ไม่พบความแตกต่างของลักษณะของแผลเป็นหลังผ่าตัด ในผู้ป่วยทั้ง 4 กลุ่มอย่างมีนัยสำคัญทางสถิติ แต่ในผู้ป่วยทั้ง 4 กลุ่มพบว่าแผลเป็นจะมีความรุนแรงมากกว่า ที่บริเวณด้านล่าง 1/3 ของแผล และแผลเป็นจะมีการยืดออกมากขึ้นเมื่อระยะเวลาหลังผ่าตัดนานขึ้นซึ่งจะมีค่ามากที่สุดที่ระยะเวลา 6 เดือนหลังผ่าตัด อย่างมีนัยสำคัญทางสถิติ นอกจากนั้นยังพบว่าผู้ป่วยผู้หญิงจะมีความกว้างของแผลมากกว่าผู้ชายอย่างมีนัยสำคัญทางสถิติบริเวณของแผลด้านบน 2/3

สรุป: จากการศึกษาไม่พบความแตกต่างกันระหว่างวิธีการเย็บแผลและชนิดของไหมที่ใช้ต่อการเกิดแผลเป็น หลังผ่าตัดของผู้ป่วยผ่าตัดหัวใจ