Institutional report - Cardiac general

Is the use of Steri-Strip[™] S for wound closure after coronary artery bypass grafting better than intracuticular suture?

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Abstract

Several methods have been used in wound closure after coronary artery bypass grafting (CABG). In this study, the safety and efficacy of one of these methods, Steri-Strip[™] S is compared with the traditional intracuticular suture method. Eighty-one patients undergoing CABG were prospectively randomized into two groups according to the method of skin closure: Steri-Strip[™] S group and traditional suture group. Comparison between the two methods was done with regards to the length of the wound and the time needed to close it. The median closure time with Steri-Strip[™] S was 5.45 ± 3.35 min vs. 7.53 ± 3.41 min in the suture group. A pain score of ≥ 6 at the first postoperative day was found in 30% of the patients in the suture group vs. 14% of the patients in the Steri-Strip[™] S group (P=0.07). Cosmetic evaluation showed a non-significant difference in the linear visual analogue score in favor of Steri-Strip[™] S group compared to the intracuticular suture group (73.1 vs. 70.1) (P=0.07). Steri-Strip[™] S is a fast, safe alternative for wound closure of the sternotomy incision and graft harvesting site. A larger study is needed to establish the potential beneficial effect of Steri-Strip[™] S on wound infection prevention.

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Keywords: Surgical tape; Sutures; Surgical wound; Coronary artery bypass grafting

1. Introduction

During coronary artery bypass grafting (CABG) a sternotomy incision is made and usually a vein or radial artery is harvested from one of the extremities to be used as a conduit. These inflicted wounds are traditionally closed in two layers; one running subcutaneous suture and one running intracuticular suture. These wounds are at risk for surgical wound infection increasing the postoperative cost, hospital stay and antibiotic use. Swenne et al. [1] found that monofilament suture for skin closure was the most important risk factor for surgical wound infection at the saphenous vein harvest site.

Several studies acknowledge that intracuticular suture closure promotes localized inflammatory reaction and increases risk of infection [2, 3].

Other disadvantages of using an intracuticular suture are: inflicting of micro-traumata of the skin due to use of a needle, variability between surgeons, and strangulation or dehiscence of the skin when the suture is too tight or too loose, respectively. It is also time-consuming and there is a risk of needle stick injuries [4]. Non-invasive skin closure methods, such as skin closure tapes do not have these disadvantages and have proven to be a feasible and safe alternatives for surgical wound closure [5]. However, sur-

gical tape closure is not widely used in surgery because of fear of dehiscence of the wound after placement. A new commercially available wound closure tape produced by 3M is the 'Steri-Strip™ S'. It is constructed of soft polyurethane pads and interlaced polyester filaments to provide strong, secure skin closure on any length of wound. It uses two independent adhesive strips, which are placed on either side of wound-edges and subsequently are pulled together, after which they are fixed with multiple filament straps assuring better wound edge approximation and more strength after fixation.

In this study, we investigated the value of 'Steri-StripTM S' method in decreasing postoperative wound pain and complications compared to the traditional method of skin closure in patients undergoing CABG.

2. Materials and methods

2.1. Patients

A total of 81 patients in the age group of 18 years or older who underwent CABG in Catharina Hospital Eindhoven from January 2008 to July 2008 were enrolled in the study. The trial was conducted according to the principles of the declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act (WMO). The local Ethics Committee approved the study protocol and all participants were asked to sign a written informed consent.

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At baseline, patients were randomly assigned to either Steri-Strip $^{\text{\tiny M}}$ S treatment or intracuticular suture treatment.

2.2. Operative techniques

All patients underwent CABG, according to standard hospital practice with or without cardiopulmonary bypass (CPB) and had a saphenous vein or artery radialis harvested through a longitudinal incision in one of the extremities. Perioperative Cefalozin for 24 h was given as antibiotic prophylaxis. All sternal and extremity wounds were closed in layers with a running subcutaneous suture using an absorbable braided synthetic suture to relieve tension, close dead space and appose wound edges.

In the Steri-Strip™ S group, the skin was closed with Steri-Strip™ S (URL: www.3M.com/SkinHealth) which are placed on each side of wound-edges and subsequently pulled together, after which they are fixated. This causes the wound-edges to lie side by side. If applied the Steri-Strip™ S were removed two weeks after placement. In the intracuticular suture treatment group the skin was closed using a running absorbable monofilament synthetic suture. All wounds in both treatment groups were covered for three days with a standard dressing ensuring a total barrier between wound and air. Compressive elastic bandage was applied for 24 h, after which all patients wore an elastic stocking for six weeks to prevent oedema. Length and time required to close the skin of the surgical wound were recorded in the operation theater.

2.3. Follow-up

Postoperative evaluation of the wounds was performed at 1, 2 and 3 days, 2 and 6 weeks follow-up visits. During these visits, a linear visual analogue score (VAS) (where 0 represented no pain and 10 represented unbearable pain) was preformed to assess pain. At two and six weeks postoperatively an independent physician evaluated the surgical sites for infection, dehiscence, erythema or skin irritation. During the same postoperative visits, the physician rated the healing of the sternal and extremity wound separately according a four-point scale (where 1 represented not satisfied, 2 partially satisfied, 3 satisfied and 4 extremely satisfied).

Digital photographs of the sternal and extremity wound were taken at two and six weeks postoperatively. Consequently, these photographs were evaluated in pairs of photographs by a panel of a dermatologist and a cardiothoracic surgeon, who were blinded for the therapy. The observation panel was asked to rate the healing of the sternal and extremity wound separately again according a linear VAS (where 0 represented extremely dissatisfied and 100 extremely satisfied). Furthermore, they made comments of any adverse events they might observe.

At the six weeks postoperative visit all patients were asked to give a satisfactory score (where 1 represented not satisfied, 2 partially satisfied, 3 satisfied and 4 extremely satisfied).

Six patients were excluded from the analysis: two patients due to operative death, three patients due to re-exploration, and one patient had a prolonged intensive care stay.

2.4. Statistical analysis

All analyses are based on the intention to treat principle. χ^2 -Test was used to assess differences between categorical variables and unpaired t-tests to compare numeric variables. To determine non-inferiority, the two-sided 95% confidence interval (CI) of the difference was calculated and compared it with the maximum allowable difference of 5%. P-values of <0.05 were considered to be statistically significant. All analyses were performed using Statistical Product and Service Solutions Release 8.0 (SPSS Inc, Chicago, IL, USA) statistical software.

3. Results

A total of 81 patients participated in the study (age range 39–80 years, 66 male patients and 15 females). There were no significant differences in baseline characteristics summarized in Table 1. During follow-up, one patient died postoperatively due to heart failure and incomplete revascularization and five patients underwent re-exploration due to postoperative bleeding. There was no significant difference in hospital stay between the Steri-Strip™ S group and intracuticular suture group; although there was a tendency of shorter hospital stay in the Steri-Strip™ S treatment group (7.8 days vs. 9.3 days) (Table 1).

In both groups none of the patients developed wound infection, dehiscence of the wound, skin irritation or other serious adverse events.

Wound closure with Steri-Strip $^{\text{TM}}$ S was faster although not significant compared to intracuticular suture closure (median time 5.45 min vs. 7.53 min) (Table 2).

Evaluation of the wound one day postoperatively showed that the percentage of patients with a pain score of ≥ 6 was 30% in the suture group and 14% in Steri-StripTM S group (P=0.07). The second and third postoperative day, respectively, 19% and 4% of the patients had a pain score of ≥ 6 in the suture group vs. none in Steri-StripTM S group (P=0.02) and P=0.40. Even with a pain score of 5 or higher the percentage of patients was lower in the Steri-StripTM S

Table 1
Baseline characteristics

	Steri-Strip™ S (n=39)	Suture (n=42)	P-value	
Age (years)	64.7±10.2	64.2±9.4	0.86	
Male/female, n	32/7	34/8	0.89	
Operation				
CABG	33 (85%)	34 (81%)	0.60	
CABG and valve	6 (15%)	8 (19%)	0.60	
Diabetes	7 (18%)	8 (19%)	0.89	
COPD	3 (8%)	3 (7%)	0.82	
PVD	8 (21%)	7 (17%)	0.61	
Serum creatinine (mg/dl)	1.02 ± 0.26	1.02 ± 0.35	0.98	
BMI (kg/m²)	27.3 ± 4.0	27.2 ± 2.9	0.88	
Radial artery use	2 (5%)	2 (5%)	0.82	
ECC time (min)	81 ± 39.4	85 ± 32.1	0.68	
Hospital stay (days)	7.6 ± 3.4	9.3 ± 9.9	0.33	
30-day mortality	0	1 (2.7%)	0.33	
Lost in follow-up	2 (5%)	4 (9%)	0.45	

BMI, body mass index; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; ECC, extra-corporeal circulation; PVD, peripheral vascular disease.

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Table 2
Data of wound closure in both groups*

Steri-Strip [™] S (n=39)	Suture (n=42)	P-value
5.45 (2.83-22)	7.53 (2.06-13.93)	0.35
37 (22-90)	35.5 (20-61)	0.93
4.11 (1.35-8.18)	4.16 (1.18-11.30)	0.61
22 (16–26)	22 (17–27)	0.81
	5.45 (2.83–22) 37 (22–90) 4.11 (1.35–8.18)	(n=39) (n=42) 5.45 (2.83-22) 7.53 (2.06-13.93) 37 (22-90) 35.5 (20-61) 4.11 (1.35-8.18) 4.16 (1.18-11.30)

^{*}Data are expressed as median (range).

group than the percentage of patients in the intercuticular suture group (Fig. 1). Wound evaluation two and six weeks postoperatively showed no differences in satisfactory scores both objectively (by the physician) or subjectively (by the patients themselves) (Table 3).

Postoperative cosmetic evaluation by a blinded observational panel showed a slight difference in the VAS in favor of Steri-StripTM S group compared to the suture group if observed by a dermatologist 73.1 vs. 70.1 (P=0.07). There was no difference in VAS if observed by a cardiothoracic surgeon (Table 3).

4. Discussion

This study demonstrates that the use of Steri-StripTM S surgical skin closure device is a reasonable and safe alternative in a clinical setting if compared to wound closure with the traditional intracuticular suture. The most significant outcome was that there were no wound infections, dehiscence of the wound or skin irritation.

Karabay et al. [6] and Risnes et al. [7] demonstrated that the use of non-absorbable transcutaneous sutures in comparison with absorbable intercutaneous sutures reduces the incidence of superficial wound infection in patients undergoing medial sternotomy up to 8%. Non-absorbable sutures are removed at $\sim 7-10$ days after surgery in contrast to absorbable intracuticular sutures, that can stay for up to

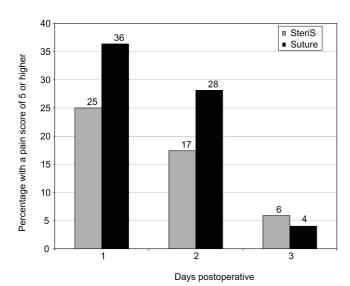


Fig. 1. Postoperative pain score in both groups. Day 1, P=0.34; day 2, P=0.32; day 3, P=0.77.

three months [7]. The longer the suture is situated in the cutis the greater the risk of inflammatory response and opportunistic infections through bacterial colonization. This may explain the difference in the rate of infection between the different wound closure techniques described. Adhesive skin closure tapes are applied on the surface of the skin thereby avoiding foreign objects in the intracutanenous layer; thus eliminating the possibility of bacteria colonization on the intracuticular suture. This might be beneficial in reducing intracuticular wound infections. Luckraz et al. [8] compared the use of adhesive paper-tape to suturing for closure of port-sites of video-assisted thoracoscopy. They confirmed the safety and cost-effectiveness of this new technique.

The median sternotomy and peripheral extremity scar can provoke dissatisfaction and psychological distress for both male and female patients especially young patients. Use of Steri-Strip $^{\text{TM}}$ S contributes to improved cosmetic results and can be beneficial in the psychosocial acceptations of CABG surgery.

Although our study was performed in a clinical setting, without exclusion criteria e.g. age, diabetes, peripheral vascular disease (PVD) and chronic obstructive pulmonary disease (COPD), there were also limitations. We could not make a distinct difference in prevalence of wound infection between the two groups. Studies show that the prevalence of wound infection after coronary bypass surgery occurs ~5%−8.9% [9, 10]. We did not see any occurrence of wound infection in our population suggesting that Steri-Strip™ S is just as good in preventing wound infections as traditional wound closure techniques. In this regard, Lazar and colleagues [11] found that 3M Steri-Strip S skin closure improves wound healing of saphenous vein sites, compared to traditional subcuticular skin closure techniques.

A six-week follow-up period is mandatory to evaluate cardiothoracic wound infection because higher infection rates are reported if follow-up is extended [12]. A longer follow-up period after surgery is needed to correctly assess scar formation and could have had a different outcome on the cosmetic rating. In this regard, Quinn et al. [13] found no difference in cosmetic assessment of wound closure of traumatic wounds in suture or tissue adhesive after three months and one year in their study population. They stated that cosmetic assessment of wounds three months after wound closure provides a good time-point of long-term cosmetic outcome.

We conclude that Steri-Strip[™] S is a safe alternative for wound closure of the sternotomy incision and conduit

Table 3
Satisfactory scores during follow-up in both groups

	Steri-Strip™ S (n=37)	Suture (n=38)	P-value	
Physician				
2 weeks	3.09 ± 0.58	$\boldsymbol{3.22 \pm 0.65}$	0.54	
6 weeks	3.63 ± 0.48	3.53 ± 0.67	0.48	
Patient				
6 weeks	3.38 ± 0.90	3.45 ± 0.67	0.67	
VAS dermatologist	73 ± 5.44	70 ± 8.15	0.07	
VAS cardiac surgeon	65 ± 6.57	65 ± 5.53	0.49	

VAS, visual analogue score.

harvesting site. However, larger sized studies are needed to determine if Steri-Strip™ S actually reduces the prevalence of wound infections.

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eComment: Assessment of sternal scars following coronary artery bypass grafting

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Steri-StripTM S wound closure following CABG surgery appeared to be faster than conventional suture as well as associated with less postoperative pain levels [1]. We would like to congratulate the authors for their efforts in performing a randomized trial on this issue. However, the authors failed to provide a significant difference in the cosmetic evaluation of the thoracic scar. One might argue that the visual inspection and assessment on a visual analogue scale from 0 to 100 does not necessarily reflect wound scarring effectively. The Vancouver Scar Scale for example has been introduced to reflect scarring in a more objective fashion with high interrater reliability [2]. Another potential assessment score is the Patient and Observer Scar Assessment Scale in this regard [3].

Furthermore, wound generation is a rather dynamic process with changes observed over at least 12 months. The authors assessed the sternal scars six weeks postoperatively which is, in our view, too early given the staged process of wound healing and regeneration. An interesting study focussing two time points (3 months and 18 months after burn injury) sought to correlate patients' opinion and Vancouver Scar Scale (VSS) data [4]. Notably, the three months data did not show any correlation, while at 18 months patients' opinion of the scar and the VSS correlated highly.

In order to overcome the afore-mentioned limitations, we would like to suggest that the authors re-evaluate their patients at least one year following surgery using both, the Vancouver Scar Scale as well as a patient assessment given the high level study design performed by the authors.

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