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SHORT COMMUNICATION

Randomised clinical trial of suture compared with adhesive strip for skin closure after HRT implant

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To determine which method of skin closure was associated with less bleeding, 250 women were randomly allocated to have either a suture closure (3-0 Dexon II) or an adhesive strip closure (Steri-Strip) following subcutaneous insertion of hormone (HRT) implants. Data were collected via a tested questionnaire and analysed. Significantly, more women in the adhesive strip group recorded postprocedure bleeding (RR = 2.26; 95% CI 1.42–3.60) and considered the bleeding excessive (RR = 4.17; 95% CI 1.18–14.76) and unacceptable (RR = 12.52; 95% CI 1.63–96.19). Pain scores and symptoms of local infection were similar in both groups. Routine use of adhesive strips for implant skin incision closure is not recommended.

Introduction

The subcutaneous implantation of oestrogen and testosterone pellets in the management of climacteric symptoms is widely used in the United Kingdom and other parts of the world[1,2]. The procedure involves making a small 5 mm skin incision, which can be closed with a suture, Band Aid plaster or recently with an adhesive strip. There is no information in the literature on which method of closure is preferable but anecdotal reports suggest that adhesive strips or Band Aid plasters are associated with more postprocedure bleeding. Although there have been studies on the use of adhesive tapes on large incisions[3,4], none has directly compared sutures with adhesive strips in the closure of small abdominal wall skin incisions in an outpatient setting.

The main objective of this study was to determine which method of skin closure following HRT implant was associated with less postprocedure bleeding and pain.

Methods

The study protocol was reviewed and approved by The South Essex Local Research Ethics Committee. Women who were referred to the implant clinic during the study period (1 May 2001 to 30 November 2001) were invited to participate in the study. Invitation letters were sent along with patient information leaflets 14 days before their clinic appointment.

Patients were randomised either to the suture group or to the adhesive group. Computer generated the randomisation schedule and an assistant sealed the allocations in opaque serially numbered envelopes. The clinic nurse opened the allocation envelope after a written consent was obtained.

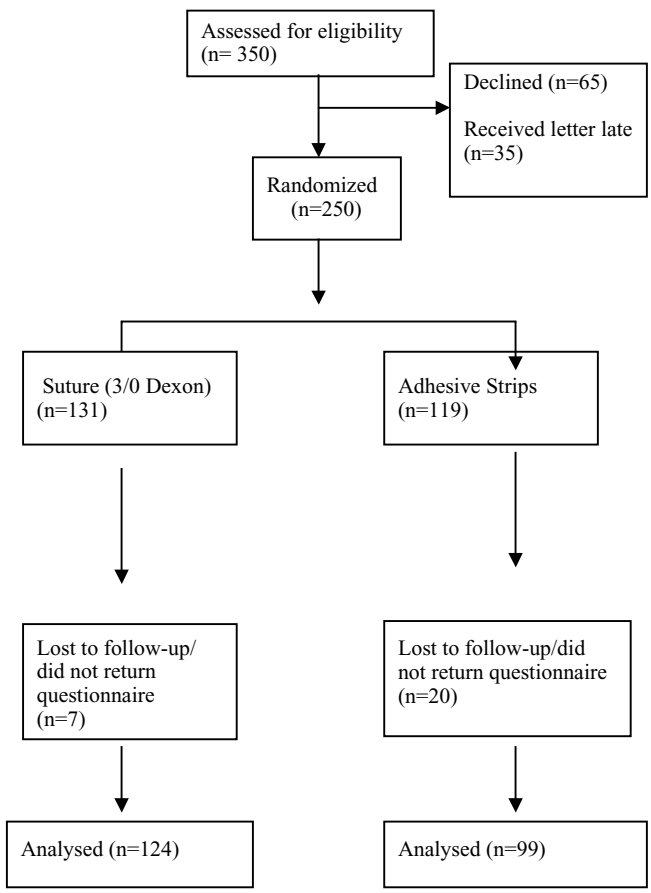

Fig. 1. Flow chart of trial.

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Table 1. Baseline characteristics of women at trial entry. Values are given as mean [SD], *n* (%).

	Adhesive group ($n = 99$)	Suture group ($n = 124$)
Mean [SD] age (years)	50.8 [8.8]	50.9 [6.7]
Race		
White	96 (97)	119 (96)
Other	3 (3)	5 (4)
Parity		
0	14 (14.1)	19 (15.3)
≥1	85 (85.9)	105 (84.7)
Prior oophorectomy	91 (91.9)	116 (93.5)
Prior implant use	87 (87.9)	110 (88.7)

Following randomisation, there were no withdrawals from the trial (Fig. 1).

The usual clinic procedure was followed and the hormone pellets were inserted as described by Thom and Studd[5]. The skin incision was then closed with a single stitch of 3-0 Dexon II suture or sterile adhesive strips (Steri-Strip), completely occluding the skin incision.

Each woman was given a tested questionnaire, which she would complete on the third day following the implant procedure. A prepaid stamped envelope was provided for the return of the questionnaire. The questionnaire ascertained the presence and duration of bleeding, the intensity of pain using a 10-point linear visual analogue pain scale, the presence of redness, swelling and discharge and whether resuturing was required. Collated data were entered on the computer by an assistant and cross checked by one of us (DOS).

Statistical methods

It was estimated that there was a 15% rate of bleeding problems using adhesive strip. To demonstrate a 10% reduction in bleeding complications at an alpha level of 0.05 and 80% power, 93 women were required in each arm of the study. Allowing for a 40% non-return rate, 250 women were recruited into the study.

Statistical analysis

The baseline data were analysed for statistical significance by using the Student's *t* test and the χ^2 test. $P < 0.05$ was considered significant. Relative risk (RR) and 95% confidence interval (CI) were calculated.

Results

Questionnaires were returned by 89.2% of the participants and only 6.3% of these did not answer all the questions. No questionnaire was returned unfilled. The two groups were similar for baseline characteristics (Table 1). Significantly, more women in the adhesive group reported postprocedure bleeding (RR 2.26; 95% CI 1.42–3.60), and considered the bleeding to be excessive (RR = 4.17; 95% CI 1.18–14.76) and unacceptable (RR = 12.5; 95% CI 1.63–96.19). There was no significant difference in the pain scores (RR = 0.77; 95% CI 0.52–1.15) and symptoms suggestive of local infection (Table 2). Six cases in the adhesive group needed resuturing and none in the suture group.

Discussion

This study confirms anecdotal reports that women whose skin incisions are closed with adhesive strips experience postprocedure bleeding more than those whose incisions were sutured. More of these women who had adhesive strips also considered the bleeding to be 'excessive' and 'unacceptable'. This can potentially lead to dissatisfaction with the procedure. The reason for postprocedure bleeding cannot readily be explained. It may be that the women promptly return to full activity immediately after the procedure and that body movements cause ineffective wound occlusion by the adhesive strip. In the study by Pedersen *et al.*[3], there was no incidence of wound haematoma following the use of adhesive strips but the subjects were patients with limited activity following major surgery.

Table 2. Comparison of outcomes in the two groups. Values are given as *n* (%).

	Adhesive group ($n = 99$)	Suture group ($n = 124$)	RR (95% CI)
Bled >2 hours	38 (38.4)	21 (16.9)	2.26 (1.42–3.60)
Excessive bleeding	10 (10.1)	3 (2.4)	4.17 (1.18–14.76)
Unacceptable bleeding	10 (10.1)	1 (0.8)	12.52 (1.63–96.19)
Redness[a]	51 (51.5)	79 (65.3)	0.78 (0.62–0.99)
Swelling[b]	32 (33.3)	43 (36.4)	0.91 (0.63–1.32)
Discharge[c]	6 (6.5)	2 (1.7)	3.77 (0.77–18.26)
Pain	28 (28.3)	45 (36.3)	0.77 (0.52–1.15)

[a]Based on 99 and 121 women, [b]96 and 118 women and [c]93 and 117 women in the adhesive and suture groups, respectively, that completed these aspects of the questionnaire.

There was no difference in the pain scores in this study. Rosen and Carlton[6] observed that patients whose laparoscopy wounds were closed with adhesive strips experienced the greatest level of pain in the immediate post-operative period. It may be that the laparoscopic procedure itself contributed to the pain.

Although the method of skin closure in those who have received hormone implant in the past was not ascertained, it is unlikely that this information would significantly alter the findings of this study. Quantifying the amount of blood loss in studies such as this is difficult and complex. Therefore, reliance was placed on subjective assessment recorded by the participants with the expectation that any bias would be nullified as both groups are equally affected. This could be perceived as a limitation of this study.

In conclusion, this randomised trial showed that more women whose implant skin incisions were closed with adhesive strips recorded postprocedure bleeding and felt that the bleeding was excessive and unacceptable. The authors therefore recommend that adhesive strips should not be the first choice for routine closure of skin incisions for HRT implants.

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