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Cyanoacrylate topical tissue adhesive for closure of permanent pacemaker wounds

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Key words

permanent pacemaker, sutures, tissue adhesive, wound management

doi: 10.5837/bjc.2014.024 Br J Cardiol 2014;**21**:115 t is unknown whether topical tissue adhesive provides comparable wound healing to absorbable sutures following cardiac device implant. This study was designed to compare wound closure using cyanoacrylate topical tissue adhesive with standard wound closure using absorbable sutures in patients receiving an elective permanent pacemaker implant.

Patients admitted for elective pacemaker implant were randomised to receive wound closure with either absorbable sutures or topical tissue adhesive (glue). Procedure duration, wound closure duration and wound size were recorded. Patients were evaluated at six and 12 weeks post-implant using validated wound evaluation scores by an experienced plastic surgeon who was blinded to the closure method.

Of 122 patients enrolled, 64 received topical tissue adhesive and 58 received absorbable sutures. Patients were well matched for baseline demographics. Use of topical adhesive was associated with shorter wound closure time (117 s, interquartile range [IQR] 92-136 vs. 277 s, IQR 231-311); no difference was seen in overall procedure duration. A total of 100 subjects completed review at 12 weeks. There was no significant difference in any of the wound evaluation scores measured. There was a trend to improvement in cosmetic appearance in patients who received topical adhesive, as judged subjectively by the blinded plastic surgeon. There was no difference in adverse event rates between the two groups.

In conclusion, use of topical tissue adhesive for wound closure following permanent pacemaker implant was not superior to traditional closure techniques with absorbable sutures with regard to cosmetic outcome.

Introduction

Closure of the skin layers following pacemaker implantation is usually achieved with absorbable sutures. This can be time-consuming and does not always achieve perfect cosmetic results. Cyanoacrylate topical tissue adhesive has been used as an alternative but only limited data exist advocating routine use for pacing.^{1,2} We undertook a prospective randomised study to compare cosmetic outcomes with cyanoacrylate and absorbable sutures for this indication.

Methods

Consecutive patients aged ≥18 years requiring elective first pacemaker implant were recruited. Exclusion criteria were presence of dermatological disease, impaired wound healing, immunosuppressive agents or active infection. All patients provided written informed consent.

Pacemaker implant was undertaken as per standard practice by six experienced operators, under conscious sedation (midazolam ± fentanyl) shielding the patient's face from the operative field. Following device implant, the pocket and middle layers were closed with polyglactin absorbable sutures (2/0 VicryI™. Ethicon, USA). Once (and only if) adequate haemostasis had been achieved, the patient was randomised to skin closure either by topical tissue adhesive (Liquiband®, Medlogic Global Ltd., Plymouth UK) or by 3/0 poliglecaprone 25 subcuticular sutures (Monocryl™, Ethicon, USA). At procedure completion, an opaque sterile bio-occlusive dressing was applied. Wound assessment was performed at 12 weeks by a plastic surgeon blinded to the closure method using the Hollander and Vancouver wound evaluation scores and an analogue scar scale.3-5

Using pilot data, we calculated that a total of 76 patients (38 per group) would be required to detect a 15 mm improvement in the visual analogue

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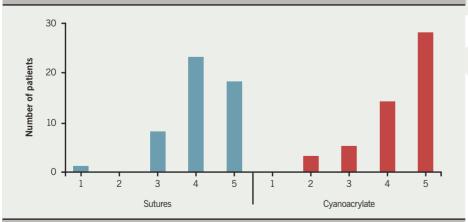
Table 1. Intergroup comparison of baseline demographics			
Demographic variable	Sutures	Cyanoacrylate	р
N	58	64	
Age, years	77.9 ± 12.6	77.5 ± 9.3	0.83
Male, n (%)	35 (60%)	45 (70%)	0.26
Height, m	1.69 ± 0.12	1.71 ± 0.10	0.32
Weight, kg	72.1 ± 18.2	80.5 ± 15.3	<0.01
BMI, kg/m ²	25.7 ± 6.9	26.9 ± 4.1	0.24
Diabetes mellitus, n (%)	10 (17%)	10 (16%)	0.81
Device type, n (%)			
Dual chamber	45 (78%)	50 (78%)	>0.99
Single chamber	13 (22%)	14 (22%)	>0.99
Procedural data			
Total procedure length, minutes	41 (31–57)	45 (32–58)	0.74
Wound closure time, seconds	277 (231–311)	117 (92–136)	<0.0001
Wound length, mm	37 ± 8	37 ± 8	0.76
Early complications,* n	1	2	>0.99
Wound outcome at 12 weeks	n=50	n=50	
Vancouver†			
 Vascularity (0–3) 	1 (1–2)	1 (0-1)	0.04
• Pliability (0–5)	0 (0-1)	0.5 (0-1)	0.29
• Pigmentation (0–3)	0 (0-0)	0 (0-0)	>0.99
• Height (0-3)	0 (0-0)	0 (0-0)	>0.99
• Total score (0-14)	2 (1–3)	1 (1–3)	0.34
Visual analogue scale‡			
• 0–100 mm	69 ± 15	74 ± 14	0.09

Intergroup comparisons by Fisher's exact test, unpaired t-test or Mann-Whitney U test as appropriate.

‡The visual analogue scale has a maximum score of 100 mm.

Key: BMI = body mass index

Figure 1. Modified Hollander wound evaluation score at 12 weeks



One point is assigned for each of the following parameters: scar width >2 mm; scar elevation or depression; discolouration; visible suture/staple or instrumentation marks; poor overall appearance. The maximum score is five. The median modified Hollander wound evaluation score at 12 weeks for cyanoacrylate was 5 (interquartile range [IQR] 4-5) versus 4 (IQR 4-5) for sutures (p=0.11)

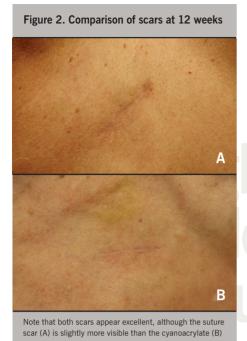
scar score with a power of 90% and 5% significance. To allow for drop out, we aimed to recruit a minimum of 120 patients. Analysis was performed on an intention-totreat basis using SPSS version 17.0.

Results

A total of 122 patients (mean age 77 \pm 10.9 years, 66% male) were recruited. Ninety-five (77.8%) patients received a dualchamber system. Fifty-eight (47.5%) patients were randomised to sutures, the remaining 64 (52.5%) patients were randomised to cyanoacrylate. Groups were well-matched for comorbidities (table 1). Total procedure duration (incision to skin closure) and incision length were similar in both groups. Skin layer closure time was shorter using cyanoacrylate - 117 (interquartile range [IQR] 92-136) versus 277 (IQR 231-311) seconds, p<0.001. Early complications were rare and unrelated to the closure method. There was no cross-over between either arm.

At six-week pacing clinic review the majority of wounds were graded as good - cyanoacrylate 50/53 (94%) and sutures 42/42 (100%), p=0.88. The three remaining wounds in the cyanoacrylate arm were considered suboptimal due to minor elevation or depression of the wound surface. No infections were noted. At 12-week follow-up, the median modified Hollander wound evaluation for cyanoacrylate was 5 (IQR 4-5) versus 4 (IQR 4-5) for sutures (p=0.11) (figure 1). Twenty-seven (54%) patients who received cyanoacrylate versus 18 patients (36%) who received sutures were considered to have an optimal scar (score of 5 on the score) (p=0.11). On the Vancouver scar scale, patients who had received cyanoacrylate had a median score of 1 (IQR 1-3) versus 2 (IQR 1-3) for sutures (p=0.34). Components of this scale were comparable between both arms, although cyanoacrylate seemed to produce wounds that were more vascular than sutures (p=0.04). Visual analogue scale assessment offered a mean score of 74 \pm 14 mm for cyanoacrylate compared with 69 ± 15 mm for sutures (p=0.09). In the cyanoacrylate arm, 17/50 (34%) versus 10/50 (20%) were considered to be excellent (p=0.38). The remainder were graded as good. A number

^{*}Complications were as follows: one pneumothorax in each group and a left-sided superior vena cava in the cyanoacrylate arm †The Vancouver scar scale ranges from 0-14, a normal wound has a score of 0,



of patients failed to attend both six- and 12week follow-up as they instead opted to be seen in community pacing clinics, thereby preventing formal wound evaluation. In all such cases, no concerns with wound healing were raised by the technical staff.

Discussion

This study demonstrates that regardless of closure method employed, pacing wound appearances are generally good, and even where early healing may be suboptimal, this can improve further with time (figure 2). At formal 12-week evaluation there were no

important differences between either closure method on the basis of the various (validated) wound assessment scores employed in this study. This is in contrast to other clinical settings, where cyanoacrylate has been shown to have better cosmetic outcome.6 The explanation for this disparity possibly relates to the nature of pacing, where scars are often of only short length (3-5 cm) and where limited instrumentation of the skin and underlying tissues is undertaken.

Wound complications of device implant are infrequent, but the consequences can be both unsightly (e.g. scarring) and devastating (e.g. pocket infection/erosion, sometimes necessitating device removal), all of which can relate to operator experience and procedure duration.^{7,8} Although the power of our study was clearly insufficient to detect a difference in rare events, data from other clinical settings suggest that cyanoacrylate offers a barrier against bacterial entry and is associated with lower rates of wound infection.9-12 This advantage was not clearly apparent in a separate prospective cardiac devices study, and it is, therefore, unknown whether cynoacrylate could be advantageous in reducing infection rates in this setting.2

Finally, although cyanoacrylate has potential for clinical advantage, the associated cost is greater. Within our institution, 3/0 poliglecaprone 25 subcuticular sutures (Monocryl™, Ethicon, USA) are procured for £2.04 and cyanoacrylate for £17.63 each. This equates to £15.59 additional cost per

case - still modest compared with the overall procedural cost.

Conclusion

In this prospective, randomised study, skin closure with both closure methods produced excellent cosmetic results with no clear advantage for either technique. However, cyanoacrylate has a number of potential advantages, including rapid skin layer closure, and provides an impervious barrier potentially protective against bacterial entry

Author contributions

TW and PJP co-designed the study, analysed the data and authored the paper; VN, RP, AL, IR and MRDB recruited patients, collected data and contributed to the manuscript; RP evaluated the wounds and contributed to the manuscript.

Conflict of interest

None declared.

Key messages

- Both sutures and cyanoacrylate provide cosmetically pleasing results
- Wound closure with cyanoacrylate is a quick and effective method for skin closure
- Cyanoacrylate may offer a protective barrier to limit bacterial wound entry
- The cost of cyanoacrylate is modestly higher than use of sutures

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