Original Article

A pilot study comparing two sites for incision during pacemaker implantation and their influence on the scar

Disha Lokhandwala, Aashna Gupta, Viral Desai, Gopi Krishna Panicker, Amit Vora

Objective: There are two most common incisions that are used during most pacemaker implantation procedures, with the first type of incision being inferior and parallel to the clavicle (Group C) and the second type of incision along the deltopectoral groove (Group D). We evaluated the scars resulting from the two types of incision to objectively evaluate the degree of superiority in cosmetic outcomes, between these two types of incisions.

Methods: Seventy-six patients who underwent left pre-pectoral pacemaker insertion were evaluated, close to 6 months after the date of the pacemaker implantation, using a simple scoring system based on atrophy, contour and colour of the scar. The likelihood of reduced severity in scar scores were compared between the two groups and the number of patients with elevation or inversion of the scar and with keloid formation were quantified.

Results: Seventy-six patients, with 47 belonging to the ‘Group C’ and 29 belonging to the ‘Group D’ were evaluated. The average length (C: 25 ± 2 mm; D: 24 ± 3 mm) and thickness (C: 25 ± 3 mm; D: 26 ± 2 mm) of the scars were not significantly different. The mean cumulative total scores in ‘Group C’ (198 ± 150) and ‘Group D’ (193 ± 131) were comparable. The odds ratio (OR) estimate showed that outcomes for atrophy (OR:0.73), contour (OR:0.53) and the cumulative total scores (OR:0.72) were also comparable.

Conclusion: This pilot study showed that the deltopectoral groove incision as a site of incision is comparable to the infraclavicular incision.

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1. Introduction

It is estimated that over 700,000 new pacemakers are implanted yearly, worldwide.¹ The pre-pectoral region is the most common site for pacemaker implantation and are known to result in visible scars at the site of implantation.² There are two commonly recognized incisions that are used during most pacemaker implantation procedures. The first type of incision is inferior and parallel to the clavicle, placed in the triangle over the anterior chest from the shoulders to the xiphoid line. The second type of incision is along the deltopectoral groove and is more in the direction of Langer’s lines, where the wound is under reduced tension and heals with minimum hypertrophy.² Each incision has its own advantages and disadvantages with the way in which the incision is made determining the ease of implant as well as access to the cephalic (for venesection), axillary and subclavian veins.

Anatomically, an incision along the Langer’s lines should heal better and, therefore, the incision along the deltopectoral groove may be considered superior to the incision parallel to the clavicle.³ The incision parallel to the clavicle is also considered to have an increased tendency for developing hypertrophic and keloid scars,⁴ probably as a result of the respiratory forces which are directed across the wound. However, the degree of superiority in cosmetic outcomes, between the scars which result from these two types of incisions, has not been objectively evaluated, till date.

We, therefore, evaluated the scars in patients who underwent pacemaker implantation, based on anatomical aspects regarding the healing of skin incisions, resulting from the incision along the deltopectoral groove and compared the 6-month old scars created by this type of incision with those created by incisions inferior and parallel to the clavicle.

https://doi.org/10.1016/j.ihj.2018.05.008
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2. Methods

Seventy-six patients who underwent left pre-pectoral pacemaker insertion from June 2015 to December 2015 were included after written informed consent. The scar assessment for each subject in this study was necessarily done close to 6 months after the date of the pacemaker implantation. This non-randomized, observational study was approved by an independent Ethics Committee.

The patients were grouped according to the type of incision (incision parallel and inferior to the clavicle in ‘Group C’ and incision along the deltopectoral groove in ‘Group D’, Fig. 1).

All patients included in the study had undergone pacemaker implantation by a single experienced cardiologist. To maintain uniformity, it was ensured that all subjects included had received the same suture material and technique of wound closure. The wound was closed with 2-0 Vicryl (J&J) using continuous sutures in 3 layers—prepectoral, subcutaneous and subcuticular (Fig. 2).

A standard case report form was used, in which the following details were recorded for each patient:

- Demographic details, including name, age, sex, address, contact details and body mass index.
- Pacemaker details, including diagnosis, date of implantation, time duration between implantation and examination and type of pacemaker.
- Clinical variables, including medical history of hypertension, diabetes mellitus, renal disease, liver disease, lung disease, heart failure, steroid use; any past surgical history; history of smoking and alcoholism.

For each patient, the scar details such as type of incision (parallel and inferior to the clavicle-‘C’ and along the deltopectoral groove-‘D’); associated itching and discomfort; length, thickness elevation, inversion of the scar (in ‘millimeters up to 2 decimal places) and keloid formation were systematically recorded. Each scar was photographed using a 13-megapixel camera in adequate lighting for all subjects. The photographs were cropped such that the reviewer cannot discern the type of incision. The photographs were then labeled with the same serial numbers and assessed by an experienced plastic surgeon. The plastic surgeon classified the scars using a simple scoring system, developed for the study (Table 1).

2.1. Statistical analysis

All statistical analyses were performed using SAS statistical software, version 9.4 (SAS Institute Inc). Demographic characteristics, such as the age and sex of patients, were analyzed using the Student t-test and the chi-square test for the inter-group comparison, respectively. The scores estimated for atrophy, color, contour and the cumulative total scores were compared between the two groups by ordinal logistic regression. The mean and standard deviation for atrophy, color, contour and cumulative total scores were also calculated. The number of patients with elevation or inversion of the scar and with keloid formation were also quantified. Post-hoc sample size calculations using nQuery based on the incisional scar scores as a primary endpoint were performed to assess the statistical power of the study and its results.

3. Results

Seventy-six patients were enrolled in this non-randomized, observational study, with 47 belonging to the ‘Group C’ and 29 belonging to the ‘Group D’. The mean age (C: 65.3 ± 14.8 years; D: 68.2 ± 12.5 years) and BMI (C: 26.4 ± 4.7; D: 25.8 ± 3.8) of the two groups was comparable. The duration of follow-up was longer in the ‘Group C’ (58 ± 21 weeks vs 25 ± 26 weeks, p < 0.001); this is because the operator had changed from the C incision to the D incision over the last few years. The gender distribution (C: M/F = 20/27; D: M/F = 17/12) and the proportion of patients with hypertension and diabetes mellitus in the two groups were also not significantly different. (Table 2) The average length (C: 25 ± 2 mm; D:24 ± 3 mm) and thickness (C: 25 ± 3 mm; D: 26 ± 2 mm) of the scars were not significantly different. There were no patients with keloid formation, hematoma or suture line infection.

The evaluation of the 6-month old scars, with respect to atrophy, color, contour and combination of these three factors showed that the mean scores for severity of scar in Group D was comparable to Group C, with the mean cumulative total scores being 1.98 ± 1.50 in ‘Group C’ and 1.93 ± 1.31 in ‘Group D’ (Table 3). The odds ratio estimates for the severity of scars in ‘Group D’ versus ‘Group C’, after adjusting for age and time to follow-up, ranged from 0.526 to 1.230 and were not statistically significant.

The post-hoc power calculation based on the number of patients in the study, the statistical test employed for comparing the ordinal scores in the patients and the upper bound estimate of the cumulative total score as a reference, demonstrated that the power of the study was only 42%.

4. Discussion

In permanent pacemaker implantation, two types of incisions are commonly practiced. The first is infraclavicular incision and the second is along the deltopectoral groove, which have been termed as ‘C’ type and ‘D’ type incision respectively. In the “infraclavicular” (C-type) incision, a 2.5 to 3.5 cm incision is made in the infraclavicular area parallel to the lateral third of the clavicle. The C-type incision provides access to both the cephalic vein (runs across) and subclavian veins and is used for either subcutaneous or subpectoral pocket formation. However, the Langer’s lines on the chest wall run obliquely, along the deltopectoral grooves. In comparison, the ‘deltopectoral’ (D-type) incision, the incision is made from approximately 1 cm below the clavicle, in the deltopectoral groove (indentation between the clavicular head of the pectoralis major medially and the deltoid laterally).
D-type incision runs along the cephalic vein and provides easier access to the axillary vein; it may limit access to the subclavian vein and the operator needs to ensure the pocket is made medially to the incision. Langer’s lines in the deltopectoral groove run almost perpendicular to the clavicle. Hence the ‘D’ type incision runs parallel to the Langer’s lines in the deltopectoral groove. Importantly, the C incision scar is usually visible with the usual dresses worn by girls and women; this has important psychosocial fallout.

A scar is an inevitable consequence of wound repair. Wound healing occurs over a series of stages, namely coagulation, inflammation, angiogenesis, proteoglycan synthesis, collagen deposition, epithelization and remodeling. The final phase is followed by scar maturation, where in the fibroblasts, capillaries, glycosaminoglycans and immature collagen of granulation tissue and the newly healed wound are replaced by relatively acellular, avascular scar tissue composed of mature collagen and scattered fibroblasts. These scars are initially seen as inflamed tissue, which

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**Table 1**

| Atrophy | Color | Contour |
|---------|-------|---------|
| Severe  | 3     | 3       | 3       |
| Moderate| 2     | 2       | 2       |
| Mild    | 1     | 1       | 1       |
| Very mild/Not significant | 0 | 0 | 0 |

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**Table 2**

| Characteristics | ‘Group C’ (Number of patients (n = 47)) | ‘Group D’ (Number of patients (n = 29)) | p-value |
|-----------------|----------------------------------------|----------------------------------------|---------|
| Age* (years)    | 65 ± 14 (32–79)                        | 68 ± 13 (40–89)                        | 0.3808  |
| Gender          | Males 20                               | Females 17                             | 0.1734*|
|                 | Number of patients with hypertension   | 24 (51%)                               | 18 (62%)| 0.3485  |
| Number of patients with diabetes | 14 (30%) | Number of patients with diabetes | 11 (40%) | 0.4629  |
| BMI             | 26 ± 5                                 | Number of patients | 26 ± 4 | 0.557   |

Note: *Values are mean ± SD # chi-square test.
progress to symptomless plaques of mature scars. The rate of healing of a scar and its appearance is influenced by a number of factors like the age of the patient, site of incision, direction of the incision and the tension across the scar. The single most important modifiable factor in scar healing is wound tension during the proliferative and remodeling phases, which is determined by the direction of incision. The tension vectors across the skin depend on the movement of the underlying structure, and high skin tension is most closely associated with adverse scar formation. In this context, Langer’s lines have been used as indicators of tension vectors with these lines running parallel to the main collagen bundles in the dermis.7,6

Langer’s lines are often considered to be guides for elective surgical incisions. Incisions made in the direction of Langer’s lines run parallel to the direction of collagen bundles in the dermis and are more likely to improve wound healing results as they are aligned to the collagen bundles. Several published studies have advocated using Langer’s lines for planning surgical incisions in various parts of the body.7–10

In the C-type incision, the incision line runs across the Langer’s lines while in the ‘D’ type incision, the incision line runs parallel to the Langer’s lines in the deltopectoral groove. Consequently, a C-type incision leads to scars healing under relatively higher tension and has an increased risk of forming adverse scars, while the ‘D’ type incision runs parallel to the Langer’s lines, minimizes wound tension and reduces the tendency to gap and intuitively suggested the likelihood of a superior cosmetic outcome.9

In the study, the ‘D’ type incision scars were reviewed after a comparatively shorter time period as compared to the duration of follow-up after ‘C’ type incisions. Considering the statistically significant difference in the duration of follow-up between the two incision types, we adjusted for this difference while estimating the odds ratio, which demonstrated that the healing of scars due to ‘D’ type incisions was comparable to the healing of scars due to ‘C’ type incisions. While the likelihood of scar scores with reduced severity were less than 1 for incisions in the deltopectoral groove with respect to atrophy and color of scar, these were not statistically significant. Thus, in our study, the healing of scars due to ‘D’ type incisions were comparable to the healing of scars resulting from ‘C’ type incisions.

In the current approach towards pacemaker implantation, which is a minimally invasive procedure, continuous refinement of the techniques is aimed at improving outcomes and the overall patients’ satisfaction. Based on the results from our evaluation, the deltopectoral incisions for pacemaker implantation provided an aesthetic outcome which was similar to incisions inferior and parallel to clavicle.

4.1. Limitations

Our study does have certain limitations. The pacemaker incision is minimally invasive and as such, the incisional length and thickness is of relatively small magnitude. The number of subjects required as such to robustly detect the comparative improvement in scar healing between the two types of incisions with more than 80% power, based on the scoring system, is significantly high (more than 300 subjects, based on post-hoc sample size calculations). The number of subjects in our study is, in this context, small. The post-hoc power calculation, based on the number of patients in the study and the statistical test employed demonstrated that only over 40% power was achieved.

Another limitation was that the evaluation of the incisional scars was limited to only the visual inspection and scoring by a single plastic surgeon, based on their atrophy, color and contour. A panel of three or more plastic surgeons would have helped determine the agreement on the scores and adjust for any potential bias. The patient’s perception about the cosmetic result was also not considered as a point of evaluation. While this allowed the evaluation of the results to be objective and without inter-subject variability, we acknowledge that the subjective evaluation of the cosmetic results by the patients would have added to the results of the study. The non-uniformity in the follow-up period was also a limitation in our study, which may have increased the variability in our scoring of the scar and reduced the power of our study. Future prospective evaluations with a longer and uniform follow-up period may help establish a conclusive result.

5. Conclusion

The scars resulting from the incisions in the deltopectoral groove for permanent pacemaker implantation were found to be comparable to those resulting from the infraclavicular incisions, based on the scoring system. The likelihood of scar scores with reduced severity in the deltopectoral groove incisions was not statistically significant as compared to the patient group which received infraclavicular incisions. This pilot study of 76 patient cases indicates the need for further evaluation of deltopectoral groove incision in order to ascertain if this incision method should be given preference over the conventional infraclavicular incision method.

Funding sources/disclosures/conflicts of interest

The authors do not have any disclosures, funding sources or conflicts of interest to declare for this study.

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