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DEVICES

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Cosmetic outcomes and quality of life in children with cardiac implantable electronic devices

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Abstract

Background: Axillary implant location is an alternative implant location in patients for cardiac implantable electronic devices (CIEDs) for the purposes of improved cosmetic outcome. The impact from the patient's perspective is unknown. The purpose of this study was to compare scar perception scores and quality of life (QOL) in pediatric patients with axillary CIED implant location versus the standard infraclavicular approach.

Methods: This is a multicenter prospective study conducted at eight pediatric centers and it includes patients aged from 8 to 18 years with a CIED. Patients with prior sternotomy were excluded. Scar perception and QOL outcomes were compared between the infraclavicular and axillary implant locations.

Results: A total of 141 patients (83 implantable cardioverter defibrillator [ICD]/58 pacemakers) were included, 55 with an axillary device and 86 with an infraclavicular device. Patients with an ICD in the axillary position had better perception of scar appearance and consciousness. Patients in the axillary group reported, on average, a total Pediatric QOL Inventory score that was 6 (1, 11) units higher than the infraclavicular group, after adjusting for sex and race ($P = 0.02$).

Conclusions: QOL is significantly improved in axillary in comparison to the infraclavicular CIED position, regardless of device type. Scar perception is improved in patients with ICD in the axillary position.

KEYWORDS
defibrillation, implantable cardioverter defibrillator, pacemaker, pediatrics, quality of life

1 | BACKGROUND

Pacemakers and internal cardioverters/defibrillators (ICDs) are widely accepted therapies in the pediatric population. These devices are generally referred to as cardiac implantable electronic devices (CIEDs). The standard transvenous implant location is via an infraclavicular incision, typically in the left chest. This approach may produce a significant scar that tends to spread with healing and may be raised or appears red. In addition, the contour of the device may be readily evident and these cosmetic changes may affect health-related quality of life (HRQOL), especially in young patients who are concerned about their body image. While alternative cardiac device implant locations have been suggested, they did not appear to be widely adopted.[1,2]

It is known that pediatric patients with chronic medical conditions have lower HRQOL when compared to healthy controls.[3–6] Patients with CIEDs have significantly lower HRQOL compared to patients with mild congenital heart disease (CHD) and healthy controls.[7–11] While it could be suspected that lower HRQOL would be related to factors, such as device shocks, lifestyle modifications, or activity restrictions associated with underlying cardiac disease, these factors were not associated with QOL in a prior report.[8] To our knowledge, no prior manuscript has specifically evaluated surgical scar appearance or location of the scar as possibly affecting QOL in pediatric pacemaker and ICD populations. Cardiac rhythm devices are being implanted in children with increased frequency.[12,13] Improving cosmetic outcomes from surgical scars may impact HRQOL and decrease the impact of disease.[2]

The axillary implant location is the most commonly used alternative approach for CIED implantation. With this approach, there are either no scars or only a small scar on the patient's chest, with the larger device scar being hidden in the axilla.[14] The purpose of this multicenter investigation was to compare HRQOL and patient perceptions of surgical scar comparing two different implant locations (infraclavicular vs axillary) among children with a CIED.

2 | METHODS

2.1 | Research design

This is a cross-sectional, multi-institutional study from eight tertiary care pediatric cardiology centers. Institutional review board approval was obtained at each site. Patient-parent pairs completed relevant questionnaires at a single outpatient visit at routine visits (usual state of health) after device placement. Data entry and quality control were performed by the Data Coordinating Center, based at Cincinnati Children's Hospital Medical Center (CCHMC). Statistical analysis was performed at Children's Hospital Colorado.

2.2 | Population

Demographic information (including self-reported ethnicity) was collected through parent report. Clinical information was collected through chart review. The primary diagnosis was that which resulted in CIED implantation.

Patients were eligible for enrollment if they were able to speak English, they were of age 8-18 years, and had a transvenous CIED. Patients were excluded if they had complex CHD, a prior sternotomy (including an epicardial CIED), thoracotomy or other significant scarring not caused by transvenous CIED implantation, implantation in the preceding 3 months, significant life events within the preceding 6 months (eg, serious illness [personal or family], death of family or friends, divorce/separation, or discharge of defibrillator), significant comorbid disease, or a diagnosed developmental delay that prohibited them from being able to complete the patient forms.

Our patient population was also compared to a healthy control population similarly to as reported in a previously published study.[8] This healthy control population was obtained from the initial PedsQL psychometric article and the PedsQL data from within the Pediatric Cardiac Quality of Life inventory (PCQLI) Validation Study.[6]

2.3 | Implantation procedure

Patients were analyzed based on CIED implant location type (infraclavicular vs axillary). Patients in the infraclavicular group had implantation of their CIED with a standard approach of a single incision in the infraclavicular area and the device implanted either in prepectoral or submuscular pocket.[14] Implantation of an axillary device was performed by using two different techniques.[1,15] The first technique involves making a small infraclavicular incision for lead placement and an axillary incision for placement of the device.[1] The second technique involves accessing the axillary vein, followed by making a 4-6-cm incision along the posterolateral margin of the pectoralis major muscle,[15] or making an incision along the anterior axillary line with the device placed in the anterior chest under the pectoralis muscle. Examples of the surgical scarring resulting from CIED procedures are presented in Figure 1. It is important to note that the decision with respect to device location or implant technique was determined by the patient and the physician at the implanting center. Patients included in this study had their devices implanted for >3 months prior to be asked to fill out questionnaires. Patients were therefore not randomized to device location. Also of note is that some implanting centers would utilize only one technique or would offer both. There was no specific date at which a center changed from one technique to the other.

2.4 | Testing inventory

2.4.1 | Patient scar assessment questionnaire (PSAQ)

The PSAQ (validated in adults) was used by patients to convey an opinion of their linear scar.[2] Adolescents (13-18 years) were asked to evaluate the scar on five domains: appearance, symptoms, consciousness, and satisfaction with appearance, and satisfaction with symptoms. Each domain is evaluated independently. A higher score reflects a poorer perception of the scar related to the domain being evaluated.

2.4.2 | Quality of life assessments

Patient-parent pairs completed the generic Pediatric QOL Inventory (PedsQL) to assess patient and parent-proxy HRQOL. The PedsQL generates a Total score, and Physical Health Summary and Psychological Health Summary subscale scores. The Psychological Health Summary score is a composite of emotional, social, and school functioning.[16] Using existing published data on normal patients, the PedsQL data generated by patients and parents from this study were compared to those of healthy children.[3] The maximum score for the PedsQL Total, Physical and Psychological Health Summary, and Psychosocial Health Summary subscale scores is 100. Children and adolescents also completed the Self-Perception Profile for Children (SPPC) and Self-Perception Profile for Adolescents (SPPA), respectively.[17–19] In the QOL study of cardiac devices in pediatrics by Czosek et al.[8], having an implantable cardiac device was associated with lower QOL inventory scoring. The authors report that key drivers of patient QOL were the presence of an ICD and CHD. For patients, self-perception was a key driver and for parents, behavioral issues were a concern.

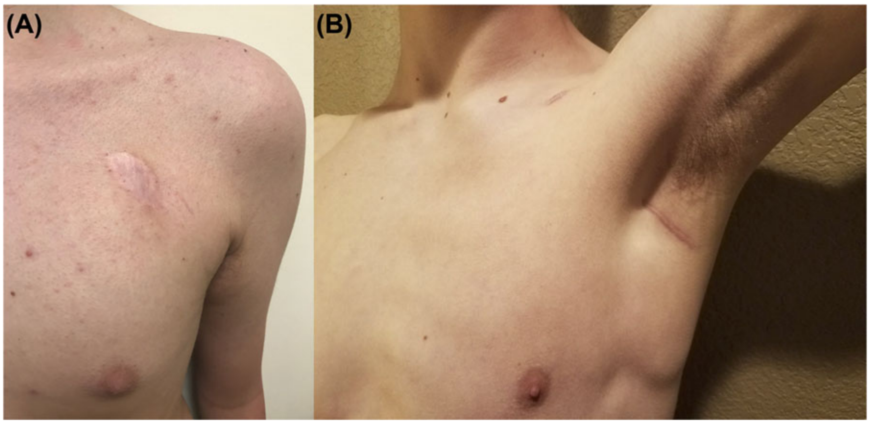

FIGURE 1 Surgical scarring and device location in patients with implantable cardiac devices. Panel A shows a patient with an implantable internal cardioverter defibrillator in the standard infraclavicular area. In this patient, the scar is stretched and is clearly visible. Because of the body habitus, the contour of the device is not evident as it would be in a smaller patient. Panel B shows a patient with an implantable internal cardioverter defibrillator with a 2-incision axillary approach. There is a small incision in the infraclavicular area which is less visible than in the patient in Panel A. There is a larger incision in the axillary area for the placement of the device. Because it is under the patient's arm, it is much less visible [Color figure can be viewed at wileyonlinelibrary.com]

2.5 | Statistical analysis

Patient and parent demographics between the axillary and infraclavicular groups were compared using *t*-tests and chi-square tests for continuous and discrete variables, respectively. We considered four outcome measures: PSAQ, PedsQL (Total, Physical Health Summary, and Psychosocial Health Summary), SPPC, and SPPA. Two-sample *t*-tests were used to assess whether there was a significant difference in QOL between the axillary, infraclavicular, and control groups for all patients, with a Bonferroni correction used to adjust for multiple comparisons. Paired *t*-tests were used to test the difference between patient and parent assessments. Pearson correlation coefficients between the PSAQ subscales and their corresponding global assessment variables were used to assess internal validity.

Multivariable linear models for the total PedsQL score, the difference between patient and parent PedsQL scores and PSAQ scores were used to test for an interaction between type of device and location of device. We considered seven variables as potential confounders in our multivariable models: age at first diagnosis, duration of device/time with scar, sex, race (white vs other), income (<50 000, 50-100 000, and >100 000), cardiac diagnosis (normal heart structure, cardiomyopathy, and CHD) and participation in independent education plans. Variables were included in the final model if they were significantly associated with the outcome based on simple linear regression. The significance was set at 0.05 and 0.017 for comparisons in PedsQL between the axillary, infraclavicular, and healthy control groups. For this comparison R version 3.1.1 software (R Foundation for Statistical Computing, Vienna, Austria, http://www.R-project.org/) was used.

3 | RESULTS

3.1 | Patient demographics

One hundred and forty-one patients were enrolled in the study (2011-2014). Axillary devices were implanted in 55 (39%) and infraclavicular devices in 86 (61%) patients. A summary of device type and implant location by center (blinded) is shown in Figure 2. Patient and parent demographics comparing the axillary versus infraclavicular implant location are presented in Table 1 and in Appendix Tables A and B for

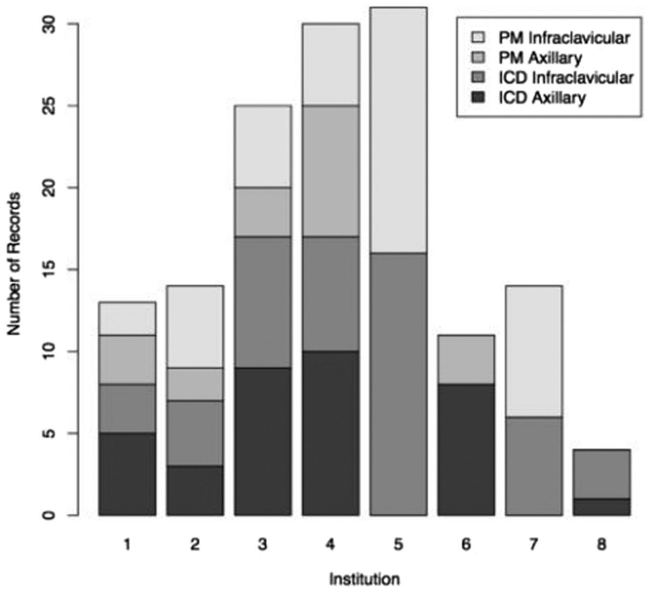

FIGURE 2 Device type and implant location by center. ICD = internal cardiac defibrillator; PM = pacemaker.

comparison of implant location by device. A greater proportion of children with a device in the axillary location were in individualized education programs (individualized objectives of a child intended to help the child reach educational goals more easily) (P = 0.0008). There was no significant difference between axillary and infraclavicular groups with respect to maternal education (P = 0.44) or family income (P = 0.46). There was no difference in the number of additional catheter- based or minimally invasive cardiac procedures unrelated to device or lead functionality (Appendix Table C). Additional cardiac electrophysiologic procedures in both groups included generator change, lead revisions, and device relocation.

3.2 | Patient scar assessment questionnaire

All four subscales were moderately to strongly correlated with their global assessment variables: appearance (rho = 0.6), consciousness (rho = 0.74), satisfaction with appearance (rho = 0.85), and

TABLE 1 Demographics of patients comparing axillary and infraclavicular device implant location

	Overall (*n* = 141)	Axillary (*n* = 55)	Infraclavicular (*n* = 86)	*P* value
Age at diagnosis, mean (SD)	9.3 (5.2)	10.2 (5.0)	8.7 (5.3)	0.10
Age at enrollment, mean (SD)	14.2 (2.8)	14.2 (3.1)	14.3 (2.7)	0.82
Time (years) with device, mean (SD)	2.7 (2.8)	2.1 (2.3)	3.2 (3.2)	0.02
Proportion of patients ≥13	101/139 (73)	36 (65)	65 (77)	
Sex, male	75 (52.8)	22 (41.5)	49 (57.7)	0.07
Device type, ICD	83 (58.8)	36 (65.4)	47 (54.7)	0.22
Race				0.08
White	116 (80)	40 (72.7)	73 (84.9)	
All others	29 (20)	15 (27.3)	13 (15.1)	
Education programs				**0.0008**
Individual education plan	37 (25.5)	23 (41.8)	14 (16.3)	
Regular school	108 (74.5)	32 (58.2)	72 (83.7)	
Family income				0.46
Less than \$50 000	41 (30.4)	12 (23.5)	27 (33.7)	
\$50 000-\$100,000	52 (38.5)	21 (41.2)	299 (6.3)	
Greater than \$100 000	42 (31.1)	18 (35.3)	24 (30.0)	
Cardiac diagnosis				
Normal heart structure	108 (74.4)	42 (76.3)	62 (72.1)	
Cardiomyopathy	23 (15.9)	9 (16.4)	14 (16.3)	0.77
Congenital heart disease	14 (9.7)	4 (7.3)	10 (11.6)	
Total cardiac EP procedures				0.37
0	106 (75)	42 (76)	64 (74)	
1	23 (16)	10 (18)	13 (15)	
2	7 (5)	3 (5)	4 (5)	
3	5 (4)	0 (0)	5 (6)	
Electrophysiologic diagnosis[a]				0.32
Sinus node dysfunction	9 (5)	2 (3)	7 (6)	
Cardioinhibitory syncope	7 (4)	5 (8)	2 (2)	
Second/third degree AV block	38 (22)	14 (22)	24 (22)	
Ventricular tachycardias	90 (52)	34 (53)	56 (51)	
Other	30 (17)	9 (14)	21 (19)	
Infection	1 (1)	0 (0)	1 (1)	1
Complication	19 (13)	5 (9)	14 (16)	0.33
ICD				0.26
Primary prevention	58 (70)	28 (78)	30 (64)	
Secondary prevention	25 (30)	8 (22)	17 (36)	
ICD discharge	52/83 (63)	26 (72)	26 (55)	0.18
Number of appropriate discharges**	18/29 (62)	6/10 (60)	12/19 (63)	1
Median	2 (2, 5)	2 (1, 2)	3 (2, 6)	0.28
Number of inappropriate discharges**	10/28 (36)	5/10 (36)	5/18 (28)	0.47
Median	2 (1, 5)	1 (1, 2)	3 (2, 6)	0.29

*Unless otherwise indicated, all data is *n* (number) with %l.
**Median (interquartile range). *P* value from Wilcoxon rank sum test.
[a]Multiple diagnoses possible.
$p < 0.05$ is statistically significant. AV = atrioventricular; ICD = implantable cardioverter defibrillator; EP = electrophysiology; IEP = individualized education program; SD = standard deviation.

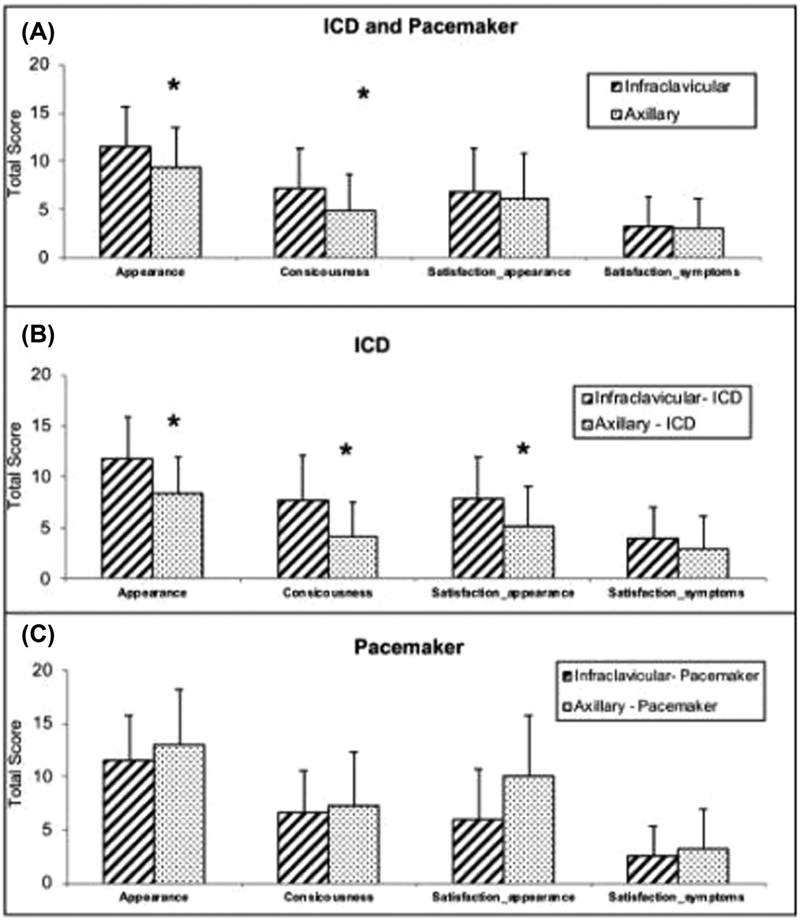

FIGURE 3 PSAQ scores reported for appearance, consciousness, satisfaction with appearance, and satisfaction with symptoms. (A) Comparison of infraclavicular and axillary patients. Patients with an infraclavicular device scored significantly higher (poorer scar perception) in the appearance ($P = 0.01$) and consciousness ($P = 0.006$) domains when compared to patients with an axillary device. (B) Comparison of PSAQ scores by implant location in patients with an ICD. Patients with an infraclavicular ICD scored significantly higher (poorer scar perception) in the appearance ($P = 0.001$), consciousness ($P = 0.0008$), and satisfaction with appearance ($P = 0.01$) domains when compared to those with an axillary ICD. (C) Comparison of PSAQ scores by implant location in patients with a pacemaker. There was no significant difference in PSAQ scores in any domain when comparing the axillary and infraclavicular group. ICD = implantable cardioverter defibrillator; PSAQ = patient scar assessment questionnaire. *Denotes statistical significance

satisfaction with symptoms (rho = 0.83). Patient PSAQ scores are reported in Figure 3.

Duration of device, race, and income were significantly associated with at least one of the PSAQ subscales and were adjusted for in each subscale's model. Age at first diagnosis, individual education plans, and cardiac diagnosis were not significantly associated with any of the subscales. The difference in satisfaction with appearance between axillary and infraclavicular placement was significantly different between the ICD and pacemaker groups. Within the ICD group, there was no statistically significant difference between locations, although patients in the axillary group had greater satisfaction with the appearance of their scars compared to the infraclavicular group by 2 points (95% confidence interval [CI]: −4, 1). Within the pacemaker group, patients in the axillary group were significantly less satisfied with the appearance of their scars compared to the ICD group by 4 points (95% CI: 1, 8). After adjusting for device type, consciousness was rated significantly more favorably in the axillary group relative to the infraclavicular group by 2 points (95% CI: −3, 0). There was no statistically significant difference in appearance or the satisfaction with symptoms between the two locations, after adjusting for device type.

3.3 | Pediatric QOL Inventory (PedsQL)

Table 2 summarizes univariate and multivariable model results for total PedsQL. In an unadjusted analysis, there was no difference in patient PedsQL total or subscale scores between the axillary and infraclavicular groups. Sex and cardiac diagnosis were significantly associated with the PedsQL total score in univariate analysis. The association between race and PedsQL total score was not statistically significant; however, we included it as a covariate in our adjusted model based on the large effect size and previously reported importance.[8] In the multivariable model, the difference between axillary and infraclavicular placement was not significantly different between the ICD and pacemaker groups (interaction $P = 0.603$). Based on the adjusted model (shown in Table 2), patients in the axillary group reported, on average, PedsQL Total scores were 6 points higher than the infraclavicular group.

In an unadjusted analysis, patients assessed their quality of life to be, on average, higher than their parents did (mean difference: 4.8, 95% CI: 2, 7.5) ($P = 0.001$). Race and cardiac diagnosis were significantly associated with the difference in score between patients and parent-proxy reporters. In an adjusted model assessing for the difference in PedsQL Total score between patients and parent-proxy reporters, the interaction between device type and location was not significant ($P = 0.5$). In the final multivariable model, there was no difference between patient and parent-proxy reported PedsQL Total score between the axillary and infraclavicular groups ($P = 0.2$).

In comparison to healthy controls, device patients and parent-proxy reports had lower HRQOL regardless of device location (Figure 4). Figure 5 shows ICD patients compared to healthy controls. Figure 6 shows axillary patients compared to healthy controls.

TABLE 2 Univariate and multivariable predictors of PedsQL

	Univariate predictors		Multivariable predictors	
Variable	Coefficient (95% CI)	*P* value	Coefficient (95% CI)	*P* value
Sex (M vs F)	6.29 (1.51, 11.07)	0.01	7.4 (2.77, 12.03)	0.002
Race (White vs other)	−5.89 (−12, 0.23)	0.06	−1.43 (−7.41, 4.54)	0.63
Cardiac diagnosis				
Cardiomyopathy vs normal heart structure	−8.85 (−15.47, −2.23)	0.01	−6.35 (−13, 0.29)	0.061
Congenital heart disease vs normal heart structure	4.23 (−3.64, 12.1)	0.29	3.54 (−3.9, 10.98)	0.34
Congenital vs cardiomyopathy	13.08 (3.56, 22.6)	0.008	9.9 (0.62, 19.2)	0.04
Location (axillary vs infraclavicular)	3.91 (−1.04, 8.87)	0.12	6.1 (1.38, 10.82)	0.01
Device type (Pacemaker vs ICD)	7.82 (3.05, 12.58)	0.002	7.18 (2.37, 12)	0.004

In each of the categories listed, the second category is the reference group. Coefficients are differences in the means. A negative number reflects a lower quality of life. Adjusted and unadjusted linear regression coefficients are shown for each predictor that was included in the final multivariable model. Values in parentheses are 95% Confidence intervals.
CI = confidence interval; F = female; ICD = internal cardiac defibrillator; M = male; PedsQL = Pediatric Quality of Life Inventory

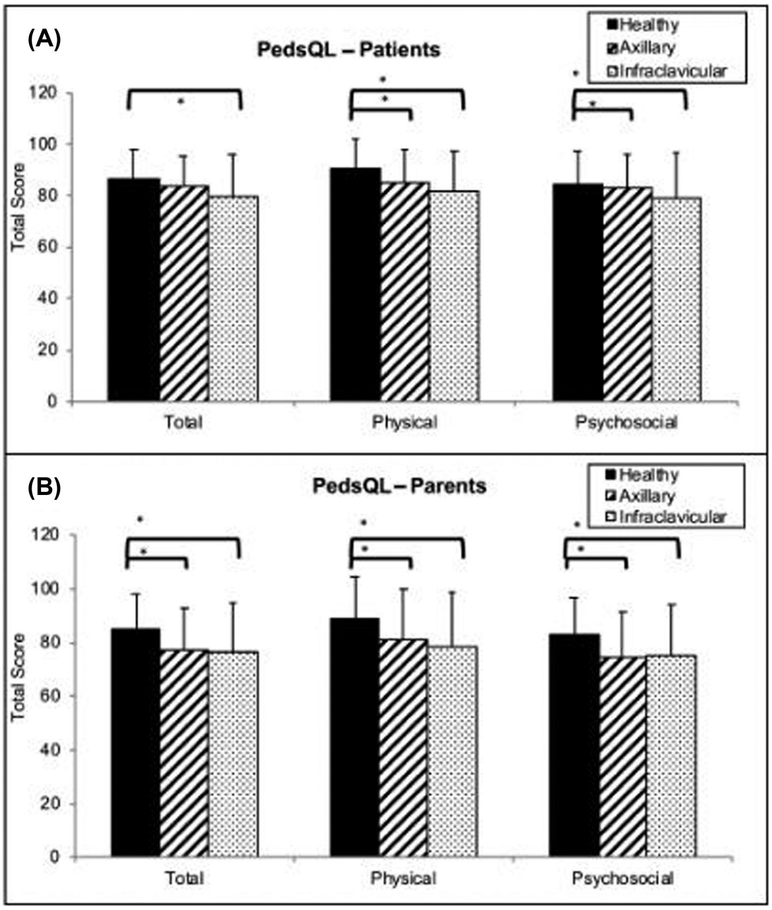

FIGURE 4 Patient and parent-proxy reported Total, Physical, and Psychosocial Health Summary PedsQL scores comparing the axillary and infraclavicular implant locations to healthy controls. (A) Comparison of PedsQL scores comparing healthy controls to axillary or infraclavicular devices patients. Patients with an infraclavicular device reported a lower HRQOL in all domains when compared to healthy controls (total and physical: $P < 0.0001$, psychosocial: $P = 0.001$). Patients in the axillary group only reported a lower HRQOL in the physical and psychosocial domain when compared to healthy controls ($P = 0.001$). There were no differences in HRQOL between the axillary and infraclavicular groups. (B) Comparison of PedsQL scores comparing healthy controls to axillary or infraclavicular devices. Parents whose child had an infraclavicular or axillary device reported a lower HRQOL in all domains when compared to healthy controls ($P < 0.0001$). There was no significant difference in parent reported HRQOL when comparing the axillary and infraclavicular locations. HRQOL = health-related quality of life; PedsQL = Pediatric Quality of Life Inventory. *Denotes statistical significance

3.4 | SPPC and SPPA

None of the SPPS or SPPA subscale scores were significantly different between the axillary and infraclavicular groups (Appendix Tables D, E, and F).

4 | DISCUSSION

This was a multicenter study evaluating patient scar perception and QOL in children with a CIED. To our knowledge, this is the first study comparing device implant location and cosmetic outcomes in children. It is challenging to attempt to quantify a patient's perception of their scar and of their perception of their CIED in general, as perhaps separate from their underlying disease state. With the PSAQ, the patients evaluate their scars on appearance, symptoms, consciousness, satisfaction with appearance, and satisfaction with symptoms. In our study, we show that patient scar perception appears to be impacted by variables of time with a scar, race, device type, and family income. For our primary research question to determine if axillary or infraclavicular device placement contributes to improved patient outcomes, the

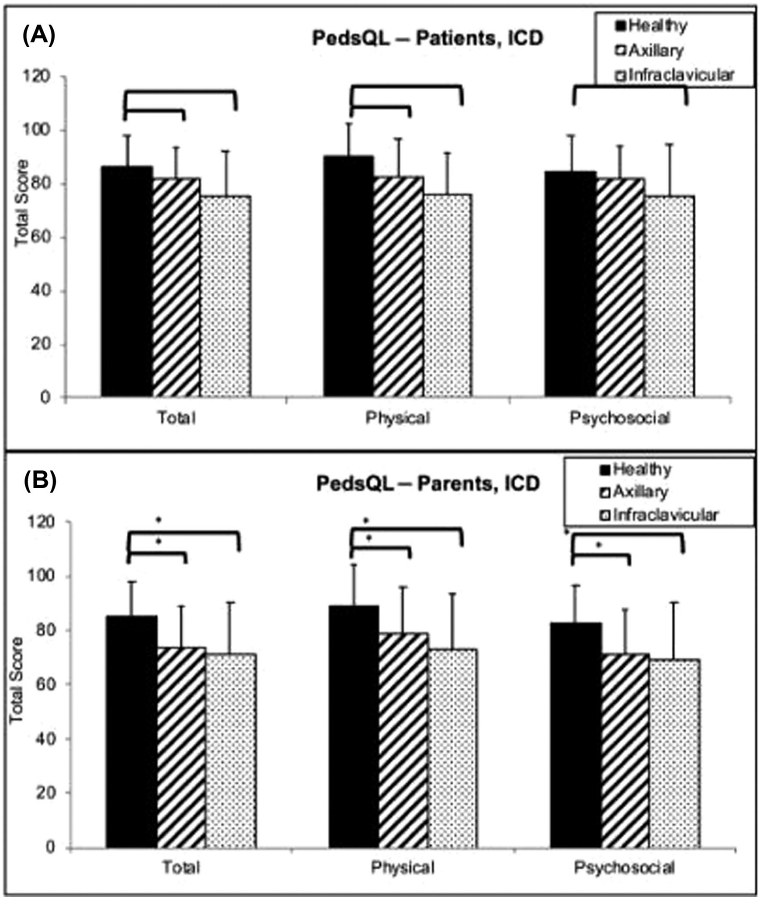

FIGURE 5 Patient and parent-proxy reported Total, Physical, and Psychosocial Health Summary PedsQL scores comparing the axillary ICD and infraclavicular ICD implant locations to healthy controls. (A) Comparisons of PedsQL scores comparing healthy controls to patients with an ICD in the axillary or infraclavicular position. When compared to healthy controls, patients with an axillary ICD had a lower HRQOL for the physical ($P \leq 0.0001$) domain. When compared to healthy controls, patients with an infraclavicular ICD had a lower HRQOL for all domains ($P < 0.0001$). There was no significant difference between HRQOL between the axillary and infraclavicular ICD. (B) Comparisons of parent-reported PedsQL scores comparing healthy controls to patients with an ICD in the axillary or infraclavicular position. Parents whose child had an infraclavicular or axillary device reported a lower HRQOL in all domains when compared to healthy controls ($P < 0.0001$). There was no significant difference between parent reported HRQOL between the axillary and infraclavicular ICD. ICD = implantable cardioverter defibrillator; HRQOL = health-related quality of life; PedsQL = Pediatric Quality of Life Inventory. *Denotes statistical significance

results are mixed. Axillary placement of a CIED seems to lead to a more favorable scar perception in patients with ICDs, with less conclusive evidence for an influence in either direction for pacemakers. As ICDs are larger devices than pacemakers and would therefore require larger surgical scars and also perhaps a larger noticeable device contour under the skin, it would make intuitive sense that device location in the axillary position would be of greater importance to patients with ICDs compared to patients with pacemakers. CIED location and device type had little effect on satisfaction with scar symptoms.

In moving from simple scar perception and appearance, our study further evaluated quality of life with the PedsQL score. Based on the adjusted model, patients in the axillary group reported, on average, PedsQL Total scores were 6 points higher than the infraclavicular group (95% CI: 1.38, 10.82) ($P = 0.01$). This would suggest that axillary implant leads to a more favorable quality of life. In addition, similar to prior studies,[8] our patients with CIED scored significantly lower than healthy controls. Thus, simply having a CIED negatively affected patient assessment of their quality of life. Interestingly, in an unadjusted analysis, patients reported a higher quality of life than their parents, although this difference was no longer seen in the adjusted analyses. Opportunities, therefore, exist to improve cosmesis and quality of life scores in children who have undergone implantation of a life-saving CIEDs.

Czosek et al reported the impact of cardiac devices on the quality of life in pediatric patients.[8] Their main conclusions were that patients with CIEDs had a lower quality of life compared to healthy controls and patients with mild forms of CHD.[8] Key drivers were the presence of an ICD and CHD. The differences between our study and this prior study are that the patient population was much different. By study design, we excluded any patient with a prior sternotomy, which therefore excluded patients who had a prior epicardial pacemaker or repaired CHD. In Czosek's study, most of the pacemaker patients had epicardial systems, and a high percentage of the ICD patients had CHD. Thus, a high percentage of their population had prior sternotomies.

While the axillary approach may provide improved QOL and patient scar perception, particularly for patients with an ICD, a recent multinational retrospective study compared the standard infraclavicular and axillary implant locations with respect to device functionality and complication rates. In this study, Rausch et al reported similar outcomes with regards to lead performance at implantation, procedural complication rates, device pocket infections, and need for reintervention.[14] Similarly, we show no differences in the number of additional cardiac electrophysiological procedures providing insight into wire and device characteristics. While the current study did not specifically investigate repeat procedures for device generator changes or lead revisions, the authors would like to provide a few insights. In our experience, the two-incisional axillary approach[14] that includes the leads being implanted in the standard infraclavicular area and then being tunneled to the axilla where the CIED is placed has similar ease of subsequent CIED surgery (such as generator change, lead extractions, etc.) compared to the standard infraclavicular approach. In the two-incisional axillary approach, the leads and the device are placed very near to the incision

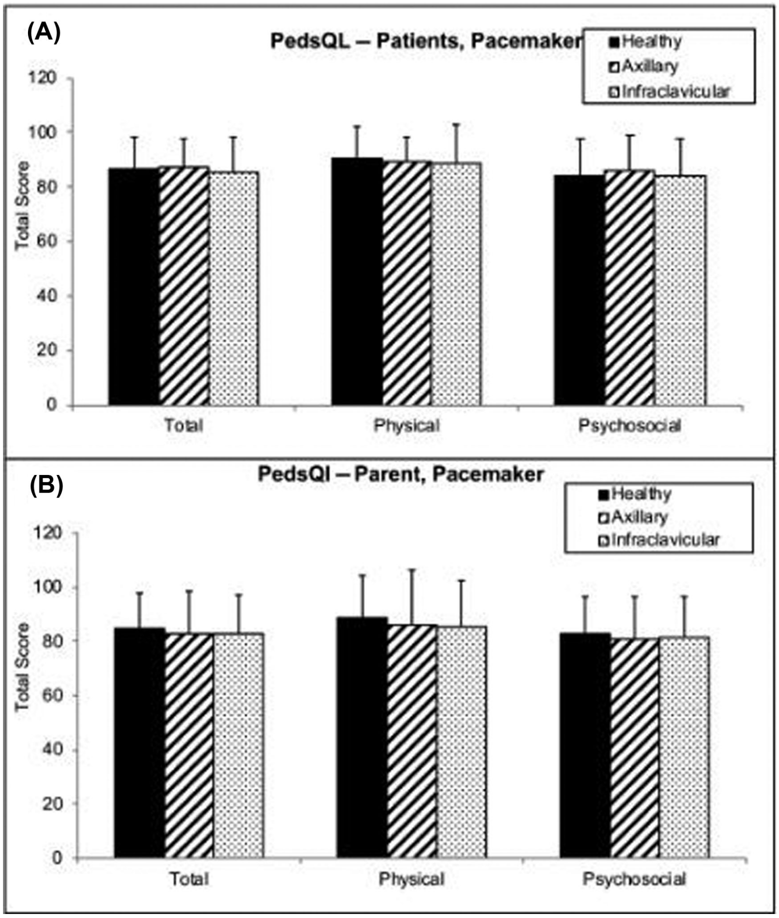

FIGURE 6 Patient and parent-proxy reported Total, Physical, and Psychosocial Health Summary PedsQL scores comparing the axillary pacemaker and infraclavicular pacemaker implant locations to healthy controls. (A) Comparisons of PedsQL scores of healthy controls to patients with a pacemaker in the axillary or infraclavicular position. There was no significant difference in HRQOL between any of the groups for any domain. (B) Comparisons of parent reported PedsQL scores for healthy controls and patients with a pacemaker in the axillary or infraclavicular position. There was no significant difference in HRQOL between any of the groups for any domain. HRQOL = health-related quality of life; PedsQL = Pediatric Quality of Life Inventory

locations and techniques for device surgeries are nearly identical. In the single incision axillary approach, however, there is a vertical incision at the anterior axilla and the device is advanced to a more anterior location. With this approach, there can be two theoretic concerns: (1) the venous access site is at a more distal location and thus there is more length of lead to be addressed during lead extractions and (2) the device is placed "deep" and distant from the incision which makes locating the device more challenging during subsequent device surgeries.

Despite the similar device functionality and complication rate, one potential reason for the lack of utilization of the alternative axillary technique may be driven by concern for lead longevity with more lead exposed to external trauma, and decreased focus on cosmetic outcomes. In previous studies, clinicians have been found to perform poorly when asked to predict HRQOL in children with cardiac disease,[20] and that lack of understanding may have significant implications on their choice of implant location and interest in alternative implant techniques.

Similar to this data, prior studies in patients with cardiac devices have shown that those with an ICD generally have lower HRQOL for both the generic and disease-specific inventories when compared to pacemakers.[8,9,21] The pacemaker group was younger than the ICD group at initial implantation, and thus may be the reason there is less impact of the scar on HRQOL. It is possible that younger patients are less likely to be concerned with appearance and be used to the scar by adolescence, compared to the adolescent who has a new scar to adjust to.

While scar perception was demonstrated to be an important factor, it is unlikely to be the only mechanism affecting HRQOL. Specifically, poorer scar perception in the ICD group as a whole, and in the ICD infraclavicular group, but not in the pacemaker group, may be confounded by factors related to the disease necessitating implantation and the overall severity of the underlying disease process. In addition, based on the lack of difference in scores for the PSAQ satisfaction with symptoms subscale, it is unlikely that pain, is affecting scar perception. The impact of scar appearance, consciousness, and satisfaction with appearance appear to play a much bigger role in scar perception. Furthermore, worse HRQOL in patients with an ICD may be confounded by potential for shock as well as additional activity-based restrictions. This is further suggested by the fact that the ICD group scored significantly lower in the physical domains and in the disease impact and psychosocial score in the PCQLI inventory. We attempted to control for disease severity and its impact on HRQOL by not including patients who had experienced a recent life-altering event. Importantly, though, there was no significant difference in the proportion of patients who had a device shock between the axillary and infraclavicular group.

This study has several important limitations. Factors related to lower scar perception in the ICD group could not be elucidated from this study. The reason for the lower scar perception of the axillary pacemaker group compared to the infraclavicular pacemaker group is unclear, and could not be assessed using selected study inventories. Blinded review of scars could not be performed as many of the photographs obtained were of insufficient quality. We did not compare

HRQOL between pacemakers and ICDs by device position due to small sample size in those specific groups. The PSAQ is validated in adults, and we used it in adolescents.

5 | CONCLUSIONS

CIED implant location and type appear to have some effect on scar perception and quality of life as assessed by the PSAQ and HRQOL in both the generic and cardiac specific inventories, with the axillary group having better scar perception when compared to the infraclavicular group for the ICD group in particular. The axillary implant location can improve overall quality of life and can improve scar perception with the ICD device.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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APPENDIX: Table A. Comparison of axillary ICD and infraclavicular ICD

	Axillary ICD (*n* = 36)	Infraclavicular ICD (*n* = 47)	P Value
Age at diagnosis, mean (SD)	11.7 (3.9)	10.5 (4.9)	0.26
Age at enrollment, mean (SD)	15.1 (2.5)	14.7 (2.4)	0.45
Proportion of patients ≥13	29 (81)	36 (80)	
Sex, Male	17 (48.6)	26 (56.5)	0.48
Race			0.15
White	27 (75)	41 (87.2)	
All others	9 (25)	6 (12.8)	
Kid's education programs			**0.01**
Special program (IEP)	16 (44.4)	9 (19.2)	
Regular school	20 (55.6)	38 (80.8)	
Maternal education			0.34
Less than high school	2 (5.7)	2 (4.6)	
High school graduate	7 (20.0)	10 (23.3)	
Partial college or trade school	13 (37.1)	20 (46.6)	
College graduate	6 (17.2)	9 (20.9)	
Postgraduate degree	7 (20.0)	2 (4.6)	
Income			0.07
Less than $50 000	6 (17.7)	17 (41.4)	
$50,000-$100 000	15 (44.1)	15 (36.6)	
Greater than $100 000	13 (38.2)	9 (22.0)	
Cardiac diagnosis			0.79
Normal heart structure	23 (63.9)	31 (66.0)	
Cardiomyopathy	9 (25.0)	13 (27.6)	
Congenital heart disease	4 (11.1)	3 (6.4)	
Total cardiac procedures			0.48
0	34 (94.4)	39 (83)	
1	1 (2.8)	4 (8.4)	
2	1 (2.8)	2 (4/3)	
3	0 (0)	2 (4.3)	
Electrophysiologic diagnosis			0.43
Sinus node dysfunction	35 (97.2)	47 (100)	
Cardioinhibitory syncope	1 (91.2)	0 (0)	
Second-degree AV block	0 (0)	0 (0)	
Third-degree AV Block	0 (0)	0 (0)	
All Others	0 (0)	0 (0)	
ICD discharge	26 (72.2)	26 (55.3)	0.17

[*]Unless otherwise indicated, all data is *n* (number) with %. $p < 0.05$ is statistically significant.
AV = atrioventricular; ICD = implantable cardioverter defibrillator; IEP = individualized education program; SD = standard deviation.

APPENDIX: Table B. Comparison of axillary and infraclavicular pacemaker

Age at diagnosis, mean (SD)	Axillary pacemaker (*n* = 19)	Infraclavicular pacemaker (*n* = 39)	*P* Value
Age at enrollment, mean (SD)	7.4 (5.6)	6.6 (5.0)	0.55
Proportion of patients ≥13	12.4 (3.5)	13.8 (2.9)	0.11
Sex, Male	7 (37)	29 (74)	
Race			0.03
White	5 (27.8)	23 (59.0)	
All others			
Kid's education programs			**0.03**
Special program (IEP)	12 (63.2)	34 (87.2)	
Regular school	7 (36.8)	5 (12.8)	
Maternal education			0.77
Less than high school	1 (5.5)	1 (2.6)	
High school graduate	3 (16.7)	6 (15.8)	
Partial college or trade school	3 (16.7)	12 (31.6)	
College graduate	8 (44.4)	14 (36.8)	
Postgraduate degree	3 (16.7	5 (13.2	
Income			0.72
Less than $50 000	6 (35.3)	10 (25.6)	
$50 000-$100 000	6 (35.3)	14 (35.9)	
Greater than $100 000	5 (29.4)	15 (38.5)	
Cardiac diagnosis			0.08
Normal heart structure	19 (100)	31 (79.5)	
Cardiomyopathy	0 (0)	1 (2.5)	
Congenital heart disease	0 (0)	7 (18.0)	
Total number of cardiac procedures			**0.01**
0	19 (100)	26 (66.7)	
1	0 (0)	12 (30.8)	
2	0 (0)	1 (2.5)	
3	0 (0)	0 (0)	
Electrophysiologic diagnosis			0.18
Sinus node dysfunction	4 (21.1)	14 (35.9)	
Cardioinhibitory syncope	3 (15.8)	2 (5.1)	
Second-degree AV block	0 (0)	4 (10.3)	
Third-degree AV block	0 (0)	0 (0)	
All others	12 (63.1)	19 (48.7)	

*Unless otherwise indicated, all data is *n* (number) with %.
AV = atrioventricular; IEP = individualized education program; SD = standard deviation.

APPENDIX: Table C. Summary of additional catheter based or minimally invasive cardiac procedures unrelated to device or lead functionality

	Procedure 1		Procedure 2	
	Axillary	Infraclavicular	Axillary	Infraclavicular
Cardiac catheterization with device closure of an ASD or PDA	1 (100)	3 (43)	0 (0)	0 (0)
Endomyocardial biopsy	0 (0)	2 (29)	0 (0)	0 (0)
Implantation of another monitoring device (loop recorder)	0 (0)	2 (29)	0 (0)	0 (0)
Ablation procedure	0 (0)	0 (0)	0 (0)	2 (100)

*All data is *n* (number) with %.
ASD = atrial septal defect; PDA = patent ductus arteriosus.

APPENDIX: Table D. All Patients: SPPC and SPPA

Variable	Axillary (*n* = 55)	Infraclavicular (*n* = 86)	*P* Value
Athletic competence	2.8 ± 0.7	2.9 ± 0.7	0.35
Behavioral conduct	3.2 ± 0.7	3.2 ± 0.6	0.78
Close friends	3.2 ± 0.8	3.3 ± 0.6	0.64
Global self-worth	3.4 ± 0.5	3.3 ± 0.6	0.10
Physical appearance	3.1 ± 0.7	3 ± 0.7	0.54
Romantic appeal	2.9 ± 0.7	3 ± 0.6	0.54
Social acceptance	3.2 ± 0.6	3.2 ± 0.6	0.56

*Values are presented as mean ± standard deviation.
SPPC = athletic competence, behavioral conduct, global self-worth, physical appearance; SPPA = athletic competence, behavioral conduct, close friends, global self -worth, physical appearance, romantic appeal, social acceptance; domains denoted are from the "What I am Like," portion of the SPPC and SPPA.

APPENDIX: Table E. ICD: SPPC and SPPA

Variable	Axillary (*n* = 36)	Infraclavicular (*n* = 47)	*P* Value
Athletic competence	2.8 ± 0.8	2.9 ± 0.7	0.67
Behavioral conduct	3.1 ± 0.7	3 ± 0.7	0.83
Close friends	3.2 ± 0.9	3.3 ± 0.6	0.57
Global self-worth	3.4 ± 0.5	3.2 ± 0.6	0.15
Physical appearance	3.1 ± 0.7	3.1 ± 0.7	0.92
Romantic appeal	2.9 ± 0.7	3 ± 0.6	0.44
Social acceptance	3.2 ± 0.6	3.2 ± 0.6	0.72

*Values are presented as mean ± standard deviation.
SPPC = athletic competence, behavioral conduct, global self-worth, physical appearance; SPPA = athletic competence, behavioral conduct, close friends, global self -worth, physical appearance, romantic appeal, social acceptance; domains denoted are from the "What I am Like," portion of the SPPC and SPPA.

APPENDIX: Table F. Pacemaker: SPPC and SPPA

Variable	Axillary (*n* = 19)	Infraclavicular (*n* = 39)	*P* Value
WIAL_SCHOLASTIC	3.1 ± 0.7	3.1 ± 0.7	0.72
Athletic competence	2.8 ± 0.6	3 ± 0.7	0.34
Behavioral conduct	3.4 ± 0.5	3.3 ± 0.5	0.42
Close friends	3.2 ± 0.6	3.2 ± 0.7	0.85
Global self-worth	3.5 ± 0.5	3.3 ± 0.6	0.36
Physical appearance	3.2 ± 0.7	3 ± 0.7	0.28
Romantic appeal	2.9 ± 0.7	2.9 ± 0.7	0.94
Social acceptance	3.3 ± 0.6	3.2 ± 0.7	0.58

*Values are presented as mean ± standard deviation.
SPPC = athletic competence, behavioral conduct, global self-worth, physical appearance; SPPA = athletic competence, behavioral conduct, close friends, global self -worth, physical appearance, romantic appeal, social acceptance; domains denoted are from the "What I am Like," portion of the SPPC and SPPA.