Evaluation of a novel mechanical compression device for hematoma prevention and wound cosmesis after CIED implantation

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Abstract

Background: An important complication of cardiac implantable electronic devices (CIED) implantation is the development of hematoma and device infection.

Objective: We aimed to evaluate a novel mechanical compression device for hematoma prevention and cosmetic outcomes following CIED implantation.

Methods: An open, prospective, randomized, single-center clinical trial was performed in patients undergoing CIED implantation. Patients were randomized to receive a novel mechanical compression device (PressRite, PR) or to receive the standard of care post device implantation. Skin pliability was measured with a calibrated durometer; the surgical site was evaluated using the Manchester Scar Scale (MSS) by a blinded plastic surgeon and the Patient and Observer Scar Scale (POSAS). Performance of PR was assessed through pressure measurements, standardized scar scales and tolerability.

Results: From the total of 114 patients evaluated for enrollment, 105 patients were eligible for analysis. Fifty-one patients were randomized to management group (PR) and 54 to the control group. No patients required early removal or experienced adverse effects from PR application. There were 11 hematomas (14.8% vs. 5.9% in the control and PR group respectively, \( p = \text{NS} \)). The control group had higher post procedure durometer readings in the surgical site when compared with the PR group (7.50 ± 3.45 vs. 5.37 ± 2.78; \( p < .01 \)). There were lower MSS scores in the PR group after 2 weeks (\( p = .03 \)).
1 | INTRODUCTION

Over 1.2 million pacemakers and 300,000 defibrillators are implanted annually worldwide, and this patient cohort requires generator change procedures every 8–10 years. As the population continues to age, these numbers continue to rise.1 Up to 35% of patients undergoing cardiac implantable electronic devices (CIED) are prescribed antiplatelet and/or anticoagulant therapies, which can further increase the risk of hematoma.2,3 The development of hematoma is associated with up to 21-fold increase in risk of device infection, which is one of the most dreaded CIED complications.4–10

Current strategies to reduce postoperative hematoma include variable practices including application of pressure dressing, sandbags or ice packs.11 However, the impact of these strategies is nonuniform and ineffective such that they are not widely used. In addition, the cosmetic appearance of scars affect patient perception and quality of life.12 There are currently no standardized tools to improve scar appearance post CIED implantation.

This study was designed to evaluate the efficacy and safety of a pneumatic transparent mechanical compression device (PressRite, PR) in comparison to the conventional strategies in patients undergoing cardiac device implantation.

2 | METHODS

An open, prospective, randomized, single-center clinical trial was performed in patients who underwent cardiac device implantation at the University of Virginia (UVA) Medical Center from January 2020 to May 2020. The University of Virginia Institutional Review Board approved this study. Written informed consent was obtained from all study subjects.

2.1 | Patient selection

One hundred and fourteen patients were assessed for eligibility and 112 patients were selected to for enrollment. The inclusion criteria were adult patients (> 18 years old) who were undergoing de novo CIED or generator change procedures and were able to consent for CIED implantation and randomization for the study. Exclusion criteria were a recent sternotomy, and any other chest, shoulder or abdominal surgery precluding the use of adhesive pads to secure the PR.

2.2 | Randomization

After initial assessment for enrollment, a total of 112 patients were randomized using the UVA Online Collaborative Research Environment (OnCore) tool. Fifty-six patients were allocated in the PR group and 56 in the control group (Figure 1). Four patients in the PR group had their procedure canceled, delayed or postponed and one patient elected to withdraw from the study. Thus, fifty-one patients were included in the final analyses from which two patients did not receive the PR but were kept in the PR group based on the intention to treat analyses. In the control group, two patients had their procedures postponed and a total of 54 patients were included in the final analysis. The patients assigned to the management group had a PR applied over the medical bandage Primapore (Smith+ Nephew, Memphis, Tennessee) or Aquacel (ConvaTec, Bridgewater, NJ) over the surgical site for minimum of 2 hours.

The UVA electrophysiology group comprised of seven electrophysiologists as the time of the study. As reflective of national practice patterns and lack of guidelines in the absence of strong recommendations, the control group was permitted to have postoperative dressings at the discretion of the operator. Patients randomized to the control group received the regular standard of care that could either be 1) medical bandage Primapore or Aquacel over the surgical site or 2) conventional pressure dressing (stack of gauze with tape for compression) on top of medical bandage Primapore or Aquacel over the surgical site per physician’s discretion.

2.3 | PressRite (PR) device description and application

PR is a modular biocompatible, transparent, lightweight, and durable pneumatic compression device that was designed to deliver sufficient pressure consistently over a 2–4 h application period and accommodate varying upper body anatomy, Table 1. (patent pending)

Device compression system is a modular assembly consisting of 1) Pneumatic compression system (transparent air inflation mecha-

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**Conclusion:** We have demonstrated the safety of PR application and removal. In addition, PR appears to improve postoperative skin pliability, which could facilitate wound healing.
TABLE 1 Baseline characteristics, demographics and use of antiplatelets and anticoagulants

|                      | Control (n = 54) | PR (n = 51) | p   |
|----------------------|-----------------|-------------|-----|
| Age (Mean ± SD)      | 65.35 ± 16.04   | 70.45 ± 14.07 | .087|
| Female (%)           | 27.8%           | 35.3%       | .40 |
| White or Caucasian   | 64.8%           | 82.2%       | .01*|
| African American     | 27.8%           | 11.8%       | .01*|
| Left ventricular ejection fraction | 0.48           | 0.43        | .62 |
| HTN                  | 68.5%           | 70.6%       | .81 |
| DM                   | 27.8%           | 21.6%       | .46 |
| CAD                  | 42.6%           | 33.3%       | .32 |
| CKD                  | 29.6%           | 25.5%       | .63 |
| Hematoma             | 14.8% (n = 8)   | 5.9% (n = 3) | .20 *(Fisher’s)* |

Use of antiplatelets, anticoagulants, and immunosuppression

|                      |               |             |     |
|----------------------|---------------|-------------|-----|
| Antiplatelet         | 63.0%         | 43.1%       | .04*|
| Anticoagulation      | 42.6%         | 58.8%       | .09 |
| Immunosuppression    | 3.7%          | 5.9%        | .11 |
| Hospitalization      | 18.5%         | 33.3%       | .83 |

Device, manufacturer and type of procedure

|                      |               |             |     |
|----------------------|---------------|-------------|-----|
| Single chamber pacemaker | 3.8%        | 0%          | .63 |
| Dual chamber pacemaker       | 30.8%       | 39.2%       |     |
| Single chamber ICD         | 11.5%        | 5.9%        |     |
| Dual chamber ICD           | 21.2%        | 17.6%       |     |
| Biventricular ICD          | 30.8%        | 33.3%       |     |
| Subcutaneous ICD           | 1.9%         | 3.9%        |     |
| De Novo device implantation | 61.5%       | 58.8%       | .23 |
| Generator change          | 30.8%        | 21.6%       |     |
| Upgrade                  | 7.7%         | 17.6%       |     |
| Lead revision             | 0%           | 2%          |     |
| Medtronic                | 66.0%        | 60.8%       | .87 |
| Boston Scientific         | 22.0%        | 23.5%       |     |
| St. Jude                  | 12.0%        | 15.7%       |     |

TABLE 2 Survey following PressRite removal

| Surveyed questions          | Mean ± SD     |             |     |
|-----------------------------|---------------|-------------|-----|
| Pressure                    | 2.16 ± 3.2    |             |     |
| Pain                        | 1.65 +/- 2.9  |             |     |
| Itching                     | 0.29 ± 0.8    |             |     |
| Soreness                    | 1.43 ± 2.8    |             |     |
| Decreased mobility          | 0.83 ± 2.2    |             |     |
| Discomfort                  | 1.62 ± 2.7    |             |     |
| Device removal              | 3.08 ± 3.3    |             |     |
| Overall experience (0 to 10 being the best possible experience) | 7.6 ± 2.8 | | |

suring sensor (Kikuhi MeIDIeTraDe, Soro, Denmark). Pressure transducer was calibrated prior each measurement. After device removal, patients were asked to complete a survey evaluating their experience and tolerability (Table 2).

2.4 Implant site assessment

Postoperative survey: After removal of PR, the patient completed a postoperative survey that assessed different aspects of tolerance on a scale of 0–10.

Durometer Read-outs: Prior to the procedure, study investigators used Model 1600 Type OO Dial durometer (Rex Gauge, IL) to measure skin pliability at the surgical site (S) and contralateral site (CL) at the following time points: 1) preprocedure (baseline); 2) postprocedure within 24 h over the thinnest part of the dressing; 3) at the 2 week follow-up visit; and 4) at the 3 month follow-up visit. Three readings were obtained from the quadrant of interest and the average value was used for analysis. Higher durometer readouts correlate with higher skin tension and lower pliability. The durometer placement and readout technique has been previously reported.

Surgical Scar Evaluation: At the 2-week and 3-month follow-up period, the Manchester Scar Scale (MSS) and the Patient and Observer Assessment Scale (POSAS) was completed to assess wound healing. The physician component was evaluated by a blinded plastic surgeon. Owing to the COVID pandemic, follow up visits were transitioned to remote and patients were contacted up to 3 times to share their site follow up photographs when possible.

2.5 Endpoints of interest

The primary endpoint was the incidence of postoperative pocket hematoma in the group of patients using the hematoma prevention device versus controls. Secondary endpoints included durometer readings, POSAS and MSS scores, CIED revision, and CIED infection rates. Surgical site hematoma was analyzed according to the Bleeding Academic Research Consortium classification.
2.6 | Data analysis

Quantitative data were expressed as the mean ± standard deviation and median ± percentiles. Comparisons between groups were performed using an unpaired Student’s t-test (two-tailed) or U-Mann Whitney test (based on the distribution of the values). Comparisons of means from the same individual were performed using a paired Student’s t-test. Categorical data were compared by Chi-Square test. One-way ANOVA was used to assess changes in durometer readings over time in both groups. p values of less than .05 were deemed to be significant. Data were analyzed according to the intention-to-treat model. SAS software was used for performing statistical analysis (Version 9.4, SAS Institute Inc.).

3 | RESULTS

3.1 | Study population

From the total of 114 patients initially screened, two patients declined to participate, and seven patients were removed from the study due to having the procedure canceled, delayed or postponed. Our final analysis was performed with 51 patients in the management group (PR) and 54 patients in the control group. Patient enrollment process is shown in Figure 1.

3.2 | Baseline characteristics

Patient characteristics, demographics, medication review, and procedural characteristics are shown in Table 1. The average age, gender, baseline comorbidities in both groups were similar. There were a higher number of Caucasian patients in the PR group (82.2%) compared with the control group (64.8%, p = .01). A higher number of patients in the control group were on antiplatelet agents (63.0% vs. 43.1%; p = .04). No differences were seen in the use of anticoagulant, or immunosuppressive medications. The distribution of the type of device, manufacturers and type of procedure (de novo vs. generator changes) was similar in both groups.

3.3 | PR application and post PR removal survey

The average pressure delivered by the PR was 34.68 mmHg. There were no instances of removing PR devices owing to patient intolerance (Table 2).

The patients in the PR group were surveyed to evaluate their tolerability and overall experience using this novel device. The mean score was 7.6 ± 2.8. Pain, pressure, and discomfort levels were low and none of the studied subjects experienced major adverse events associated with PR use.
TABLE 3  Surgical site hematoma according to the Bleeding Academic Research Consortium

| Type              | Control   | PR         |
|-------------------|-----------|------------|
| Type 0 (no bleeding) | 85.2% (46) | 94.1% (48) |
| Type 1 (not actionable bleeding) | 11.1% (6)  | 5.9% (3)   |
| Type 2 (actionable bleeding)     | 3.7% (2)   | 0%         |
| Type 3 (clinical, laboratory, or imaging evidence of bleeding requiring specific action) | 0%         | 0%         |
| Type 4 (CABG-related bleeding)   | 0%         | 0%         |
| Type 5 (fatal bleeding)          | 0%         | 0%         |
| Total bleeding episodes         | 14.8% (8)  | 5.9% (3)   |

3.4 | Outcomes

There were eleven surgical site hematoma occurrences in the study. Eight were in the control group and three in the PR group (14.8% vs. 5.9%, p = .27) (Table 3).

Of the eight patients in the control group (8/54), three were on antiplatelet agents, three were on anticoagulation and two were on antiplatelet and anticoagulant agents. Six out of these eight patients underwent conservative management, while two of them had actionable bleeding (with testing of clotting time, platelet count, and hemoglobin). None of the patients underwent invasive management, transfusion, or device revision.

On the other hand, three patients in the PR group (3/51) developed surgical site hematoma. The first case was a biventricular ICD generator change and was only on aspirin. The second case had a biventricular ICD generator change and was on warfarin monotherapy. The last INR check was 2.2 four days prior to the procedure. The third patient had a single chamber pacemaker generator change and was on aspirin and apixaban that was held 48 hours prior to the procedure. All three patients had conservative management. None of the bleeding episodes were higher than BARC 3 for both groups.

3.5 | Post-operative durometer readouts higher in the control group

The preprocedure durometer readings for the surgical and contralateral sites were similar for both groups. In the PR group, the preprocedure versus postprocedure durometer readings in the surgical and contralateral sites were not significantly different. (4.2 ± 2.2 vs. 4.8 ± 2.7 and 4.6 ± 2.1 vs. 5.3 ± 2.7; p = NS). The control group had higher postprocedure durometer readings in the surgical site when compared with the PR group (7.50 ± 3.45 vs. 5.37 ± 2.78; p < .01) (Figure 3).

3.6 | Surgical scar evaluation based on MSS scores better in the PR group

Significantly lower MSS scores were seen in the PR group after two weeks (p = .03, Figure 4). The POSAS scores were similar in both groups at 2-weeks and 3-months follow-up. Representative scar images for both groups are shown in Table 4.

3.7 | Follow up data

A detailed chart review after one year of enrollment was performed showing that there were no device infections, lead extractions or revisions in the studied population. Three patients in the control group (1 STEMI and 2 cardiogenic shock) and six patients in the PR group died during follow up (1 NSTEMI, 2 cardiogenic shock, 1 VT/VF, 1 peritonitis, 1 unknown cause of death).

4 | DISCUSSION

In this randomized clinical trial, we demonstrated: 1) safety and reliability of PR application; 2) lower postoperative durometer readings over the surgical site in the treatment group compared with the control group; and 3) lower MSS scores in the treatment group after 2 weeks of follow-up.

The intervention in this study was designed to overcome the limitations of current mechanical compression devices, which are opaque, block visual access to the site and are not titratable for pressure application. In addition, most of the alternative solutions for mechanical compression are site specific. The modular assembly of PR device lends to universal site application as demonstrated in our study where we had left pectoral site, right pectoral site and left lateral site placements. Furthermore to our knowledge, there is no mechanical compression device for CIEDs with the ability to dynamically adjust pressure.

In addition, nurses and technicians were trained to place the PR on a mannequin in a short orientation session using a mannequin. The easy application and removal with minimal baseline training could translate to scalability. In this study, we have demonstrated the safety and tolerability of PR with no adverse events. No patients required early removal for discomfort and there were no adverse effects noted.

One of the study endpoints is based on assessment with a durometer which is a well-validated handheld instrument that measures the skin pliability by measuring the skin compliance to a compression pin with readouts in durometer units. It is highly reliable, reproducible, convenient and painless. Higher readouts signal reduced skin pliability which can occur with postoperative swelling and consequently with fibrosis.

We have previously demonstrated the usefulness of durometers for scar assessment in patients undergoing CIED implantation compared to control volunteers. Our baseline findings in control patients in this study are consistent with what we previously reported. In addition, we now show that the durometer readouts in the PR group were lower on the surgical site post operatively and similar to the contralateral site. This suggests adequate compression and dispersion of surgical swelling. This in turn could putatively reduce skin tension and permit better scar healing.
Given the low event rate of hematomas in this study, we did not find a discernible difference in the two groups; however, the PR group had a lower hematoma rate that did not meet statistical significance. Based on these findings, we believe additional studies with greater numbers of patients will help define clinical effectiveness.

With respect to surgical scar assessment, the MSS and POSAS scales have been previously demonstrated to have high reliability and validity.\textsuperscript{21-24} The MSS score in the present study provided a signal for effectiveness of treatment at 2 weeks; however, more definitive assessment was affected by high dropout rates during the COVID pandemic because the in hospital /in clinic follow up visits were not possible.

As our population continues to age and the need for CIED implants grows, the utility of a reliable, safe, and easily applied mechanical compression device could offer advantages to reduce risk of hematomas and putatively improve wound healing metrics. This represents an exploratory feasibility pilot trial with encouraging results that justify larger multicenter trials to validate concept observations.
TABLE 4 Representative images of surgical scars in the PressRite and control groups at 2 weeks and 3 months

| Images          | Durometer readout surgical site | MSS at 2 weeks and 3 months | Total POSAS at 2 weeks and 3 months |
|-----------------|---------------------------------|----------------------------|-----------------------------------|
| PressRite 2 weeks | 8                               | Color - 4, Matte - 1, Contour - 1, Distortion - 2, Texture - 3 | 11                                |
| PressRite 3 months | 4                               | Color - 1, Matte - 1, Contour - 1, Distortion - 1, Texture - 1 | 6                                 |
| Control 2 weeks  | 7                               | Color - 2, Matte - 1, Contour - 2, Distortion - 2, Texture - 2 | 14                                |
| Control 3 months | 4                               | Color - 1, Matte - 1, Contour - 1, Distortion - 1, Texture - | 12                                |

4.1 Limitations

This represents a small-randomized clinical trial in a single center. The COVID-19 pandemic disrupted a planned systematic follow-up. A larger study with multicenter participation could expand on the real-life applicability of PR. Validation in other institutions would add scientific rigor to our initial observations.

5 CONCLUSION

This study was a feasibility pilot trial to evaluate the PressRite device. It showed that the PR is a safe and well-tolerated pneumatic compression device that reduces the incidence of surgical site hematomas and attenuates swelling with improved wound healing in patients undergoing CIED procedures.
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