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Effectiveness of a Non-Taped Compression Dress in Patients Receiving Cardiac Implantable Electronic Devices

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Background: Hematoma and skin damage are not uncommon after cardiac implantable electronic device (CIED) placement. The use of conventional hemostatic gauze and tape seems to be suboptimal in controlling these complications. This study aimed to evaluate the impact of a novel compression dress with a special pad and elastic bands for postoperative care.

Methods: A total of 175 CIED recipients were randomly divided into two groups: an experimental group with 85 patients who used a non-taped compression dress and a control group with 90 patients who used conventional gauze ball and elastic tapes. Skin integrity, hematoma, and oozing were compared between these two groups within 7 days after surgery.

Results: The mean age of the patients was 71.2 ± 13.3 years, and 83 (47.4%) were male. The results of the experimental vs. control group were as follows: skin integrity – 96.5% vs. 86.7% ($p < 0.05$); hematoma – 0% vs. 7.8% ($p < 0.05$); and oozing – 1.2% vs. 7.8% ($p < 0.05$). All observed endpoints were better in the experimental group.

Conclusions: The use of a non-taped compression dress was associated with less unfavorable outcomes in terms of skin integrity and hemostasis.

Key Words: Cardiac implantable electronic device (CIED) • Complication • Compression dress • Hematoma • Pocket

INTRODUCTION

When placing a cardiac implantable electronic device (CIED), a pocket is created subcutaneously or submuscularly at the chest or abdominal wall. The incidence of hemorrhagic complications associated with this type of surgery is estimated to be 4.6%.[1] The development of postoperative hematoma is associated with procedure-related infections.[2] In addition, postoperative infections and impaired skin integrity can result in prolonged hospital stay, increased healthcare-related costs, and unfavorable outcomes.[3-6]

Hematoma, oozing, and skin tears are commonly seen when a CIED pocket is compressed using conventional gauze and tape, especially in the elderly. In addition, adhesive tape designed for pressure dressings can cause skin erosion.[7] Although clinically relevant for minimizing the incidence of postoperative complications, the efficacy of conventional hemostatic gauze and tape is considered to be suboptimal. It has also been found that bulla and tears usually develop soon after applying

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or removing tapes in the elderly and those with fragile skin.[8-11] Therefore, we developed a novel compression dress without tapes to improve patient comfort as well as the postoperative outcomes.[12] This study aimed to investigate the effects of this novel compression dress on a chest wall pocket after implanting a CIED.

METHODS

Study design

This was a single-center observational study with a quasi-experimental randomized control design, conducted in two intensive care units (ICU). All implant procedures were carried out by a cardiovascular team, as was postoperative care. The implanters were randomly assigned from the same team. The types of CIED included cardiac resynchronization therapy, implantable cardioverter defibrillators, and pacemakers. A 4-6-cm cutting wound was located on either the left or right anterolateral chest wall. During periprocedural and postoperative phases, antiplatelet or anticoagulant therapy was only discontinued in the case of complicated hemorrhage. The patients were randomly assigned to either of the two ICUs by hospital administrators at the admission center.

All CIED recipients were divided into two groups: the experimental group assigned to ICU-A who used the novel compression dress, and the control group assigned to ICU-B who used conventional hemostatic gauze and tape instead (Figure 1). These two methods have been routinely used in these units, respectively. Skin integrity and the presence of oozing, hematoma, and subcutaneous emphysema around the CIED pocket were observed by the in-hospital healthcare providers or outpatient physicians for 1-7 days after implantation. ICU referral was the postoperative routine of the hospital.

The research, including data collection, was approved by the Institutional Review Board of MacKay Memorial Hospital.

Conventional compression dress

The conventional compression dress consisted of three components: a large gauze ball placed on the pocket, two to three pieces of elastic adhesive tape for fixation, and a sandbag on the top for adequate pressure. In practice, the medical staff repeatedly adjusted the sandbag to maintain its location and ensure patient comfort. Since the sandbag was not radiolucent, it needed to be removed when preparing the patients for radiography. All elastic tapes and gauze were also removed after 12 hours of supine chest compression and when checking the wound. Allergic bulla or skin tears usually occurred during this procedure.

Non-taped compression dress

The novel compression dress consisted of only two components: a pressure pad attached to the pocket, and three elastic bands to fit a variety of body shapes (Figure 2). The pad and bands were attached by buckles and Velcro (Figure 3). The pressure device was a static balance of a 2-cm-thick triangular pad, 500 g in weight, applying a constant pressure on an area of around 10 × 10 cm^2. All materials in the pad, the bands, and the buckles were (semi-)radiolucent, so pressure could be maintained even during fluoroscopy. Postoperative care, as well as the compression time, were the same as that in the control group. Replacing conventional gauze and adhesive tape with elastic bands was supposed to prevent skin damage arising from allergies and tearing. In addition, the novel dress also provided constant pressure on the CIED pockets and allowed for free motion regardless of the patient's posture.

Statistics

SPSS software (version 20.0, SPSS, Inc., Chicago, IL,

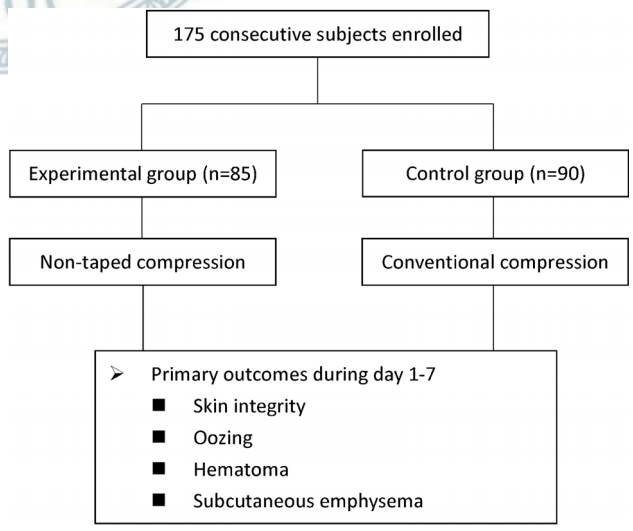

Figure 1. *Flow of the study.*

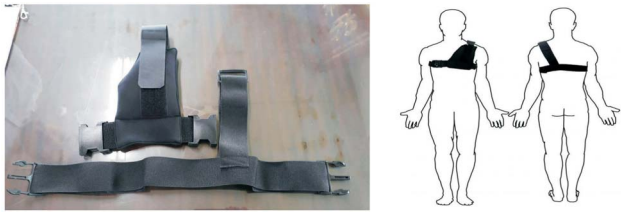

Figure 2. *Non-taped compression dress.*

Figure 3. *Demonstration of non-taped compression dress.*

USA) was used to analyze the data. Results are presented as mean (SD) or number of patients (percentage). The two-sample t-test was used for comparisons of continuous variables between the groups, and the χ^2 test was used for comparisons of categorical variables.

RESULTS

Baseline characteristics

Of the 175 consecutively enrolled patients, 83 (47.4%) were male and the mean age was 71.2 (±13.3) years. Around 40% and 70% of the patients had underlying diabetes and hypertension, respectively (Table 1), and 31.4% and 16% had kidney and structural heart diseases, respectively. The prevalence of these characteristics was similar in both groups (Table 1). There were no significant differences between the two groups in terms of therapeutic interventions [(warfarin: 8.2% vs. 5.6% (p = 0.483); non-vitamin K oral anticoagulant (NOAC): 25.9% vs. 13.3% (p = 0.055); aspirin: 14.1% vs. 21.1% (p = 0.226); clopidogrel: 14.1% vs. 18.9% (p = 0.396); and dual-antiplatelet therapy: 4.7% vs. 1.1% (p = 0.154)]. Regarding the types of CIED used, 77.6% and 78.9% of the patients received pacemakers (p = 0.714) in the experimental and control groups, respectively.

Coagulation profiles were also similar in the two groups [hemoglobin: 12.39 vs. 12.52 (p = 0.64); platelet count: 213.8 × 10^3 vs. 204.9 × 10^3 (p = 0.763); and PTINR: 1.19 vs. 1.13 (p = 0.210)].

Outcomes of wound care

There were no statistically significant differences in the characteristics of the recipients between the two groups (Table 2). The results of the experimental vs. control group in terms of wound outcomes were as follows:

Table 1. Baseline characteristics

Variable	Experimental group (n = 85)	Control group (n = 90)	p value
Male	36 (42.4%)	46 (51.1%)	0.246
Age, mean (SD)	70.8 (13.7)	71.8 (12.8)	0.636
BMI, mean (SD)	24.8 (3.9)	24.8 (3.9)	0.964
Underlying disease			
Diabetes	34 (40.0%)	34 (37.8%)	0.763
Hypertension	61 (71.8%)	63 (70%)	0.797
Heart disease	11 (12.9%)	17 (18.9%)	0.283
Kidney disease	29 (34.1%)	26 (28.9%)	0.456
Stage 1-3	14 (16.5%)	12 (13.3%)	
Stage 4-5	8 (9.4%)	6 (6.7%)	
End-stage	7 (8.2%)	8 (8.9%)	
Medication			
Warfarin	7 (8.2%)	5 (5.6%)	0.483
NOAC	22 (25.9%)	12 (13.3%)	0.055
Aspirin	12 (14.1%)	19 (21.1%)	0.226
Clopidogrel	12 (14.1%)	17 (18.9%)	0.396
Dual antiplatelet	4 (4.7%)	1 (1.1%)	0.154
Type of device			
Pacemaker	66 (77.6%)	71 (78.9%)	0.714
Defibrillator	14 (16.5%)	16 (17.8%)	
Resynchronization	5 (4.6%)	3 (3.3%)	
Hb, mean (SD)	12.39 (2.07)	12.52 (2.05)	0.640
Plt, mean (SD), (10^3)	213.8 (78.8)	204.9 (69.1)	0.763
PT (INR), mean (SD)	1.19 (0.43)	1.13 (0.22)	0.210

BMI, body mass index; Hb, haemoglobin; NOAC, non-vitamin K oral anticoagulant; Plt,Platelet; PT (INR), prothrombin time (international normalized ratio); SD, standard deviation.

Table 2. Outcome of wound care

Variable	Experimental group (n = 85)	Control group (n = 90)	p value
Skin integrity	82 (96.5%)	78 (86.7%)	0.021
Oozing	1 (1.2%)	7 (7.8%)	0.037
Hematoma	0 (0%)	7 (7.8%)	0.009
Subcutaneous emphysema	0 (0%)	2 (2.2%)	0.167
Pocket infection at 1 year	3 (3.5%)	4 (4.4%)	0.758

skin integrity – 96.5% vs. 86.7% (p = 0.021), hematoma – 0% vs. 7.8% (p = 0.037), and oozing – 1.2% vs. 7.8% (p = 0.009). The incidence of subcutaneous emphysema was not significantly different between the two groups, and the incidence of pocket infections within one year of implantation was similar between the two groups [3.5% in the experimental group vs. 4.4% in the control group (p = 0.758)].

DISCUSSION

Efforts to reduce the incidence of complications are considered to be an important responsibility of a medical team.[13-15] Close observation of the wound, prompt detection of hematoma, and management with a compression dressing are critical steps to avoid serious complications.[13,16] Pressure bandages are a preventive management strategy for hematoma, and they are widely used for puncture sites.[8,17-19] However, the usefulness of pressure bandages for postoperative care of a CIED pocket is not clear, even though compression dressings are commonly used. Thus, this study is valuable in terms of proving the usefulness of postoperative compression and demonstrating the effectiveness of a non-taped method over the conventional method.

Our first hypothesis was that a conventional sandbag could not guarantee a constant pressure. In contrast, the novel compression dress provided a constant pressure on the surface of the pocket, which essentially reduced the incidence of hematoma to 0% compared to 7.8% in the control group and 4.6% according to the literature.[1] As the pressure pad and elastic bands were designed to be individually adjustable, the compression dress could fit the lateral chest wall of individuals of various shapes and body sizes. In addition, the lower incidence of oozing observed in the experimental group also prevented the need for additional interventions.

Another hypothesis was that elastic adhesive tape itself may cause skin damage. In this study, skin integrity was preserved more in the experimental group. Elastic bands and Velcro prevented the patients from developing bulla, tears, or detachment, which are commonly seen with conventional elastic tapes. The use of conventional elastic tapes can lead to contact allergic reactions and the development of violent shear force on removal. The results of this study also confirmed the safety and comfort of the novel compression dress, which are also in accordance with skin care principles in the elderly.[8-11]

Easy and time-saving procedures are critical to maintain consistent surgical efficacy. Elastic bands and a pressure pad can easily be adapted in terms of curve, length, and strength to fit various needs, and thus better skin care can be achieved. Taken together, our data strongly support the use of non-taped compression instead of conventional compression in medical routine practice after CIED implantation.

CONCLUSIONS

Non-taped compression was associated with better postoperative hemostasis and skin integrity in these patients after CIED implantation.

DECLARATION OF CONFLICT OF INTEREST

All the authors declare no conflict of interest.

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