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ORIGINAL ARTICLE

Stapling for wound dehiscence after cardiac implantable electronic device implantation

İmplante edilebilir elektronik kardiyak cihaz yerleştirilmesi sonrası oluşan yara açılmasının yönetiminde stapling yöntemi

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ABSTRACT

Objective: Wound dehiscence (WD) has been reported as a complication in 0.3% of cardiac implantable electronic device (CIED) procedures. Stapling has not previously been reported as a treatment modality for WD. Presently described is the experience of a single center with WD and its management.

Methods: A retrospective chart review of all patients who underwent CIED implantation between 2009 and 2016, a total of 759 devices, was performed.

Results: There were a total of 11 (1.4%) patients with WD. The majority 9/11 patients were female, 5 of 11 (45.5%) had diabetes, and 2 of the 11 patients were immunocompromised due to recent chemotherapy. WD occurred in 6 patients after generator change, in 2 patients after a biventricular device upgrade, in 1 patient after biventricular implantable cardioverter defibrillator (ICD) implantation, in 1 patient after dual-chamber pacemaker implantation, and in 1 patient after subcutaneous ICD implantation. The median time of WD was 6 weeks post procedure (range: 1–20 weeks). In all of the patients, wound stapling was performed under sterile conditions after administering intravenous narcotic analgesics. Eight patients received intravenous antibiotics and all patients received at least 2 weeks of oral antibiotics. Blood cultures were negative in 8/11 (72.7%) patients. However, the wound cultures in 5 patients were positive. The staples were removed in a median of 16 days (range: 9–36 days). All of these patients were successfully treated with stapling and none of the devices required extraction.

Conclusion: Stapling under sterile conditions may be an acceptable treatment strategy to manage WD after device implantation. This can be performed as an outpatient procedure and can help avoid unnecessary device extraction.

ÖZET

Amaç: İmplante edilebilir elektronik cihazları (İEEC) yerleştirilmesi sonucu komplikasyon olarak %0.3 oranında yara açılması bildirilmiştir. Yara açılmasında tedavi yöntemi olarak pens atma (stapling) yöntemi daha önce bildirilmemiştir. Bu yazıda yara açılmasında tek bir merkezin deneyimi ve tedavi yöntemi sunuldu.

Yöntemler: 2009 ila 2016 yılları arasında toplam 759 İEEC takılan hastaların tümünün hasta kayıtları geriye dönük olarak gözden geçirildi.

Bulgular: Yara açılması olan toplam 11 (%1.4) hasta vardı. Hastaların çoğu 9/11 hasta kadın olup 11 hastanın 5'i (%45.5) diyabetikti, yakın zamanlı kemoterapi nedeniyle ikisinin bağışıklık sistemi risk altındaydı. Cihazın enerji kaynağı değiştikten sonra 6, daha üst model biventriküler cihaz kullandıktan sonra 2, biventriküler kardiyoversiyon defibrilatörü (ICD) implantasyonundan sonra 1, iki odacıklı kalp pili yerleştirilmesi sonrası 1 ve deri altına ICD yerleştirilmesi sonrası ise 1 hastada yara açılması oluştu. İşlemlerden ortalama 6 hafta (dağılım, 1–20 hafta) sonra yara açılması oluşmuştu. Hastaların hepsinde steril koşullar altında, intravenöz narkotik analjezikler verildikten sonra açılmış yaralara pens atılmıştı (stapling). Sekiz hastaya IV antibiyotikler verildi ve hastaların hepsi en az 2 hafta oral antibiyotikler aldı. Çalışmaya kabul edilen 11 hastanın 8'inde (%72.7) kan kültürleri negatifti. Ancak 5 hastanın yara kültürleri pozitifti. Stapling telleri ortanca 16 (9–36 gün) günde çıkartıldı. Bu hastaların tümü stapling yöntemiyle başarılı bir şekilde tedavi edilmiş olup cihazların hiçbirinin çıkartılması gerekmemiştir.

Sonuç: Cihaz implantasyonuna bağlı yara açılmasında steril koşullar altında pens atma (stapling) kabul edilebilir bir tedavi stratejisi olabilir. Bu işlem poliklinikte uygulanabilir ve gereksiz yere cihazın çıkartılmasından kaçınmaya yardımcı olabilir.

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The indications and implantation rates of cardiac implantable electronic devices (CIEDs) are increasing all over the world. This has led to a concurrent increase in complications associated with CIEDs. Device infection and endocarditis are the complications that are most dreaded by electrophysiologists. The current expert consensus from the American Heart Association/American College of Cardiology/Heart Rhythm Society recommends the removal of all apparatuses (device and leads) in patients with definite CIED infection, lead endocarditis, pocket abscess, device erosion, or bacteremia.[1] Wound dehiscence (WD) can be the first sign of device infection and an alarm for imminent extraction. Device extractions can be tedious and have significant economic and healthcare consequences for the patient. Hence, identifying early signs of infection and implementing measures to prevent CIEDs infection is essential.

In this paper, we aimed to present the case series of 11 patients with WD who have been managed with wound stapling successfully without necessity of complete device extraction.

METHODS

A retrospective chart review of all patients who received a CIED between 2009 and 2016 at the University of Arkansas for Medical Sciences was conducted. A total of 759 charts were assessed and yielded a case series of 11 patients who had WD. The data collection included demographic details, medical history, wound characteristics, and follow-up data. The data analysis was performed using a Microsoft Excel (Microsoft Corp., Redmond, WA, USA) statistical package.

Patient selection

All of the patients with WD were seen in the device clinic and the decision to treat them as an outpatient versus an inpatient was based on the size of the dehiscence (wound less than 0.5 cm was stapled in an outpatient procedure). If the wound size was >0.5 cm, the patient was admitted for a septic workup (blood culture, wound culture, complete blood count, C-reactive protein [CRP] level and erythrocyte sedimentation rate [ESR]) and administration of empiric intravenous antibiotics was pursued. If the septic workup was negative (no evidence of bacteremia, systemic, or localized infection), the patient was discharged home with oral antibiotics for infection suppression. The usual hospital stay was 36 to 48 hours, based on the time required for blood culture results to be resulted in negative. Whenever possible, wound cultures were collected, even though their clinical significance is limited due to skin flora contamination. Patients who had WD and clear signs of pocket infection (pus leaking, redness, severe site pain and swelling, fever) were not included in this study and were referred directly for device explant. Figure 1a illustrates a representative case of WD.

Abbreviations:

CIED	*Cardiac implantable electronic device*
CRP	*C-reactive protein*
ESR	*Erythrocyte sedimentation rate*
ICD	*Implantable cardioverter defibrillator*
WD	*Wound dehiscence*

Stapling technique

In all, 8 patients were admitted to the hospital and 3 patients were managed in the clinic. An intravenous narcotic analgesic was administered to the patients before stapling. The wound was cleaned with hydrogen peroxide and then stapled under sterile conditions. The staples were placed about 0.5 to 2 mm apart, with the aim of preventing further dehiscence and achieving minimally approximate edges. The placement of the staples was according to the physician's experience. Dermabond (2-octyl cyanoacrylate; Ethicon, Inc., Somerville, NJ, USA) wound closure adhesive was then used to cover the wound. Sterile gauze was placed on top and covered with tape with minimal tension. The wound was kept covered with the sterile gauze until the next clinic visit. Patients were requested not to expose the area to water. Figures 1b and 2a show the wound stapling and wound closure adhesive.

Follow-up

Wound follow-up visits were scheduled weekly. If the wound had healed completely (sides approximated without any openings), the staples were removed and no further gauze covering was required. The objective was to have the staples in place for the minimum duration possible in order to prevent scarring and decrease the potential for infection from the staples. However, the staples were not removed until complete wound healing took place. Certain wound sites healed faster than others. Patients were given oral antibiotics to suppress infection and they were instructed to take those antibiotics until 1 week after complete wound healing had occurred. Figures 1c and 2b show healed

wounds immediately after the removal of the staples. Complete healing 1 week after staple removal can be seen in Figure 2c.

RESULTS

A chart review of 759 device implants revealed a total of 11 patients with WD (1.4%). The majority (9/11, 81.8%) were female, and 6/11 (54.5%) of the patients were African-American. The mean age was 50 years (±16 SD), and the mean body mass index was 30.2 kg/m^2 (±4.2 SD). About 8/11 (70%) of the patients had congestive heart failure, 5/11 (45%) had diabetes, 7/11 (63%) had hypertension, 2/11 (18%) were smokers, and 2/11 (18%) had active cancer and had recently received chemotherapy.

WD occurred in 6 patients after generator change, in 2 patients after biventricular device upgrade, in 1 patient after biventricular ICD implantation, in 1 patient after dual chamber pacemaker implantation, and in 1 patient after subcutaneous ICD implantation. The median time of WD was 6 weeks post procedure (range: 1–20 weeks). The blood cultures were negative in 8/11 (72.7%) of the patients. The remaining 3 patients didn't have blood cultures drawn, as their wound was less than 5 mm in size. The wound culture was positive in 5 patients (2 methicillin-resistant *Staphylococcus aureus*, 1 *Serratia marcescens*, 1 *Pseudomonas aeruginosa*, and 1 *Proteus mirabilis*). Table 1 displays some of the data collected for the present case series. None of the 11 cases had any evidence of pocket or deep tissue infection (i.e., yellow or purulent discharge, pain, swelling, or abnormal lab results).

Table 2 shows the admission lab results, including white blood cell count, CRP level, and ESR. Patients who were admitted to the hospital received intravenous vancomycin and cefepime until the septic work up was negative, and were discharged on oral antibiotics for infection prophylaxis and suppression. Patients whose wound was stapled in the clinic received oral antibiotics: doxycycline, cephalexin, trimethoprim-sulfamethoxazole, levofloxacin, or amoxicillin with clavulanic acid. The duration of oral

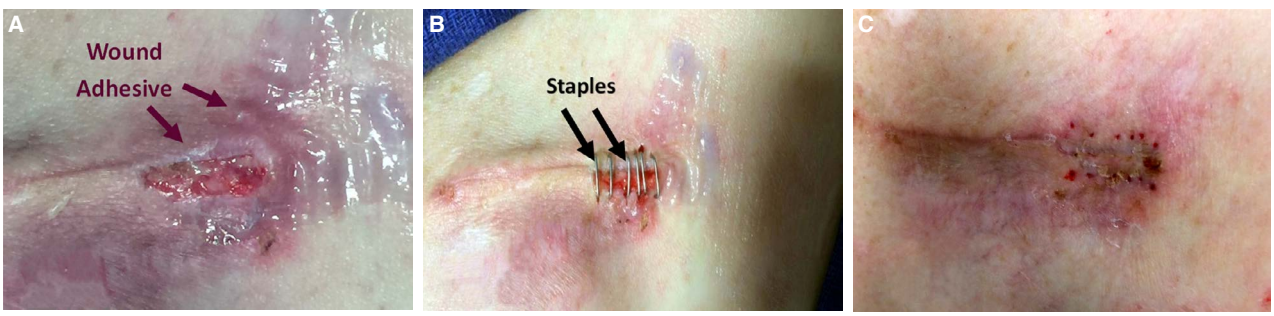

Figure 1. Case #1. **(A)** Wound dehiscence. Purple arrows indicate wound adhesive. **(B)** Staples applied to the wound are marked with black arrows. **(C)** Result after removal of staples with complete healing of wound dehiscence.

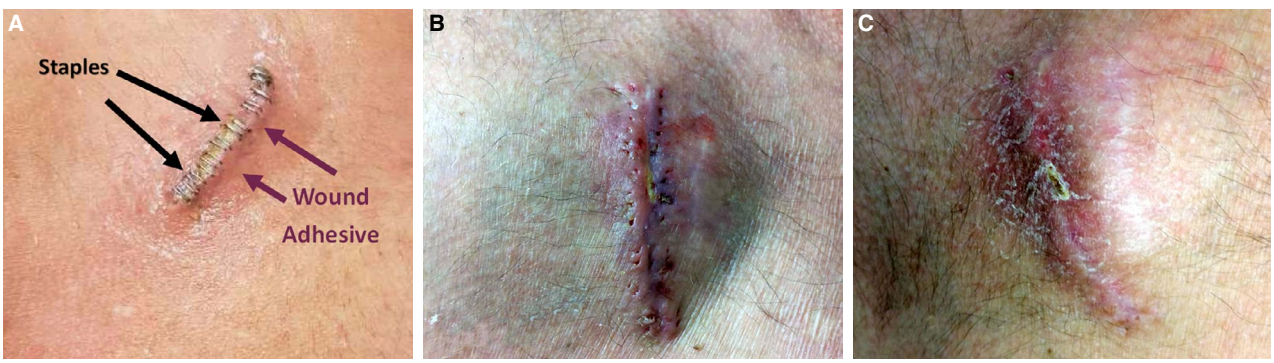

Figure 2. Case #2. **(A)** Wound dehiscence across the incision line. Staples are shown with black arrows, wound adhesive (shiny material around edges) is indicated with purple arrows. **(B)** Removal of staples and healing of wound dehiscence. **(C)** Picture taken 1 week after removal of staples.

Table 1. Characteristics of the study participants

Patient ID	Surgery	Device type	Wound culture	Oral ABx duration (days)	Duration between implantation and wound presentation (weeks)	Duration between stapling and healing (days)	Follow-up (months)
1	Generator change	PM	MRSA	24	16	15	23
2	Upgrade to BiV	ICD	–	14	1	15	24
3	Generator change	ICD	–	21	20	19	5
4	Generator change	PM	–	20	6	16	23
5	New	PM	–	14	8	9	12
6	Generator change	ICD	MRSA	45	6	21	10
7	Generator change	PM	Serratia marcescens	45	3	22	21
8	New	ICD	Pseudomonas aeruginosa	14	7	9	23
9	Generator change	ICD	–	21	4	14	18
10*	New subcutaneous	ICD	Proteus mirabilis	14	4	20	10
11*	Upgrade to BiV	ICD	–	21	8	36	2

(*): Patient deceased. ABx: Antibiotic; BiV: Biventricular device; ICD: Implantable cardioverter defibrillator; PM: Pacemaker.

Table 2. Lab data for study participants

Patient ID	CRP (mg/L)	ESR (mm/hr)	WBC (k/uL)	Neutrophil (%)
1	<5	9	7.98	49.4
2	5.3	45	4.72	44.9
3	6.9	34	5.87	55.9
4	Patient did not have labs drawn			
5	<5	10	10.26	66.4
6	6.9	59	6.61	57.6
7	<5	9	9.81	70.9
8	5.4	20	3.9	25.9
9	8.6	24	8.65	67.8
10	<5	43	7.63	64
11	33	35	6.46	64.4

CRP: C-reactive protein; ESR: Erythrocyte sedimentation rate; WBC: White blood cell.

antibiotic use ranged from 14 to 45 days, with a mean of 21 days.

The median length of time for wound healing and staple removal was 16 days. Two patients required more than 3 weeks due to a small wound opening. All of the staples were removed except 1 at the opening, which healed in another week. All patients were successfully managed with stapling and none of the devices required extraction. Follow-up duration for the patients ranged between 5 to 24 months (median of 21 months, average 18 months) without any recurrence of WD or occurrence of CIED infection.

DISCUSSION

CIED infections pose a huge burden on healthcare systems. Cabell et al.[2] reported a 42% increase in CIED infections between 1990 and 1999 in Medicare beneficiaries. One retrospective study across 23 years found 12 device infections out of 1307 devices (9 per 1000).[3]

One meta-analysis reported a higher odds ratio for device infections in the following cases: diabetes mellitus (Odds ratio [OR]: 2.08), end-stage renal disease (OR: 8.73), chronic obstructive pulmonary disease (OR: 2.95), corticosteroid use (OR: 3.44), history of previous device infection (OR: 7.84), pre-procedural fever (OR: 4.27), postoperative hematoma (OR: 8.46), abdominal pocket (OR: 4.01), and epicardial leads (OR: 8.09).[4]

According to the guidelines of the Heart Rhythm Society, extraction of the device and leads is indicated in cases of device infection, valvular endocarditis, lead

endocarditis, or sepsis.[1] They recommend against device removal in cases of superficial or incisional infection.[1] Minimal data is available to guide the management of superficial WD, but clinical practice suggests wound washout and gentle debridement with a course of antibiotics prophylactically.[5] Exposure of the device, lead components, or dehiscence in the subcutaneous tissue mandates removal of the device.[1,5]

Several case series in the literature report management of device infections without removal of the device. Local flap coverage and formation of a new pocket for a new device was successful in 5 out of 6 cases of exposed leads.[6] Chronic antibiotic suppression has also been used in patients with infected devices who either declined extraction or were too high-risk for surgery due to medical comorbidities. One study reported a 44% (21/48) mortality rate at 1 year and a reinfection rate of 18%.[7] Use of a closed antimicrobial irrigation system within the pocket was successful in 5 cases in which lead extraction carried a high risk.[8]

WD is often an early sign of impending CIED infection and management has been urgent device extraction. WD can happen at any time after device implantation, and our study had a range of between 1 and 20 weeks between implantation and the occurrence of WD. It is notable that many of our cases had late WD presentation, which might not be related to implantation, but rather could be due to excess tissue tension. Another reason for this late presentation could be overuse of the arm or an asymptomatic superficial infection that led to tissue weakness and eventual dehiscence.

It is also worth mentioning that 8 of 11 cases with WD were a re-procedure (either upgrade or generator change) in which the same incision site from the previous surgery was used. When an incision is made to a previously operated area, the tissue is known to be more frail and at risk for dehiscence. A compromised immune system, or a suppressed inflammatory response, such as in diabetic patients, could also play a role in dehiscence as an insufficient response to an offending microorganism may lead to a superficial infection.

All of our patients had negative blood cultures, but 5 had positive wound cultures. Superficial wound cultures are not accurate and do not determine if a wound is infected. The yield of such tests has been known to be low, especially since skin has flora that may grow on cultures. Wound cultures may have influenced our decision to use oral antibiotics when the wound culture was positive as a preemptive prophylactic intervention. Such superficial cultures are different from deep wound cultures obtained during surgical procedures, which are crucial in the management of infections.

We implemented the same procedural steps in all of the patients, with an emphasis on sterile technique. We believe that staples provide support and tissue approximation without significant skin tension, enabling faster healing and the opportunity for unimpeded wound drainage. Although our follow-up period averaged 18 months, it is unknown if those patients will develop device pocket infection or endocarditis in the future and this will remain a limitation of our study. Nonetheless, we believe that if an infection were going to occur, it would most likely be apparent within a few weeks of dehiscence.

Our case series demonstrated success in preventing device infection and further complications by using staples to help close wounds. To our knowledge, this technique has not been previously reported in the literature.

Conclusion

Wound stapling can be considered for cases of CIED WD without any evidence of pocket infection and may prevent unnecessary device extractions and infections. This technique should be further studied on a larger scale with longer follow-up.

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Keywords: Device implantation; device infection; wound dehiscence; wound stapling.

Anahtar sözcükler: Cihaz implantasyonu; cihaz enfeksiyonu; yara açılması; yaraya pens atma.