ABSTRACT. The use of cardiac implantable electronic devices (CIEDs) such as pacemakers, cardioverter-defibrillators, and loop recorders carries a risk of infection. The reported infection rate for newly implanted devices is approximately 1% and approximately 4–5% for replacement of generators. We are reporting the use of a multiple layered technique for wound closure after cardiac device implantation to reduce the risk of post-surgical infection and improve the appearance of scars. All device implantations from January 2007 to December 2012 by a single implanting physician (B.P.G.) used the layered closure technique. Of the 311 patients, 116 were males and 195 were females with a mean age of 54 years. There were 169 loop recorder implants, 105 pacemakers, 24 cardioverter-defibrillators, and 13 biventricular cardioverter-defibrillators. The follow-up period ranged from 1 month to 69 months. Of the 311 patients selected there was only one infection. This is an infection rate of 0.32% compared with the reported 1%. In addition, all of the patients studied were pleased with the appearance of the scar. This layered closure technique has provided a reduction in the infection rate of implantable cardiac devices as well as an improvement in the final cosmetic appearance of the scar.

KEYWORDS. Pacemakers, ICD, Wound.

Methods
This was a single center retrospective review of newly implanted cardiac devices including pacemakers, cardioverter-defibrillators, and loop recorders from 2007 to 2012.
2012 at the University of Toledo Medical Center. The data collected included age, sex, body mass index, and comorbidities such as diabetes mellitus, hypertension, obesity, coronary artery disease, current or history of smoking, and chronic steroid treatment. At follow-up, the documentation addressed signs of infection and satisfaction with the cosmetic appearance of the scar.

Surgical technique

After an initial sharp skin incision, meticulous blunt dissection was employed to create a new subfascial pocket. After device placement, the pocket was rinsed with an antibiotic solution. The fascial layer was closed with a 2-0 absorbable braided polyfilament suture (Figures 1 and 2). The subdermal layer was then closed with a series of interrupted sutures using 3-0 absorbable monofilament suture material. Each of the deep sutures was approximately 5 mm apart from each other, with the suture knot buried deep in the subcutaneous tissue. A final continuous subcuticular suture was placed in the superficial dermis using a 4-0 absorbable monofilament (Figure 3). The skin surface was then sealed with surgical tissue adhesive and the wound was dressed with a non-adherent gauze pad and a transparent adhesive film dressing. The patients were allowed to shower immediately after implantation. All patients were seen 1 week after implantation to remove the dressing and check the wound. The patients were then seen at follow-up intervals of monthly, every 3 months, or every 6 months.²

Results

Of the 311 patients included in the study, 116 were males and 195 were females with a mean age of 54 ± 25 years. There were 169 loop recorder implants, 105 pacemakers, 24 cardioverter-defibrillators, and 13 biventricular cardioverter-defibrillators (Figure 4). The follow-up period ranged from 1 month to 69 months after implantation. There was one case of wound dehiscence, one case of allergic reaction to the metal of the device, and one case of infection. Thus, an infection rate of 0.32% was observed in our series. Figure 5 shows the risk factor profile of our study population.

Discussion

The past decade has shown an increase in the number of CIEDs being implanted; however, the infection rate is increasing at a much faster rate. Our study evaluates a multiple layered closure technique and the effect on
device infection. Our study shows an infection rate of 0.32% with the multiple layered closure technique, which is a significant reduction compared with the nationally reported rate of 1%. Most published studies show an infection rate of 2.4–6.9% for CIEDs. Figure 6 compares studies with similar patient characteristics and risk factors to our study. However, our study of all devices shows a significantly lower rate of infection. Hercé et al.³ have determined specific risk factors associated with increased rates of infection. These risk factors include age, diabetes, and corticosteroid use. Figure 4 shows the percentage of our population with these risk factors as well as diabetes, hypertension, obesity, coronary artery disease, smoking, and corticosteroid use. Figure 6 shows the distribution of risk factors of our patient population compared with that of Gil et al.¹ Given the distribution of risk factors in our patient population, we would predict a higher rate of infection. Gil et al.¹ report an infection rate of 2.4% compared with our reported rate of 0.32%.

With the passage of new legislation in October 2012, CMS will no longer reimburse hospitals for the treatment of surgical site infections after implantation of IECDS. Given this environment of cost containment, there is an apparent need for a technique to lower rates of infection. We have demonstrated a reduction in the infection rate with a multiple layered closure technique. Currently the approximate cost of an infected device is $28,000–58,000 and could range upward of $100,000.² Given the current rate of implanted IECDS each year, about 500,000, and the currently published infection rate of 1%, a conservative estimate of 5,000 infected devices at a cost of $28,000 per device would be approximately $140,000,000 in non-reimbursed costs. Using the modified closure technique with our reported infection rate of 0.32% and the current rate of IECDs implanted each year, approximately 1,600 infected devices at a cost of $28,000 per device would be approximately $44,800,000 in non-reimbursed costs. The use of the modified closure technique could save $95,200,000 per year of non-reimbursed funds. Figure 7 shows the potential savings of using the modified closure technique. The potential saving is all non-reimbursable funds. This estimate only takes into account the lowest of the national average infection rate and the lowest cost of replacing IECDS.

**Limitations**

Our study has some limitations. This was a retrospective study. For a 50% reduction in the reported infection rate (1%) a sample population of about 2,589 would be needed (α = 0.05, p = 0.80). Given our result of an infection rate of 0.32% and the same parameters, a sample size of 1,273 would be needed for adequate power. A larger study is being conducted now to obtain the required sample size for adequate power.

**Conclusions**

This study is a comprehensive review of the use of the modified closure technique at a single institution for newly implanted cardiac devices over a 6-year period. The data from our study show a reduction in infection rates when compared with previously published results. Our results could lower infection rates for CIEDs and potentially save institutions millions of dollars per year.
References


