The management of exposed cardiac pacemaker pulse generator and electrode using restricted local surgical interventions; subcapsular relocation and vertical-to-horizontal bow transposition techniques

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Summary—This paper describes an approach to the treatment of exposed pacemaker generator and electrode. Local infection is controlled by the administration of systemic antibiotics and topical antibacterial solutions. Because the generator and lead are enveloped by an inert synthetic coating, it is possible to eradicate an infection without their removal if it is due to a weak opportunistic pathogen fully sensitive to antibiotics. Thereafter, subcapsular relocation of the exposed generator or vertical-to-horizontal transposition of the exteriorised lead is carried out. These surgical interventions are designed to overcome the vertical force which tends to cause the extrusion of the pacing hardware.

Since 1960, when the first cardiac pacemaker was implanted by Chardack et al. (1960, 1961), the plastic surgeon has been confronted with two main problems related to this procedure. One is local infection and the other is the exposure of the pulse generator or electrode due to pressure necrosis of the overlying skin. The soft tissue complication rates vary from 1 to 15 per cent (Coburn et al., 1972; Imparato and Kim, 1972; Sowton et al., 1974; Chari and Suri, 1977; Chait and Ritchie, 1979; Garcia-Rinaldi et al., 1985; Fayman et al., 1986; Hurst et al., 1986).

This paper is aimed to present the combined management approach in two patients who were successfully treated with systemic antibiotics and topical antibacterial solutions followed by restricted local surgical methods. A long-term follow-up is presented.

Case reports

Case 1
A 72-year-old woman was referred to the plastic surgery department with an exposed right infraclavicular electrode and a history of recurrent local and systemic staphylococcal infections during the previous 12 months (Figs 1 and 2). The infections were treated successfully by systemic antibiotics and by local antibacterial solutions. The patient had a previous left radical mastectomy and in addition to her progressive cardiac insufficiency she suffered from a cerebrovascular accident. Under local anaesthesia, the exposed wire was thoroughly cleansed and the bridge of skin underneath the bowed electrode was incised, releasing the bow from the surrounding fibrotic tissue. A wide subfascial pocket was created and the exposed lead was transposed from its vertical to a horizontal position, without any coiling of the electrode taking place. The wound was irrigated thoroughly with povidone iodine, saline and antibiotic solutions. The lead was anchored subfascially, while the location of the pulse generator was not entered or changed. The subcutaneous tissue and skin were sutured in layers. No drain was used. The patient left hospital 7 days after surgery with an uneventful follow-up of 19 months (Fig. 3).

Case 2
A diabetic 78-year-old man was referred to our department with a pacemaker generator exposed through a 1 cm opening in the surgical scar. His post-surgical history revealed that a month following the insertion of the pacing system a sinus infected with gram-negative Staphylococcus appeared at the suture line. The sinus enlarged within several days, exposing the pulse generator. Topical wound irrigation and systemic antibiotics had been administered and the open wound diminished to the above size (Fig. 4).

Under local anaesthesia the edges of the surgical wound were excised and the infected pocket was widely opened. The pulse generator and its connecting electrode were freed of all tissue attachments without detaching them from the heart or body surface (unipolar system).
The pocket was thoroughly irrigated and a circumferential capsulotomy was performed. Then a new pocket was created underneath the previous one and above the pectoralis major muscle. After irrigating the new pocket, as well as the pulse generator and electrode, with disinfecting and antibiotic solutions, the cleansed pacing unit was resited in the new, deeper location. The floor of the previous pocket served as a roof for the new one, thus covering the pacing system (Figs 5 and 6). The surgical wound was closed in two layers without drainage. The patient was discharged 7 days after surgery, with a trouble-free follow-up of 12 months.

Discussion

Phibbs and Marriott (1985) discussed the complications of permanent transvenous pacing units and stated that in the presence of infection the pacing system should be removed. According to these authors the mortality associated with infection, if the pacemaker is not removed, is in the range of 66 per cent. However, removal and reintroduction of the pacing apparatus involved potential problems and complications since the number of alternative sites for reimplantation is limited and it is therefore important to consider whether it is possible to salvage an exposed, well-functioning unit by employing a local surgical approach which will eliminate the basic cause of the problem. A number of methods have been suggested to achieve this aim. The general approach consists of the administration of systemic and topical antibiotics in conjunction with local skin or muscle flaps (Coburn et al., 1972; Imparato and Kim, 1972; Kim et al., 1974; Chari and Suri, 1977; Chait and Ritchie, 1979; Golan et al., 1981; Garcia-Rinaldi et al., 1985; Fayman et al., 1986). Although many methods were innovative, the overall outcome of these techniques still proves rather disappointing in view of the high recurrence rates.

The principal causes of pacemaker system extrusion are pressure necrosis of the overlying skin and infection, which may be related to one another (Boncheck, 1972; Golan et al., 1981; Garcia-Rinaldi et al., 1985; Phibbs and Marriott, 1985; Goldman, 1986).

The pulse generator is constructed from titanium, a light corrosion-resistant metal, covered by a passive oxide surface film which causes very little tissue reaction. However, scratch marks on the surface which break the protective oxide layer may set up a reaction in the surrounding tissue (Chari and Suri, 1977). The pacing lead is enveloped with silicone rubber which also gives rise to little reaction (Brody, 1988).

In dealing with an infected pacing system, success has been reported by an in situ conservative
treatment without removal of the pacemaker units (Boncheck, 1972; Furman et al., 1972; Golden et al., 1973; Holswade, 1979). The treatment described by Boncheck consisted of intravenous antibiotics, local wound irrigation with bacteriocidal antibiotic solutions and surgical repair by enlarging the existing capsule pocket. In 1986 Hurst et al. salvaged infected cardiac pacemaker pockets by local debridement and insertion of a closed irrigation system. Other proposed methods are subfascial pocket relocation of the unit (Garcia-Rinaldi et al., 1985) or the use of local skin flaps (Chari and Suri, 1977). The rationale on which these methods are based is that the materials enveloping the cardiac pacemaker and electrode are inert. Thus, careful surgical debridement and resterilisation of the infected pocket and foreign body may eradicate the infection without complete replacement of the pacemaker system.

Because most clinical infections associated with prosthetic implants are due to a weak, antibiotic-sensitive and opportunistic pathogen such as *Staphylococcus epidermidis* which cannot attack and dissolve the generator metal or the silicone rubber enveloping the pacing lead, it is possible to irrigate the exposed generator or lead with disinfecting solutions that will eradicate all surrounding pathogens and the sterile pacing hardware can be relocated primarily without the fear of recurrent infection. Reinforcement of this concept is ex-
pressed by Wong and co-workers (1987) who described the successful control of *S. epidermidis* infections in the presence of silicone implants which were not removed.

Frequently the patient in whom the pacemaker system is implanted is old and debilitated and suffering from other systemic diseases such as diabetes etc. Some are thin, with little subcutaneous tissue and poor skin turgor and are prone to pressure necrosis of the skin, and the pulse generator or lead become exposed.

Marked contracture of the skin around the pulse generator has been noted following pacemaker replacement and may herald skin erosion (Imparato and Kim, 1972) and it may be due to adherence of the skin to the underlying capsule or as a response to bacterial proliferation (mainly *S. epidermidis*) around the cardiac pacemaker (Burkhardt, 1988).

From the above it can be concluded that the main guideline in the management of the exposed cardiac pacemaker is to eliminate the basic mechanical forces causing it. The surgical management of an exposed infraclavicular pacemaker electrode has not, to our knowledge, previously been described in the literature. The main mechanical force which accounted for the erosion of the overlying skin was the acute vertical bend of the bowed lead. The transposition of this bend from a vertical to a horizontal position as well as anchoring the lead subfascially abolished the vertical pressure on the covering skin (Fig. 3). Chait and Ritchie (1979) proposed this principle of horizontal placement of the lead loop as deep as possible, as a technical point which might reduce the risk of exposure.

The exposed pulse generator was managed by creating additional double fibrous layer padding above it, as well as providing a new and large subcapsular pocket. The increased coverage will have a better chance of resisting the extruding mechanical force of the pacing unit. In addition, we have used the subcapsular relocation technique on two other patients for the treatment of impending extrusion of the pacemaker generator due to capsular contracture associated with signs of pressure necrosis of the overlying skin.

A preoperative chest X-ray is valuable because it determines the exact location of the pacemaker generator as well as the course and excess of the lead. When relocating the pacemaker unit, care must be taken to ensure that the pacing wires are wound smoothly around the generator without kinking or acute bends. Parenteral antibiotics are started preoperatively and continued for 7 days.

Thorough irrigation of the infected tissue and unit with antibacterial solutions, careful technique and prevention of a haematoma are all considered essentials for successful repair. These proposed methods are applicable when the infection is clinically limited to the extrusion site and when the organism is of low pathogenicity. They should not be used in patients with generalised sepsis, evidence of intrathoracic infection or immunosuppressive conditions.

These short, restricted local surgical interventions, under local anaesthesia, permit early ambulation of the patient. They prevent the risky removal and reintroduction of the entire pacemaker system. In addition, the proposed techniques do not harm the surrounding healthy tissue and do not use up another pacing site, which are already limited in number.

**References**


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