Subpectoral implantation of a cardioverter defibrillator under local anaesthesia

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Abstract

Objective—To evaluate patient acceptability of submuscular implantation of a cardioverter defibrillator (ICD) under local anaesthesia with conscious sedation.
Design—Retrospective review. Patient acceptability in the second half of the study was routinely assessed within 24 hours.
Setting—Regional cardiac centre.
Patients—45 consecutive patients with either aborted sudden death or haemodynamically unstable ventricular tachycardia were referred for ICD implantation.
Interventions—A subpectoral implantation technique was employed. Twelve procedures were performed under general anaesthesia. Thirty three patients were sedated with midazolam and diamorphine, and local anaesthesia was achieved with bupivicaine. Ventricular fibrillation for defibrillation threshold testing was induced by alternating current, T wave shock, or ultrarapid burst pacing. Patients were contacted after the procedure to assess acceptability.
Results—32 patients having implantation under local anaesthesia did not recall the surgical procedure. One patient described an awareness of "pushing" as the generator was positioned in the pocket. Seven patients said that the procedure was painless but recalled a test shock, four describing it as mildly uncomfortable. All 33 patients stated that they would be willing to have a second implant under local anaesthesia. Twelve patients who had the implant performed under general anaesthesia had no recollection of the procedure. Mean (SD) total procedure duration was significantly longer in those who had general anaesthesia (93 (16) *v* 67 (17) minutes; p = 0.0009).
Conclusions—Subpectoral implantation of ICDs may be performed safely with patient acceptability under local anaesthesia with conscious sedation.
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Pectoral placement of cardioverter defibrillators (ICDs) in most adult patients has become commonplace with the development of transvenous lead systems and downsizing of pulse generators.[1–5] Both subcutaneous and submuscular implantation techniques under general anaesthesia have been described.[6–9] The subpectoral technique has been advocated as older generation pacemakers of comparable size to current ICD devices are associated with significant risk of erosion and wound complications.[10 11] In addition, lead displacement is more frequently noted with subcutaneous implantation.[12] The use of local anaesthesia with conscious sedation is widely reported for prepectoral implantation of permanent pacemakers and more recently for ICDs that are significantly larger, may be inserted submuscularly, and require testing of defibrillation thresholds (DFT) at implant.

This study evaluated patient acceptability of a subpectoral implantation technique under local anaesthesia with conscious sedation.

Patients and methods

Between August 1995 and August 1997, 45 consecutive patients receiving ICDs (37 men and eight women, mean (SD) age 56 (14) years) underwent implantation using a subpectoral technique in a regional cardiac centre. Twenty patients (44%) had experienced aborted sudden death and 25 (56%) had haemodynamically unstable ventricular tachycardia refractory to medical treatment. Twenty nine patients had coronary artery disease: overall mean (SD) ejection fraction determined by echocardiography or left ventriculography was 41(20)%.

All procedures were performed in a catheter laboratory using strict sterile technique. Twelve consecutive procedures were performed under general anaesthesia. The following protocol was adopted for 33 subsequent procedures under local anaesthesia with conscious sedation:
(1) Two implanting physicians, a nurse with anaesthetic training, two further nurses, and two technicians were present for all procedures
(2) Patients were sedated with midazolam and diamorphine and local anaesthesia was achieved with 0.5% bupivicaine infiltrated down to the external intercostal fascia
(3) All patients received supplemental oxygen through a face mask
(4) Oxygen saturation was monitored continuously by pulse oximetry and blood pressure non-invasively using a Dinamap
(5) Depth of sedation was assessed by response to interrogation, observation of respiratory pattern, and spontaneous movement to painful stimuli. A 1.0 J synchronised shock was delivered to measure lead impedance before defibrillation threshold testing. Adequacy of sedation for DFT testing was assessed by response to

this low energy shock and a further bolus of midazolam was given if required

(6) Bolus doses of naloxone and flumazenil were available to reverse sedation immediately, if needed.

Devices (Medtronic Jewel (Minneapolis, Minnesota, USA) or CPI Ventak Mini (Cardiac Pacemakers Inc, St Paul, Minnesota, USA)) were implanted in a submuscular pocket. A Seldinger approach to the subclavian vein was used in all patients for lead (Medtronic Transvene or CPI Endotak) placement. Venous puncture was made in the submuscular tissue plane, avoiding the need for the implanted lead to traverse muscular and fascial planes on way to the subclavian vein. Ventricular fibrillation for DFT testing was induced by alternating current,[12] T wave shock,[20] or ultrarapid burst pacing.[12] Four patients had additional coils positioned in the superior vena cava. Procedure time was defined from induction of general anaesthesia or conscious sedation to time leaving the catheter laboratory. Patient satisfaction and recall of the procedure were recorded by questionnaire. The last 24 of the 33 patients who received ICDs under local anaesthesia completed the questionnaire the day after the procedure. All others were contacted retrospectively.

STATISTICS

Data are expressed as means (SD). Procedure duration between the two groups was compared using an unpaired *t* test.

Results

There were no significant differences in ejection fraction, underlying aetiology, age, sex, or presence of ischaemic heart disease between the patient groups having an implant under general or local anaesthesia. The mean (SD) number of inductions of ventricular fibrillation at implant was 2.3 (1.3). Procedure duration was significantly longer in patients who had general anaesthesia (93 (16) *v* 67 (17) minutes; p = 0.0009).

All 12 patients who had general anaesthesia for ICD implantation had no recollection of the procedure or test shock. Ten patients said that they would be willing to undergo implant under local anaesthesia.

Thirty two patients undergoing implant under local anaesthesia did not recall the surgical procedure. One patient described an awareness of "pushing" as the generator was positioned in the subpectoral pocket. Seven patients who said that the procedure was painless recalled a test shock, describing it as an awareness (n = 3) or mildly uncomfortable (n = 4). Recollection of a test shock seemed to be unrelated to the method of induction of ventricular fibrillation. All 33 patients said that they would be willing to have a second implant under local anaesthesia. The mean (SD) total dose of midazolam used was 7.8 (2.3) mg and diamorphine 4.7 (1.8) mg. There were no episodes of apnoea or arterial hypotension and assisted ventilation was not required.

All 45 patients were satisfied with the cosmetic result. After a mean (SD) follow up period of 13.7 (7.7) months there were no documented episodes of device or lead erosion, lead displacement or fracture, or formation of seroma or haematoma. Limitation of shoulder or arm movement was not reported. One non-cardiac death occurred after 12 months of follow up.

Two patients could not be implanted under local anaesthesia because of an inadequate DFT. Both patients required a second procedure under general anaesthesia with placement of a Sub-Q-Array (Medtronic) in one and an Endotak array (CPI) in the other. Two patients developed a pneumothorax relating to subclavian vein cannulation. The pneumothorax was managed conservatively in one patient and treated successfully by aspiration in the other.

Discussion

Pectoral placement of ICDs in most adult patients is now routine with the reduced size of pulse generators and the development of transvenous lead systems.[1 2 6 7] Subcutaneous device placement using the subclavian or cephalic veins for the lead is a relatively simple technique comparable to that of permanent pacemaker insertion, but is associated with a higher incidence of lead displacement and concern exists over the incidence of device erosion.[3 10 11] The safe use of local anaesthesia with sedation in a series of 27 patients who underwent either subcutaneous abdominal (n = 23) or subcutaneous pectoral (n = 4) device placement has been described.[13]

Subpectoral implantation of ICDs is more complex and usually requires general anaesthesia.[14] Different methods for lead placement with a subpectoral generator have been described.[6–8 15] Where lead complications have been reported, the technique invariably involves traversing the fascial and muscular planes to enter the venous system.[12 16–20] Ideally, the subclavian vein should be entered in the same tissue plane as the device pocket to prevent lead displacement resulting from contraction of the clavicular belly of pectoralis major.

Conscious sedation in the absence of an anaesthetist using a combination of benzodiazepines and opioids is widely used for colonoscopy, endoscopic retrograde cholangiopancreatography, dental, ureteroscopic, and orthopaedic procedures.[21–26] The safety, efficacy, and patient tolerability of such procedures using such a combination is well documented. For both agents rapid pharmacological reversal is possible: flumazenil is a safe and effective agent to reverse benzodiazepine induced respiratory depression, and naloxone may be used to reverse opiate induced sedation.[27] The efficacy of flumazenil in reversing midazolam induced sedation in the presence of an opioid has been reported.[28] In many centres conscious sedation for post-implantation defibrillation testing is routine. This suggests that an opiate and midazolam may be a safe and efficacious combination for induction of conscious sedation in the cardiac catheter laboratory for subpectoral ICD implantation.

This retrospective study shows patient acceptability of submuscular ICD implantation under local anaesthesia and confirms the lack of complications relating to the wound and lead. Despite the need for more extensive dissection than with a prepectoral approach, submuscular implantation was well tolerated, with 32 of 33 patients having complete amnesia for the procedure when performed under local anaesthesia. Seven patients recalled a test shock but none found it distressing or painful. All were willing to have repeat testing or system revision under local anaesthesia. This observation suggests that the combination of midazolam, a benzodiazepine with amnesic, anxiolytic, and sedative hypnotic properties, an opiate analgesic agent, and local anaesthesia achieves adequate sedation and analgesia for subpectoral ICD implantation and defibrillation testing, obviating the need for general anaesthesia. This has important implications in terms of procedural cost, duration, and safety in patients with a high incidence of coronary artery disease and impaired left ventricular function at greater risk from general anaesthesia. Strickberger *et al* reported a 4% complication rate directly related to intubation and general anaesthesia during ICD implantation.[14] Scheduling delays may arise when an anaesthetist is required for ICD placement with resultant increases in the length and cost of inpatient stay.

We therefore advocate a subpectoral pocket for ICD placement in adult patients, which may be performed safely with patient acceptability under local anaesthesia with conscious sedation in the cardiac catheter laboratory.

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