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Clinical Research

Performance of a Radiation Protection Cabin During Extraction of Cardiac Devices

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ABSTRACT

Background: Operators who extract cardiac devices are exposed to considerable irradiation and excess risk of radiation-induced disorders. A dedicated radioprotection cabin was developed to offer complete protection against radiation. This randomized study was designed to ascertain the protection against radiation conferred by a radioprotection cabin and the safety during extraction of cardiac devices.

Methods: Thirty-seven consecutive patients who presented with an indication for extraction of a cardiac device were randomly assigned to a standard extraction technique (n = 19), vs extraction with the use of a radiation protection cabin (n = 18). Fluoroscopic exposure was compared using electronic dosimeters placed on the thorax, back, foot, and head of the operator.

Results: The procedural times and total fluoroscopic exposure times and the complication rates were not significantly different between the 2 groups. The mean dose of radiation delivered to the thorax and back was similar in both groups ($P = 0.3$ and $P = 0.8$, respectively). In contrast, the mean doses of radiation delivered to the head and to the feet were respectively 68 and 390 times less in the cabin group than in the control group ($P < 0.001$).

Conclusions: The cabin offers nearly full body radioprotection and eliminates the need to wear a lead apron, without increasing procedural time or complication rate during cardiac device extraction.

RÉSUMÉ

Introduction : Les opérateurs qui procèdent à l'extraction des dispositifs cardiaques sont exposés à une irradiation importante et un risque additionnel de troubles radio-induits. Une cabine de radioprotection a été conçue expressément pour offrir une protection complète contre la radiation. Cette étude aléatoire a été réalisée pour vérifier la protection qu'offre la cabine de radioprotection contre les radiations et la sécurité durant l'extraction des dispositifs cardiaques.

Méthodes : Trente-sept (37) patients consécutifs qui présentaient une indication d'extraction d'un dispositif cardiaque ont été choisis de manière aléatoire pour subir une technique d'extraction standard (n = 19) *vs* une technique d'extraction comportant l'utilisation d'une cabine de radioprotection (n = 18). L'exposition radioscopique a été comparée en utilisant les dosimètres électroniques placés sur le thorax, le dos, le pied et la tête de l'opérateur.

Résultats : Les durées d'intervention, les durées d'exposition radioscopique totales et les taux de complications ne différaient pas de manière significative entre les 2 groupes. La dose moyenne de radiations auxquelles le thorax et le dos étaient exposés était similaire dans les 2 groupes ($P = 0,3$ et $P = 0,8$, respectivement). En revanche, les doses moyennes de radiations auxquelles la tête et le pied étaient exposés étaient respectivement de 68 et de 390 fois moindres dans le groupe utilisant la cabine que dans le groupe témoin ($P < 0,001$).

Conclusions : La cabine offre une radioprotection corporelle presque entière et dispense du port d'un tablier de plomb, sans augmenter la durée d'intervention ou le taux de complications durant l'extraction du dispositif cardiaque.

As the rate of cardiac devices implanted increases rapidly worldwide, extractions of chronically implanted endocardial leads are being attempted by a growing number of physicians. Indeed, the management of overt device infection is relatively standardized and based on prolonged antimicrobial therapy and extraction of all the implanted material. In nonfunctional leads, extraction of the failing lead can also be proposed when there is a clinical goal that balances the risk of removal.[1,2] Despite important technological progress, the extraction of chronically implanted transvenous lead systems remains a complex procedure, associated with prolonged procedural duration and considerable irradiation for the patient and the medical professionals.[3-6] Protection of the medical staff against radiation exposure is an issue that has sometimes been neglected. Operators who extract cardiac devices are also most

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of the time implanters of pacemakers and cardiac defibrillators and are exposed to considerable irradiation. During a standard extraction of a cardiac device, the protection against radiation is incomplete because the head is unprotected by the lead apron, the thyroid collar, or the leaded eyeglasses. Medical professionals might therefore be exposed to doses exceeding the threshold associated with an increased risk of radiation-induced disorders. Furthermore, the bulk and encumbrance represented by the apron are the cause of discomfort, lumbalgia, and orthopedic spinal disorders.[7] The procedure of extraction can be divided into 3 steps: local surgery with removal of the generator and liberation of the proximal end of the lead, extraction of the lead using fluoroscopic surveillance, and wound closure. A radiation protection cabin had been previously validated for invasive electrophysiological procedures using a femoral approach.[8] Such a cabin allows performance of catheter ablation procedures and even single or dual chamber pacemaker implantation with negligible radiation exposure for the operator surrounded by 2-mm lead-equivalent walls.[9] Such a cabin, however, provides limited access to the patient through 2 arm holes, precluding the use of traction devices or powered sheaths inside the cabin. A completely new version of the radioprotection cabin, the Cathpax CRM cabin (Lemer Pax, Carquefou, France), specifically developed for implantation and extraction of cardiac devices, has been designed to offer complete protection against radiation and to handle the constraints associated with the procedure.

The present study was designed to demonstrate the safety and to ascertain the protection against radiation conferred by this cabin during extraction of cardiac devices.

Methods

Thirty-seven consecutive patients who presented with class I or II indications for extraction of single-, dual-, or triple-chamber pacemaker or implantable cardioverter defibrillator[1] were randomly assigned to standard extraction technique, using as recommended, lead apron, thyroid collar, and leaded eyeglasses (control group, n = 19), vs extraction with the use of a radiation protection cabin (cabin group, n = 18). The criteria for inclusion in the study were: (1) presence of ≥ 1 transvenous lead implanted ≥ 4 years earlier; (2) class I or II indications for extraction[1]; and (3) informed consent granted by the patient. A team of the same 2 operators performed all extraction procedures. This study was reviewed and approved by our institutional ethics review committee.

Extraction procedure

The techniques of lead extraction implemented in this study have been previously described elsewhere.[6] The procedure was performed using general anaesthesia in a surgical suite, with the chest and abdomen prepared for emergency sternotomy. The standard procedure started with removal of the generator and liberation of the proximal end of the lead. A locking stylet (LLD system, Spectranetics Co, Colorado Springs, CO) was introduced and advanced as far inside the lead as possible using fluoroscopic surveillance. When in place, the stylet was locked in its position. For leads with retractable screws, withdrawal of the screws was attempted. An extraction with laser was attempted first. A CVX-300 Excimer laser system (Spectranetics Co) was used, with 14-French (F) or 16-F sheaths as appropriate for the diameter of the lead. The laser and outer sheaths were advanced over the lead body to the first site of fixation, before the delivery of 5- to 10-second bursts of Excimer laser energy, separated by 10-second interruptions to ablate the tissue and free and advance the sheath to the next binding site. The sheath was usually advanced over the lead until its end was a few millimeters away from the endocardium. The outer sheath was advanced and counter traction was applied to remove the lead.

If the laser approach was unsuccessful or inappropriate, femoral extraction was attempted using a large 16-F sheath with a Byrd Workstation hemostatic retrieval set (Cook Vascular, Bloomington, IN), inserted via the femoral vein and advanced through the inferior vena cava into the right atrium. Either a Dotter helical basket (Cook Vascular), to grasp the lead floating inside the atrium, or a Needle's Eye Snare (Cook Vascular) if the distal lead fixation was not successfully detached from its myocardial insertion, was used.

Complete extraction was defined as the removal of the entire lead, and partial extraction as the removal of most of the lead components, except for the electrode tip or < 2.0 cm of wire or insulation. Procedures were classified as unsuccessful when these end points were not reached. Procedural complications were classified as major or minor. Major complications were life-threatening or required a major treatment intervention as previously described.[1]

The radiation protection cabin

The movable Cathpax CRM cabin (Lemer Pax; Fig. 1) was specifically designed for device implantation and extraction. Device extractions are complex procedures that often require a second operator. We thus used the double version of the cabin (45.4 inches wide), which accommodates 2 personnel (equally protected). At the beginning of the procedure the cabin was covered with a dedicated sterile drape kit to preserve rigourous aseptic conditions. The initial prefluoroscopic preparation, the surgery, and the wound closure were performed with the cabin opened; in contrast, the extraction of the lead, when radioprotection was required, was performed with the upper part closed. Total freedom of arm movement was possible in the front and sides when the upper part was closed or opened. A 2-mm lead equivalent leaded glass and a 2-mm lead-shielded cabin frame ensured radioprotection.

Fluoroscopy

We used a monoplane pulsed Allura Xper FD10 fluoroscopy system (Philips, Eindhoven, The Netherlands) with automatic exposure rate control at a low dose setting and speed of 3.7 frames per second, corresponding to a patient dose output of 9.5 μSv/s. The duration of fluoroscopic exposure was recorded at the end of each procedure.

Dosimetry

For each procedure, the operator was equipped with 4 electronic silicon diode dosimeters (THERMO FISCHER Scientific Personnel dosemeter EPD Mk2+, Siemens, Waltham, MA), placed on the back, left foot, thorax, and neck, respectively. In the control group, the 2 dosimeters on the back and the thorax were placed under the apron, and the one