Lack of interference of electromagnetic navigation bronchoscopy to implanted cardioverter-defibrillator: in-vivo study

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Aims
Electromagnetic navigation bronchoscopy (ENB) (Superdimension) is a diagnostic and therapeutic tool in patients with lung lesions. Very small data are available about potential interference of ENB magnetic field to implanted cardioverter-defibrillators (ICDs) and any documentation of ICD behaviour if a ventricular tachyarrhythmia occurs during ENB is lacking. We tested a number of selected ICDs to assess if any interference occurs by ENB magnetic field on detection of clinical ventricular fibrillation and shock delivery.

Methods and results
Thirteen patients undergoing an ICD implantation or elective replacement with a clinical indication to assess the efficacy of defibrillation underwent: (i) real-time telemetric recording from ICD during ENB activation to detect possible noise; (ii) defibrillation test during exposure to ENB board-generated magnetic field. All tested ICDs showed no noise detection at maximum sensitivity level. Induced ventricular fibrillation was correctly detected and cured by implanted device. No change in programmed ICD parameters was induced by exposure to ENB magnetic field.

Conclusion
All tested ICDs correctly operated and rescued the patients from induced ventricular fibrillation during ENB. Electromagnetic navigation bronchoscopy appears to be safe in heart patients with an ICD; however, close cardiac monitoring of these patients during ENB must be ensured as correct behaviour of all existing ICDs can only be presumed from compliance of the manufacturer to International Standards which establish procedures for electromagnetic interference checking on implantable devices on different ranges of frequency.

Keywords
Implantable cardioverter-defibrillator • Electromagnetic navigation bronchoscopy • Electromagnetic interference

Introduction
The number of patients with cardiovascular implantable electronic devices has dramatically increased during the last decade and medical/non-medical sources for electromagnetic interference (EMI) have increased as well.1,2

A potential source for EMI is electromagnetic navigation bronchoscopy (ENB) (Superdimension), a real-time navigation system combining three-dimensional computed tomography imaging with real-time fiberoptic bronchoscopy using a low-frequency electromagnetic field locator to guide the bronchoscope to a target inside or adjacent to the bronchial tree.3,4

Initial concern about possible interference to implantable cardioverter-defibrillator (ICD) from ENB location board led the manufacturer to exclude patients with an ICD from clinical studies of ENB.

More recently, a study including a small number of patients with an ICD (eight patients) documented that neither symptoms related to the effects of magnetic field nor variations in any programmed parameters occurred during and after ENB.5

But, more importantly than simply pacing patients whenever necessary, ICDs are designed to cure ventricular tachyarrhythmias and no data exist on ICD behaviour if an implanted patient should suffer a ventricular tachyarrhythmia while undergoing ENB.

The only study addressing this issue is an in-vitro research from our group which documented, during ENB operation, correct detection of simualted ventricular arrhythmias and therapy delivery by some ICDs.6

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The present study was designed to assess whether the magnetic field generated by ENB board somehow interferes with the function of ICD, especially preventing correct tachyarrhythmia detection and therapy delivery if ventricular tachycardia or fibrillation occur while an ICD patient is undergoing ENB.

Methods

Several ICD models are commercially available. Manufacturers define their models according to type (single-chamber, dual-chamber, biventricular) and with a ‘family’ name that indicates identical technical specifications; within every family, an additional alphanumeric code defines ICD models with different software on board, typically used during outpatients’ follow-up.

It is important to point out that in no way this additional software conditions ventricular arrhythmias detection and therapy; all ICD models within the same family and type are built according to identical technical specifications and, therefore, the behaviour of a single unit can be considered typical of every unit in that group.

Starting with this assumption, we studied the behaviour of 13 ICD models from different manufacturers during ventricular fibrillation induced while ENB board under patient’s thorax was activated to generate the electromagnetic field.

All tested ICDs are regularly available for implantation in our institution.

The study protocol was approved by the Ethical Committee of AOU Maggiore della Carità (approval # CE 153/12) and all patients gave written informed consent to study procedure.

The study was conducted prospectively.

Study population

From 2013, March through October, 71 patients underwent an ICD implantation or elective replacement in our institution.

The study population included a subgroup of 13 patients in whom a defibrillation test (DFT) was indicated for a clinical purpose; no patient in this study group suffered from lung pathologies.

Each patient enrolled in the study was implanted with a different ICD model, detailed in Table 1.

Results

With sensing values programmed to maximum sensitivity, none of the tested ICDs showed any electromagnetic noise detection when the ENB location board was switched on and the location probe was moved within board generated field.

Similarly, real-time telemetric recording of ICD markers did not show any problem when ICD was reprogrammed to nominal sensitivity and ventricular fibrillation was induced for DFT; ventricular tachyarrhythmia was promptly detected and therapy delivered as programmed.

Interrogation of ICDs before and after completion of the study protocol showed no change in programmed parameters (apart from specifically programmed sensitivity levels and arrhythmia detection/therapy when moving from Step 1 to Step 2 of the study protocol).

Examples are shown in Figures 1 and 2.

Discussion

Very limited data are available regarding possible interaction between ENB and ICD.

A study including a small subgroup of patients with an ICD (eight patients) documented that, differently from what was seen on magnetic resonance imaging scanning, the metal body of the ICD does not generate any artefacts causing loss of image acquisition; the same study showed that ENB does not affect programmed ICD parameters and that no symptoms related to the effects of magnetic field occurred.

What’s new?

- Electromagnetic navigation bronchoscopy magnetic field does not interfere with the function of implanted cardioverter-defibrillators (ICDs) and no specific reprogramming of the ICD is required.
- In particular, (i) no change in ICD-programmed parameters occurs during electromagnetic navigation bronchoscopy (ENB); (ii) if ventricular fibrillation occurs during navigation, the ICD promptly identifies the tachyarrhythmia and delivers electrical therapy, ensuring patient safety.
- Though all commercially available ICDs are approved according to International standards which establish procedures for electromagnetic interference checking on implantable devices on different ranges of frequency and, therefore, we can expect that all systems complying with the above rules will behave the same way, close cardiac monitoring of these patients during ENB must be ensured.

Study protocol

The ICD implantation/replacement was performed as usual in our Cardiac Pacing Unit.

After completion of the ICD implantation/replacement:

(i) the device sensitivity was programmed at maximum level(s) and the ENB location board under patient thorax was activated to generate the electromagnetic field; telemetric recording from ICD allowed real-time detection of possible noise on either atrial and/or ventricular channels; in case this happened, the ENB could be immediately switched off.

(ii) if no noise was detected, the sensing parameters of ICD were reprogrammed to nominal values, arrhythmias detection and therapy were activated and the DFT was performed during ENB board operation; again, real-time telemetric recording from ICD showed possible problems in tachyarrhythmia detection, leading to immediate switching off of ENB and external defibrillation if necessary.

Ventricular fibrillation was induced, as usual, via the ICD, using T-wave shock or low-voltage direct current.

No patient actually underwent an ENB; to simulate a real procedure the ENB probe was waved upon patient’s thorax, within the board field.

Devices

Table 1 shows patients’ data, ICD models, pacing/sensing/shock lead models, and programmed parameters during protocol Steps 1 and 2 for each patient.
<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age</th>
<th>ICD model</th>
<th>ICD type</th>
<th>Lead(s) model</th>
<th>Programmed parameters 1</th>
<th>Programmed parameters 2</th>
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<td>MDT 6947M</td>
<td>MDT 6947M</td>
<td>na</td>
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</table>

RA, right atrium; RV, right ventricle; CS, coronary sinus; LR, lower rate; AS, atrial sensitivity (mV); VS, ventricular sensitivity (mV); TDR, tachydetection rate (b.p.m.); MDT, Medtronic; SJM, St Jude Medical; BT, Biotronik; BS, Boston Scientific; GDT, Guidant; ICD-D, dual-chamber ICD; ICD-V, single-chamber ICD; ICD-CRT, biventricular ICD.
Figure 1  Patient 10. From top to bottom: Lead I (not connected), atrial electrogram, right ventricular electrogram, coil electrogram, markers channel (AS, atrial sensing; VS, ventricular sensing). Speed 25 mm/s. During sinus rhythm, telemetric recording with programmed maximum atrial and ventricular sensitivity shows no noise detection from ENB by ICD.

Figure 2  Same patient as Figure 1. From top to bottom: atrial electrogram, right ventricular electrogram, coil electrogram, markers channel (AS, atrial sensing; VP, ventricular pacing; VF, ventricular fibrillation). Strips are continuous, speed 25 mm/s. Ventricular fibrillation is induced by 0.9 J shock after ventricular pacing 200 b.p.m.; the tachyarrhythmia is promptly detected by ICD and cured by 41 J DC-shock delivery. Atrial triggered-ventricular pacing occurs after defibrillation. No interference from ENB is recorded on ICD behaviour.
Our data confirm that no changes occur in ICD programmed parameters and no spontaneous arrhythmia appears during exposure to ENB field. These findings are consistent with very low magnetic field generated by ENB location board (<0.0001 T or approximately equivalent to the earth’s gravity) and with the lack of implanted device heating as, differently from magnetic resonance, radiofrequency pulses are not needed for electromagnetic guidance in ENB.

The low magnetic field should warrant correct functioning of the ICD when detecting/treating a ventricular tachyarrhythmia as the reed-switch blocking arrhythmia detection is affected by fields as low as 0.002 T.

However, no study documented the behaviour of an ICD if ventricular fibrillation occurs during ENB.

Preliminary data from an in-vitro study from our group documented correct ICD functioning during simulated ventricular fibrillation.

The present study is unique and is the first, to our knowledge, to evaluate the behaviour of ICDs in a clinical setting, when a ventricular tachyarrhythmia occurs during ENB.

We documented that in heart patients suffering ventricular fibrillation, the function of selected ICDs is not affected by the magnetic field of ENB.

All tested devices promptly detected ventricular tachyarrhythmia and delivered programmed therapy to rescue the patients.

The study evaluated 13 devices from different ICD families and several manufacturers, including single-chamber, dual-chamber, and biventricular systems.

In effect there are many more models commercially available and it is impossible for the producers to test the devices in all different EMI environments that can occur.

However, all marketed ICDs are approved according to either the international standard NSI/AAMI PC69:2007 or the medical device European Norms EN 45502-2-1 and EN 45502-2-2 which establish procedures for EMI checking on implantable devices on different ranges of frequency.

Based on this, we can expect that all systems complying with the above rules will behave the same way as ICDs tested in the present study, which means that the ICD will correctly operate if a ventricular tachyarrhythmia occurs during navigation.

However, close cardiac monitoring of these patients during ENB must be ensured, as correct behaviour of all existing ICDs can only be presumed from compliance of the manufacturer to International Standards which establish procedures for EMI checking on implantable devices on different ranges of frequency.

Conclusions

According to our data, patients with an ICD can safely undergo ENB; no device reprogramming is required and, more importantly, the ICD will correctly operate if a ventricular tachyarrhythmia occurs during navigation.

However, close cardiac monitoring of these patients during ENB must be ensured, as correct behaviour of all existing ICDs can only be presumed from compliance of the manufacturer to International Standards which establish procedures for EMI checking on implantable devices on different ranges of frequency.

Study limitations

We were not able to test ICDs from the Sorin Group because a wireless programmer is still not available and the ENB magnetic field interfered with programming head, not allowing real-time telemetric checking of ICD operation during study and, consequently, patient safety during the study protocol.

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References