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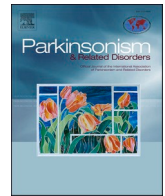
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Review article

Coexistence of deep brain stimulators and cardiac implantable electronic devices: A systematic review of safety



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ABSTRACT

As the number of patients implanted with deep brain stimulation systems increases, coexistence with cardiac implantable electronic devices (CIEDs) poses questions about safety. We systematically reviewed the literature on coexisting DBS and CIED. Eighteen reports of 34 patients were included. Device-device interactions were reported in 6 patients. Sources of complications were extensively reviewed and cautious measures which could be considered as part of a standard checklist for careful consideration are suggested.

1. Introduction

Deep brain stimulation (DBS) modulates neuronal circuit function through delivery of electrical stimulation. The system consists of an intracranial lead with multiple electrodes which is inserted at a target area, a connecting extension wire and a neurostimulator often implanted in the sub-clavicular area. DBS efficacy has been established in essential tremor, Parkinson's disease (PD), dystonia, severe obsessive compulsive disorder and refractory epilepsy [1]. Furthermore, DBS is under investigation in an extensive list of other neurological and psychiatric disorders including refractory depression, Tourette syndrome, refractory pain, bipolar disorder and anorexia [2] (see Table 1).

Cardiac implantable electronic devices (CIEDs) include pacemakers, defibrillators and resynchronization devices. They are being used for various cardiac conditions including rhythm problems, ischemic and non-ischemic cardiomyopathies and refractory heart failure [3]. Indications for using CIEDs are continually increasing and there is growing evidence of their efficacy [4].

Advances in medical care and health standards has resulted in a

growing number of elderly patients with concomitant occurrence of neurological, psychiatric and cardiac conditions. As a consequence, the number of patients who need concurrent use of a DBS and a CIED has also increased, expanding concern for safety.

1.1. Objective

In this study we systematically reviewed the published literature in order to collect evidence about the safety issues raised by coexistence of a DBS and a CIED.

2. Methods

This review was performed according to The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

2.1. Information source

We searched PubMed and Embase databases systematically for

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Table 1
Summary of reported cases of DBS and CIED coexistence.

Reference	Age/Sex	1st device implanted	Indication for CIED	CIED pulse generator model and location	Indication for DBS and DBS target	DBS stimulation mode	DBS stimulation settings	DBS model and location	F/U	complications
DBS and ICD										
Tavernier (2000) [5]	58/ unknown	DBS (2 INS)	VT	Medtronic; Abdominal region	PD; Bilateral- STN	BP + BP	1.4 V, 201 μs, 130Hz	Medtronic; R and Lt pectoral	NA	Yes (DBS reset after shock)
Obwegeser (2001) [11]	78/M	DBS	Abnormal Hiss- Purkinje function	Medtronic; R pectoral	ET; Unilateral- VIM	BP	2.2V, 90 μs, 130 Hz	Medtronic; Lt pectoral	4m	No
Rosenow (2003) [9]	71/M	DBS	Non-sustained VT	Medtronic; NA	PD; Bilateral- STN	BP-MP	R:3V, 90 μs, 185 Hz Lt:1.6V, 60 μs, 185Hz	Medtronic; Lt upper abdomen quadrant	NA	No
Ooi (2011) [13]	62/M	DBS	Non-ischemic cardiomyopathy	Medtronic; L pectoral	PD; Bilateral- STN	BP-BP	NA	Medtronic; R pectoral	34m	No
Bader (2015) [14]	51/M	DBS	VT leading to cardiac arrest	St. Jude Medical Riata; R mid-axillary	PD; NA	BP-BP	R: 2.1V, 90μs, 180Hz; L: 3V, 90μs, 180Hz	Medtronic; L pectoral	12m	No
Nayak (2020) [8]	75/M	ICD	Non-ischemic cardiomyopathy	NA; L axillary	ET; Unilateral- VIM	MP	2.8V, 60μs, 130Hz	Medtronic; L pectoral	48m	Yes (ICD sensing abnormality)
DBS and CRT-D										
Karimi (2012) [15]	68/M	DBS	Ischemic cardiomyopathy	Medtronic; Abdomen	PD; Bilateral- STN	B-MP	R:2.2V, 60 μs, 140 Hz	Medtronic; L and R pectoral	NA	No
Tejada (2018) [6]	72/M	DBS	Ischemic CMP, and low EF	Boston Scientific; L pectoral	PD; Bilateral- GPi	MP-MP	NA	Medtronic; Bilateral pectoral	12m	Yes (ICD sensing abnormality)
Tsukuda (2018) [16]	76/M	DBS	VT	Medtronic; L pectoral	PD; NA	BP-BP	R: 2.6 mA, 60μs, 130Hz; L: 1.6 mA, 60μs, 130Hz,.	Medtronic; Bilateral pectoral	1w	No
DBS and CPM										
Senatus (2004) [17]	71/M	CPM	Bradycardia- tachycardia syndrome	Medtronic; L pectoral	PD; Bilateral- STN	BP-BP	R:3.2V, 60 μs, 145 Hz L:2.6V, 60 μs, 145Hz	Medtronic; R and L lower abdominal quadrants	22m	No
	60/F	CPM	Cardiac arrhythmia after aortic valve and root replacement	St. Jude Medical; L pectoral	PD; Bilateral- STN	MP-MP	R:3.5V, 60 μs, 185 Hz L:2.5V, 60 μs, 180Hz	Medtronic; R and L lower abdominal quadrants	6m	No
Capelle (2005) [18]	64/F	CPM	AV-block	St. Jude Medical; NA	ET; Unilateral- VIM	BP	2.6V, 210 μs, 145 Hz	Medtronic; L pectoral	25m	No
	69/M	CPM	Refractory bradycardia	Biotronik; NA	PD; Unilateral- VIM	BP	2.5V, 120 μs, 130 Hz	Medtronic; R pectoral	25m	No
	74/M	DBS	Sick sinus syndrome	Medtronic; NA	ET; Bilateral- VIM	BP-BP	R:3.1V, 120 μs, 135 Hz L:2.9V, 210 μs, 160Hz	Medtronic; L pectoral	4y	No
	63/M	CPM	AV-block	Medtronic; NA	PD; Unilateral- STN	BP	3.5V, 90 μs, 135 Hz	Medtronic; L pectoral	1y	No
	68/F	CPM	Supraventricular tachycardia	Medtonic; NA	PD; Unilateral- VIM	MP	2.4V, 210 μs, 130 Hz	Medtronic; L pectoral	4m	No
	79/M	CPM	AV-block	St. Jude Medical; NA	PD; Bilateral- STN	BP	3V, 60 μs, 130 Hz	Medtronic; L pectoral	4m	No
Ozben (2006) [19]	41/M	DBS	Atrial fibrillation with high AV block	Insignia I Entra; L upper abdomen	PD; Bilateral- VIM	NA	NA	Medtronic; R pectoral	6m	No
Ashino (2009) [20]	72/M	DBS	Complete AV block	Medtronic; L pectoral	PD; Bilateral- STN	NA	R:3V, 210 μs, 185Hz L:5V, 180 μs, 135Hz	NA; R and L pectoral	3y	No
Ooi (2011) [13]	65/M	DBS	Sick sinus syndrome	St. Jude Zephyr; R pectoral	PD; Bilateral- STN	BP-BP	NA	Medtronic; L pectoral	14m	No
	78/F	DBS	Complete heart block	Biotronik; Abdomen	PD; NA	BP-BP			NA	No

(continued on next page)

reports on coexistent DBS and CIED. We did not use any range for restricting the time limit, but there was an English only article language limitation. We also performed a manual search of the references of included articles.

2.2. Search strategy

We used the following search strategy using MeSH index terms: ('cardiac pacemaker' OR 'implantable cardioverter-defibrillator' OR 'cardioverter-defibrillator' OR 'cardiac implantable electronic device') AND ('deep brain stimulat*' OR 'neurostimulat*'). Our last search was performed on October 20th 2020.

2.3. Study selection and data collection

All case reports and case series of patients with coexisting DBS and CIED were included. The devices did not have to be implanted simultaneously, and either one could have been implanted first. Reports of transcutaneous stimulators or studies with temporary devices, and reports with sequential employment of devices, i.e. the implantation of a device after removal of a previous device, were excluded. Congress posters and abstracts were also excluded.

Two authors evaluated the studies for eligibility based on the title, abstract, inclusion and exclusion criteria and thereafter extracted data. Discordance was discussed until mutual agreement was obtained. The following data were collected: Authors and year of publication, age and sex of the patients, devices type, indications for their implantation, the

Table 1 (continued)

Reference	Age/Sex	1st device implanted	Indication for CIED	CIED pulse generator model and location	Indication for DBS and DBS target	DBS stimulation mode	DBS stimulation settings	DBS model and location	F/U	complications
Boule (2012) [21]								Medtronic; Bilateral pectoral		
Bongiorni (2016) [22]	71/F	DBS	3rd degree AV block	Medtronic; NA	PD; Bilateral-STN	MP-MP	R:3.6V, 60 µs, 185 Hz L:3.8V, 60 µs, 145Hz	Medtronic; Bilateral pectoral	NA	No
Sharma (2016) [7]	76/M	DBS	<i>Symptomatic bradycardia and low EF</i>	<i>Medtronic; R pectoral</i>	<i>PD; Unilateral-STN</i>	<i>BP</i>	<i>3.3 V, 90 µs, 160 Hz</i>	<i>NA; L pectoral</i>	<i>NA</i>	<i>Yes (CPM with inappropriate sensing thresholds)</i>
	65/M	DBS	<i>Arrhythmia and heart failure</i>	<i>St. Jude Medical; Under the left DBS IPG(into the pectoral muscle)</i>	<i>PD; Bilateral-STN</i>	<i>BP-BP</i>	<i>R: NA; L: 3.5V, 90 µs, 185 Hz</i>	<i>NA; R and L pectoral</i>	<i>NA</i>	<i>Yes (DBS overstimulation symptoms)</i>
	71/M	DBS	<i>Heart failure</i>	<i>NA; Very close to the left DBS IPG</i>	<i>PD; Bilateral-STN</i>	<i>BP-BP</i>	<i>? 2.6 V, 90 µs, 130 Hz</i>	<i>NA; R and L pectoral</i>	<i>NA</i>	<i>Yes (CPM lead fracture)</i>
Nakai (2017) [23]	62/M	CPM	Sick sinus syndrome	Boston Scientific; L pectoral	PD; Bilateral (target NA)	BP-MP	NA	NA; R abdomen	6m	No
Heard (2019) [24]	73/F	CPM	Sick sinus syndrome	Medtronic; L chest (30 cm apart)	PD; Bilateral-STN	BP-BP	Max 10.5V, 1–5 mA, 130Hz	NA; R flank	NA	No
	71/M	CPM	Complete heart block and cardiac arrest	Medtronic; L chest (nearly 30 cm apart)	PD; Bilateral-STN	BP-BP		NA; R flank	NA	No
	65/F	CPM	Sick sinus syndrome	Medtronic; L chest (nearly 15 cm and 5 cm apart)	PD; Bilateral-STN	BP-BP		NA; Bilateral chest	NA	No
	71/F	CPM	AV block	Medtronic; L chest (nearly 30 cm apart)	Meige dystonia; Bilateral-STN	BP-BP		NA; R flank	NA	No
	61/F	CPM	Complete heart block	Medtronic; L chest (nearly 15 cm apart)	PD; Bilateral-STN	BP-BP		NA; R chest	NA	No
	77/M	CPM	LBBB	Medtronic; L chest (nearly 30 cm apart)	PD; Bilateral-STN	BP-BP		NA; R flank	NA	No
	77/M	CPM	NA	Medtronic; L chest (nearly 30 cm apart)	PD; Bilateral-STN	BP-BP		NA	NA	No
	77/M	CPM	paroxysmal AF, recurrent flutter	St. Jude Medical; L chest (nearly 30 cm apart)	PD; Bilateral-STN	BP-BP		NA	NA	No

AV: atrioventricular, BP: bipolar, CIED: cardiovascular implantable electronic device, CPM: cardiac pacemaker, CRT-D: cardiac resynchronization therapy-defibrillator, DBS: deep brain stimulation, ET: essential tremor, F: female, ICD: implantable cardioverter defibrillator, L: Left; M: male, MP: monopolar, PD: Parkinson's disease, R: Right; STN: subthalamic nucleus, VT: ventricular tachycardia, VIM: ventrointermediate nucleus of thalamus.

Patients with complications are in italics. Complications are further explained in the text.

device which was implanted first, the devices pulse generator location, mode of the devices (open or closed loop with sensing), follow up duration and occurrence of any interaction or complication.

3. Results

Search of the databases according to above mentioned strategy yielded in 147 records after duplicates removal. Studies were screened on the basis of their title and abstract, leading to the exclusion of 124 not relevant records. Details are displayed in a PRISMA flow chart (Fig. 1). The full texts of the remaining 23 publications were assessed for eligibility and 5 additional ones were excluded.

In total 18 studies involving 34 patients were included. The mean age of the patients was 71.1 years (range 41–79), and most patients were males (24 patients). The CIED type was CRT-D (Cardiac Resynchronization Therapy Defibrillator) in 3 patients, ICD (Implantable Cardioverter Defibrillator) in 6, and CPM (Conventional Pacemaker) in the remaining 25 patients. Indication for DBS was PD in 29 patients, essential tremor in four, and Meige syndrome (segmental dystonia) in one patient.

Overall complications were reported in 6 patients (15%). These are

described in detail below:

1. A 58-year-old PD patient with bilateral DBS (model Medtronic Itrel III) of the subthalamic nucleus (STN) programmed in bipolar configuration, was implanted with an ICD due to cardiac arrhythmias. The implantable neurostimulators were located bilaterally in pectoral regions and the ICD IPG (implantable pulse generator) was located in the abdominal wall. ICD shock delivery (34J) resulted in reset of both neurostimulators. The authors suggested to schedule a DBS programming session after each time a shock is delivered by the ICD [5].
2. A 72-year-old PD man with a history of bilateral DBS of the globus pallidus pars interna programmed in monopolar configuration, was implanted with an ICD due to ischemic cardiomyopathy and low ejection fraction. Electrophysiological testing at 6 months follow up revealed that the ICD sensed the QRS complexes as noise. This happened around the time the DBS pulse amplitude had been increased. The ICD was programmed in the primary vector. No other sensing abnormalities recurred at 12 months follow up [6]. This interaction has been related to the monopolar setting of DBS and also

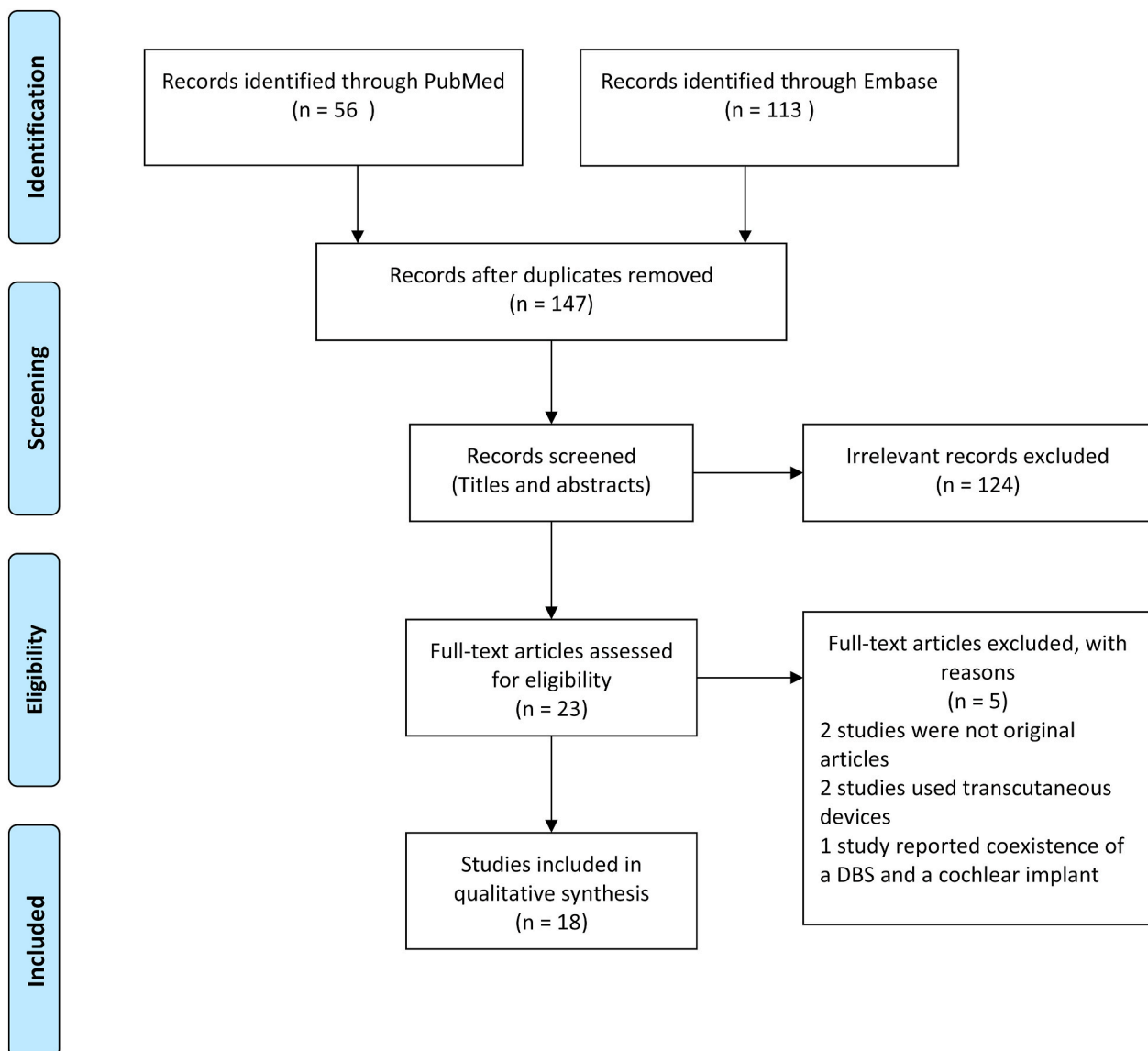


Fig. 1. PRISMA 2009 flow diagram.

close proximity of the devices pulse generators in the left pectoral area.

3. A 76-year-old man who had a unilateral (left) STN DBS for PD programmed in bipolar configuration, was implanted with a CPM due to symptomatic bradycardia and low ejection fraction. The DBS and CPM IPGs were implanted in left and right sub-clavicular regions respectively. Two months after the CPM implantation he presented with light headedness and nausea. DBS was functioning normally but electrophysiologic evaluation indicated that the CPM was previously programmed with elevated sensing thresholds in order to eliminate possible interactions with the DBS device. Turning down the CPM sensing to a minimal function of 40 beats per minute resulted in improved symptoms. At one month follow-up the patient was symptoms free [7].
4. A 65-year-old PD man who had a bilateral STN DBS programmed in bipolar configuration, was implanted with a CPM due to arrhythmia and heart failure. The CPM and DBS IPGs were located in close proximity in the left pectoral region. The patient presented with worsening PD symptoms for an unknown amount of time after CPM implantation, and the left DBS intermittent neurostimulator (INS) was found to be inadvertently turned off. After turning it on, the patient developed new acute neurologic symptoms in the form of weakness, imbalance, and generalized body tingling. Turning the left DBS INS off again, resolved the acute neurologic symptoms. His initial presenting symptoms were thought to be due to worsening PD, but the acute neurologic symptoms were attributed to left DBS and CPM IPGs interaction, therefore the DBS IPG was relocated to the left abdomen with resolution of the symptoms. No other interaction between devices were detected thereafter and the symptoms did not recur [7].
5. A 71-year-old man who had a bilateral STN DBS for PD programmed in bipolar configuration and a CPM presented with episodes of falls without impairment of consciousness only two days after a DBS programming session. Left DBS and CPM IPGs were in close proximity to each other in left pectoral area. Electrophysiological and imaging evaluation revealed a fractured left atrial lead. The atrial lead was replaced and CPM IPG was relocated farther away in the abdominal wall. No device interactions recurred [7]. Since the patient experienced symptoms only 2 days after a DBS programming session the authors assumed that the magnetic field produced by the DBS programmer might have caused the atrial lead fracture.
6. A 75-year-old man who had an S-ICD due to non-ischemic cardiomyopathy was implanted with a left ventral intermediate nucleus (VIM) of the thalamus DBS to control a long standing essential tremor. After four years of uncomplicated coexistence of the devices (2015–2019) he presented with attacks of ventricular tachycardia (VT) requiring multiple shocks from his S-ICD. On one of the recorded episodes, noise was also detected which probably had caused the shock. The authors attributed the noise to the monopolar configuration of the DBS and the secondary sensing configuration of the S-ICD. In the secondary sensing configuration the distal electrode is used for sensing, which was only 6.4 cm away from the DBS IPG in this case. The authors stated that in the secondary sensing configuration increasing the DBS voltage (from 2.8 to 3.6V) resulted in increased ICD noise. With changing DSB configuration to bipolar and S-ICD configuration to primary sensing, no adverse effect recurred in an additional 11 months follow-up [8].

In most of the 34 reported patients a bipolar setting for DBS devices were used, while in eight patients a monopolar configuration was selected in at least one lead; only two of them reported device-device interaction [6]. In at least six patients the DBS and CIED pulse generators were located in close proximity on the same side of the chest and in three of them complications occurred.

Medtronic DBS device was used in 21 patients, while data about device manufacturer is not available in 13 remaining patients. The DBS

device manufacturer is unknown in 3 out of 6 patients with complications. A more varied distribution exists among CIED devices: 20 patients had a Medtronic device (among which 2 cases experienced complications), 7 patients had St. Jude Medical devices (1 complicated case), 3 Boston Scientifics (1 complicated case), and 2 Biotronik devices. The manufacturer was not designated in the 2 remaining patients which were both among patients with complications. The overall few reports of complications, diversity of the devices, and significant unavailable data makes it difficult to draw any conclusions in this regard.

4. Discussion

In 6 of the 34 reported patients possible complications were reported. This suggests that the two kinds of devices can potentially safely coexist without interacting, when particular measures are taken.

In three cases CPM suffered from interaction with DBS: in two, the ICD reported a sensing abnormality; in the other case, inappropriate sensing thresholds of the CPM were programmed to avoid potential interference with DBS. In fourth case lead fracture of the CPM was attributed to interaction with DBS, although solid evidence of this causality is lacking.

In only one case the DBS system suffered a clear abnormality (DBS settings reset after ICD shock); in another case neurological symptoms on stimulation were attributed to the interaction of the two devices.

4.1. Potential interactions versus actual complications in this concomitant ecosystem

The landscape consists of DBS and CIED system components which are implantable (active or passive; active devices with or without sensing; delivering therapy in an open or closed loop) and physician/patient programmers. Interferences could be classified into one of the following categories as listed below:

1. Neurostimulator influence on implanted cardiac devices

Theoretically, the electrical pulses from the neurostimulation system may interact with the sensing operation from a cardiac device (CPM or ICD) and could result in an inappropriate response of the cardiac device such as pace inhibition, asynchronous pacing, or improper shocks. This review revealed only two patients who suffered this complication [6,8]. It is important to note that in these patients, the devices IPGs were in close proximity to each other and that a monopolar setting for the DBS device was chosen. Also, both reports suggested that this occurred in concomitance to increase in DBS amplitude, suggesting that a CIED check should occur every time DBS setting is changed and that stable DBS settings as used in chronic stimulation might be safe.

2. Cardiac devices influence on neurostimulators

Another theoretical complication is that the shocks delivered by ICDs may reset and turn off the DBS device or even damage the neurostimulators [9,10]. This happened in one patient [5] but there are also reports that shock waves delivered by ICDs did not affect the DBS device [9].

3. Clinician/physician programmer interaction with other active implanted devices

When a patient has a neurostimulators and another active implanted device (e.g. pacemaker, defibrillator, neurostimulators), the radio frequency (RF) telemetry signal used to program these devices may potentially reset or reprogram the other device unintentionally and/or the magnet in a cardiac programmer may accidentally activate magnetically controlled functions (if the feature is available) of some neurostimulators.

This was reported for example in patient 2 where the ICD reported a sensing abnormality around a DBS programming session [5].

One reason is that RF telemetry programmers of one device could inadvertently affect the other one. It has been shown that if a magnet is held over an CIED, it could lead the device to stop sensing during that time [11]. Most of the current generation DBS devices do not use the magnet control for switching on/off the device or changing device amplitude.

4. Patient control devices (patient programmer) may affect other implanted devices

Although this has not yet been reported, the patient control device could unintentionally change the operation of the other device.

4.2. Practical considerations and pragmatic recommendations

In order to decrease the probability of interference between a CIED and DBS, the followings could be considered:

1. **Distance between devices:** Although there are reports of uncomplicated procedures when the two devices are implanted in close proximity, the IPG and INS of each individual system should preferentially be implanted as far as possible from each other (for example on opposite body sides if feasible or sub-clavicular and abdomen if on the same side). Medtronic recommends a minimum distance of 20 cm between the DBS and CIED IPGs [12], and St. Jude Medical Infinity™ Implantable Pulse Generator's manual recommends to "maximize" the distance between the implanted systems [25].
2. **Bipolar configuration:** This review showed that device-device interactions occurred in 2 out of 8 patients with a monopolar DBS configuration. Authors believed that monopolar DBS setting may interfere with accurate ICD sensing. It is judicious to program both systems in bipolar configuration. If the effects of bipolar DBS are not satisfactory, monopolar DBS settings may be considered and were reported as safe as long as the cardiac pacemaker is in bipolar setting mode [10]. St. Jude Medical Infinity™ Implantable Pulse Generator' manual recommends to avoid programming either device in a unipolar mode.
3. **Low stimulation amplitude:** It is recommended to avoid higher DBS output amplitudes since this might affect CIED sensing [7].
4. **Regular systems check:** An extensive collaboration between cardiac electrophysiologists, neurosurgeons and neurologists is essential in order to avoid foreseeable complications. We propose that the whole team be informed of any change in device parameters. Both DBS settings and CIED settings should be checked every time the setting of the other device is changed and every time an ICD shock has been delivered.
5. **Manufacturers' indications:** Device manufacturers should be consulted to seek more information on specific guidelines for each individual device.
6. **Patient education:** It is important that the patients are aware of possible interactions and informed to contact their physician immediately if they experience symptoms that could be related to either device or to the medical condition treated by either device. Train the patient and caregivers not to place the patient control device (i.e. patient programmer, control magnet, radio-frequency transmitter, and recharger) over another active implanted medical device (e.g. pacemaker, defibrillator, another neurostimulators).

5. Conclusion

Here we have summarized the findings of 18 reports on 34 patients with concomitant CIED and DBS. There are six reports of device-device interactions, however none of them have led to long term morbidity of

the patients. Although there have been reports of uncomplicated procedures even when the distance between IPGs was less than recommended, or with monopolar DBS settings, it is advisable to adopt the above-mentioned pragmatic recommendations and strictly follow the recommendation of IPG manufactures.

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