Dual implantable electronic device therapy

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No safety and efficacy data have been reported to date with respect to the co-working of a device for gastric electrical stimulation (GES) in an implantable cardioverter defibrillator (ICD) patient. Safe and efficacious dual-device therapy in an ICD patient after implantation of a GES device was confirmed without any device interaction.

In June 2013, a 57-year-old male patient was referred to our implantable cardioverter defibrillator (ICD) clinic for ICD interrogation. A dual-chamber ICD (Maximo II DR D284DRG, Medtronic, Inc.) had been implanted in 2010 for secondary prevention of sudden cardiac death. On admission, the patient's medical history revealed the presence of a severe chronic intractable nausea secondary to diabetic gastroparesis. The failure of multiple medical treatment approaches of the patient's gastroparesis was documented, with resulting indication for implantation of a gastric electrical stimulation (GES) device.[1]

A device for GES (Enterra 3116, Medtronic, Inc.) was successfully implanted on 25 June 2013 in accordance with the manufacturer's safety recommendations for the implantation of a neurostimulator in patients with a cardiac implantable electronic device (IED). The GES device consists of a neurostimulator placed in a subcutaneous pocket in the abdominal region and two electrodes (Model 4351, Medtronic Inc.) laparoscopically implanted in the gastric muscularis propria along the greater curvature, ~10 cm proximal to the pylorus and 1 cm apart. These leads transmit electrical impulses to the stomach wall via the tip of the leads, thus promoting gastric motility. The underlying pathophysiology of GES is, however, a matter of debate.[1]

Using an interdisciplinary approach, we investigated the safety and efficacy of the co-working of the dual-IED therapy up to 3 months after GES device implantation. Before implantation of the GES device, informed consent was obtained after thorough education of potential interactions between the devices. Position of the GES device was verified intraoperatively by laparoscopic view and postoperatively by abdominal X-ray (*Figure 1*). Programming of the GES device was performed in accordance with the published algorithm.[2] In order to ascertain if the potential for crosstalk between the devices existed, output of the GES device was transiently programmed to low

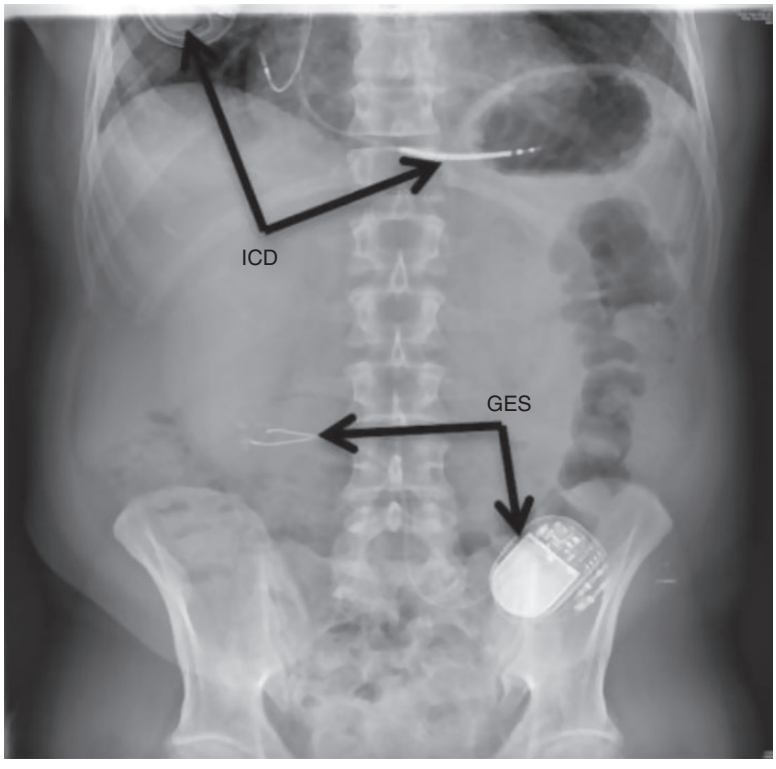

Figure 1 X-Ray of a dual-IED therapy. GES, device for gastric electrical stimulation; ICD, implantable cardioverter defibrillator leads.

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Table 1 Programmed parameters of the ICD and the device for GES

	GES				ICD																
	Therapy				Detection										Therapy						
	Rate [Hz]	Cycle ON/OFF time [sec.]	Current [μA]	Pulse width [μs]	Sensitivity [mV]		DI [ms]					SVT	Initial NID			Tachy.			Brady.			
					RA	RV	VT mon.	VT	FVT (via VT)	VF	AT/ AF [ms].		VT mon.	VT	VF	VT	FVT	VF	Mode	Lower	UTR	USR
Pre-OP	n.a.	n.a.	n.a.	n.a.	0.3	0.3	−	350	330	300	400	+	−	24	30/40	+	+	+	DDDR	60	125	110
Intra-OP	14	1/4	5	330	0.3	0.3	470	350	350	300	400	+	32	24	30/40	−	−	−	DDDR	60	125	110
PHD	2.1–60	1/4–3/2	5–12	330–450	0.3	0.3	470	350	330	300	400	+	32	24	30/40	−	−	−	DDDR	60	125	110
Final.	60	1/4	5	330	0.3	0.3	470	350	330	300	400	+	32	24	30/40	+	+	+	DDDR	60	125	110

AT/AF, monitor atrial tachycardia/atrial fibrillation; b.p.m., beats per minute; Brady., brady therapy remained unchanged during follow-up: RA output 1.5 V/0.40 ms, RV output 1.75/0.40 ms; DI, detection intervals; Final., final programming at the end of pre-hospital discharge tests until 3 months follow-up; FVT, fast ventricular tachyarrhythmia; GES, gastric electrical stimulation; Hz, Hertz; intra-OP, intraOPerative; ICD, implantable cardioverter defibrillator; mA, milliAmperes; mo, months; mon., monitor; ms, milliseconds; mV, milliVolt; μs, microsecond; n.a., not applicable; NID, numbers of intervals to detect; PHD, pre-hospital discharge; Pre-OP, PreOPerative; RA, right atrium; RV, right ventricle; SVT, SVT discriminator (PR Logic); Tachy., Tachy therapy consisted of eight sequences of antitachycardia pacing and three ventricular cardioversions in the VT zone, two sequences of antitachycardia pacing and five ventricular cardioversions in the FVT zone, one sequence of antitachycardia pacing and six shocks in the VF zone; USR, upper sensor rate; UTR, upper tracking rate; VF, ventricular fibrillation; VT, ventricular tachyarrhythmia; +, enabled; −, disabled.

stimulation rates, long stimulation cycles, high currents, and long pulse widths (*Table 1*). Since GES devices lack sensing capacity, programming of sensing parameters is not feasible, therefore disabling the GES device for detection of ICD signals. Implantable cardioverter defibrillator sensitivity settings remained unchanged during follow-up. During implantation and provocation manoeuvres, ICD therapy was disabled and detection of tachyarrhythmia stayed enabled. For safety concerns, permanent electrocardiogram monitoring was performed until ICD therapy was reestablished. Patient follow-up was conducted pre-hospital discharge, 4 weeks after discharge by phone and at 3 months after implantation in our clinic. During follow-up, efficacy of the GES device was assessed clinically by symptom relief of the patient's severe chronic nausea. Safety was ascertained by GES device and ICD interrogation with a focus on the analysis of system integrity and detection of ICD artifact sensing by evaluation of electrograms, marker channels, sensing integrity counter, and arrhythmia episodes.

No device interactions were detected intra- and postoperatively as evidenced by the lack of artifact sensing in electrograms despite maximum signal amplification, marker channels, sensing integrity counter, and arrhythmia episodes. The GES device provided symptom relief and the proper functioning of each of the dual IEDs was assured by device interrogation. Due to the growing number of patients with non-cardiac IEDs, potential interactions between these devices and ICDs have become more clinically relevant and safety concerns have emerged for dual-IED therapy.[3] Dual-IED therapy is challenging since potential device interaction might occur resulting in inappropriate ICD therapy.

In summary, we could demonstrate that co-working of a GES and an ICD device in the same patient is feasible. We recommend the selection of a careful strategy to provide safe and efficacious co-working of the dual-IED therapy.

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Conflict of interest: S.R. reports receiving honoraria for lectures from Medtronic; P.S. reports no conflict of interest; and E.H. receives research funding from Medtronic, Biotronik, St. Jude Medical, Sorin, Edwards, Philips, Braun, Stentys and honoraria for lectures from Boehringer Ingelheim, Boston Scientific, MSD Sharp & Dohme.

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