Lack of interference between small bowel capsule endoscopy and implantable cardiac defibrillators: an ‘in vivo’ electrophysiological study

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Abstract

Background: Capsule endoscopy is a widely performed procedure for small bowel investigation. Once swallowed by the patient, the capsule transmits images to an external recorder over a digital radiofrequency communication channel. Potential electromagnetic interferences with implantable cardiac devices have been postulated. Clinical studies on the safety of capsule endoscopy in patients with cardiac defibrillators are lacking.

Objective: The aim of this study was to assess potential mutual electromagnetic interferences between capsule and defibrillators.

Methods: This study used the Given M2A video capsule system. Ten different types of defibrillators were tested in a clinical setting. Before capsule ingestion, defibrillator electrical therapies were switched off. During capsule endoscopy patients were monitored with cardiac telemetry. At the end of capsule endoscopy the following defibrillator's parameters were analysed: change in device settings; inappropriate shocks; inappropriate anti-tachycardia therapy; inappropriate sensing or pacing; noise detection; device reset; programming changes; permanent electrical damages. Any technical problem related to capsule image transmission was recorded.

Results: Neither defibrillator malfunction nor interference in sensing or pacing was recorded; conversely, no capsule malfunction potentially caused by defibrillators was registered.

Conclusion: Our results suggest that capsule endoscopy can be safely performed in patients with cardiac defibrillators.

Keywords

Capsule endoscopy, automatic implantable cardiac defibrillators, electromagnetic interference

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Introduction

Capsule endoscopy (CE) is one of the most performed endoscopic procedures for small bowel investigation and is considered one of the safest in clinical practice.¹ However, potential electromagnetic interferences (EMI) with implantable cardiac devices have been postulated.^{2,3} In fact, once swallowed by the patient, the capsule transmits images from the digestive tract to an external recorder over a digital radiofrequency communication channel (434.09 MHz). This could theoretically lead to malfunction of pacemakers (PM) and automatic implantable cardiac defibrillators (AICD). Conversely, the presence of an implantable electronic device (IED)

could interfere with image transmission from the capsule to the recorder. Relatively few safety data are available on EMI between CE and IEDs. ‘In vivo’ studies are lacking, especially in patients with AICD. The aim of this study is to assess potential mutual EMI between CE and AICD in a clinical setting.

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Methods

Between October 2008 and October 2011, 14 patients with AICD were prospectively studied by using the Given M2A video capsule system (Pillcam; Given Imaging Ltd, Yoqneam, Israel). Eleven patients were males. The mean age was 66.4 years. The indication for CE was obscure gastrointestinal bleeding (OGIB) in 13 cases (7 overt- and 6 occult-type) and clinical follow up in a patient with Peutz–Jeghers syndrome. All the patients gave their written informed consent. Patients swallowed the capsule in the morning after an overnight fast; a bowel cleansing with 2 litres of polyethylene glycol solution was administered in the afternoon before the procedure.

Ten different types of AICD from five brands (Guidant, Boston Scientific Corporation, Medtronic Inc., Sorin, St. Jude Medical Inc.) were tested. All the AICD were implanted subcutaneously at the left pectoral site. The implant dates ranged from 1998 and 2010. The indication to AICD implant was post-infarctual cardiomyopathy in 10 cases (71.4%) and idiopathic dilated cardiomyopathy in 4 (28.6%). Patients' clinical data and AICD technical details are reported in Table 1. A complete technical check of each cardiac device was performed by the electrophysiologist before CE, using a manufacturer-specific programmer connected with the AICD by cable or wireless. In case of wireless connection, the Medical Implant Communications Service frequency band was used, working from 402 to 405 MHz. This technical check included the evaluation of the following parameters: battery charge, shock impedance, leads impedance and sensing, leads pacing threshold, recorded arrhythmic events. Each patient had a cardiac examination with electrocardiogram (ECG) and then was admitted to Cardiac Care Unit. Just before capsule ingestion, AICD electrical therapies were switched off (AICD re-programmed in device mode 'monitor only'). During CE the patients were continuously monitored with cardiac telemetry, performed using a Mortara X12 device (Mortara Instrument Inc., USA). This device provides a wireless transmission of the ECG through three frequency bands. These bands differ from the frequency communication channel used by the capsule system. At the end of the endoscopic procedure the patients had new cardiac examination and ECG. Furthermore, a final complete AICD check was performed in order to assess whatever effects of EMI. The following AICD parameters were analysed: changes in device settings, inappropriate shocks, inappropriate anti-tachycardia therapy, inappropriate sensing or pacing, noise detection, device reset, programming changes, permanent electrical damages. Finally, AICD electrical therapies were re-activated

and patients were discharged. CE videos were reviewed by a skilled digestive endoscopist.

Results

Over a 3 year period, 315 CEs were performed at the Endoscopy Unit. The subjects of this study were 14 patients with AICD (4.4%). The capsule reached the ileocecal valve before depletion of the battery life in all the cases except one (92.8%). No capsule retention was observed. Causes of OGIB were found in nine patients (69.2%): angiodysplasia (5 cases), NSAID-related enteropathy (2 cases), active jejunal bleeding (1 case) and large jejunal polyp (1 case). In the Peutz–Jeghers patient, two small ileal polyps were found (diameter less than 1 cm). On the basis of the CE results, six (46.1%) of the OGIB patients had significant changes in their clinical management (all underwent device-assisted enteroscopy for the treatment of bleeding lesions). No patient complained of symptoms during cardiac telemetry. The final AICD check revealed neither malfunction nor interference in sensing or pacing in all the cases (details are reported in Table 2). Conversely, no technical problems related to image transmission were observed reviewing CE videos.

Discussion

The major endoscopic concern in patients with IED is the possibility to generate EMI during electrosurgical therapies. This can emerge into device malfunctions or damages and whatever consequent injuries on patients.⁴ For this reason, particular precautions have to be taken in these subjects in order to minimize the risk of adverse events.⁵ The effects of EMI can be very different and depend on factors related to the type and settings of the electronic emitting device (frequency and duration of the signal produced, distance between IED leads and source of electromagnetic signal, electrodes and filter configuration, selected sensitivity level, orientation of the pulse generators and leads with respect to the EMI source). EMI can lead to inappropriate inhibition or triggering of pacing activity, asynchronous pacing, resetting or reprogramming of the software device, permanent structural damages, and inappropriate anti-tachycardia therapy such as pacing or shocks, that could be life-threatening in PM-dependent patients and in patients with AICD.⁶

A potential EMI cannot be excluded 'a priori' during CE, too. In fact, once ingested, the capsule generates electromagnetic waves by using the radio-frequency technology for the images transmission from the digestive tract to the external recording system worn by the patient. Even if the most recent CE guidelines do not consider the presence of a cardiac implantable device as

Table 1. Patients' clinical data and technical AICD details (A = atrium; V = ventriculium; r = right; l = left; bpm = beat per minute)

Patient	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Clinical data	Indication to Implant	Post-infarctual cardiomyopathy	Post-infarctual cardiomyopathy	Post-infarctual cardiomyopathy	Idiopathic dilative cardiomyopathy	Post-infarctual cardiomyopathy	Idiopathic dilative cardiomyopathy	Post-infarctual cardiomyopathy	Post-infarctual cardiomyopathy	Post-infarctual cardiomyopathy	Idiopathic dilative cardiomyopathy	Post-infarctual cardiomyopathy	Post-infarctual cardiomyopathy	Idiopathic dilative cardiomyopathy
Device	Spontaneous Cardiac Rhythm	Sinus Rhythm	Sinus Rhythm	PM dependent	Sinus Rhythm	Atrial fibrillation	Atrial fibrillation	Sinus Rhythm	Sinus Rhythm	Atrial fibrillation	Sinus Rhythm	Sinus Rhythm	Atrial fibrillation	Atrial fibrillation
	Manufacturer	Medtronic	Boston Scientific	Boston Scientific	Sorin	Boston Scientific	Medtronic	Guidant	Sorin	St. Jude Medical	St. Jude Medical	Medtronic	Boston Scientific	Boston Scientific
	Model	Vitality 2 DR	InSync III MarquisTeligen 100	Secura DR	Paradym CRT	Cognis 100	Secura DR	Vitality 2 DR	Paradym	Atlas HF VR	Unity	Maximo VR	Cognis 100	Cognis 100
	Implant Location	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral	Left Pectoral
Atrial lead	Manufacturer	Boston Scientific	Medtronic	Medtronic	x	x	Guidant	Boston Scientific	Sorin	x	St. Jude Medical	x	x	x
	Model	4480	Capsure Z NovusLEJ021949V 5554	Capsure Z Novusx 5554	x	x	4480	4480	Stelid II	x	1944	x	x	x
	Polarity	Bipolar	Bipolar	Bipolar	x	x	Bipolar	Bipolar	Bipolar	x	Bipolar	x	x	x
	Fixation	Passive	Tines - Steroid	Tines - Steroid	x	x	Passive	Passive	Passive	x	Passive	x	x	x
Right ventricular lead	Manufacturer	CPI	Medtronic	Medtronic	Medtronic	Boston Scientific	Guidant	CPI	Medtronic	St. Jude Medical	St. Jude Medical	Medtronic	Boston Scientific	Boston Scientific
	Model	Endotak SG 0171	RelianceSprint 6932	Sprint 6935	Quattro6935	293	171	Endotak SG 0171	Reliance6935	1570	7122	6930	293	293
	Polarity	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar	Passive	Passive	Passive	Passive	Passive	Active	Bipolar
	Fixation	Passive	Passive	Active	Passive	Active	Passive	Passive	Active	Passive	Active	Passive	Active	Bipolar
Left ventricular lead	Manufacturer	x	Medtronic	x	Boston Scientific	Guidant	x	x	Boston Scientific	St. Jude Medical	St. Jude Medical	x	Guidant	Guidant
	Model	x	4193	x	Acuity Spiral 4517	4517	x	x	4591	1056	1458 (Quartel)	x	4517	4517
	Polarity	x	Unipolar	x	Unipolar	Bipolar	x	x	Bipolar	Bipolar	Bipolar	x	Bipolar	Bipolar
	Fixation	x	Coronary sinus	x	Coronary sinus	Coronary sinus	x	x	Coronary sinus	Coronary sinus	Coronary sinus	x	Coronary sinus	Coronary sinus
Brady Parameters	Mode	DDD	DDDR	AAI<=>DDD	VVI	VVIR	VVI	DDD	DDD	VVIR	DDDR	VVIR	VVIR	VVIR
	Lower Rate	40	50	60	80	60	45	40	60	70	60	60	60	60
	Upper Rate	120	130	130	x	120	x	120	120	110	130	120	120	120
Tachy Parameters	Sensing	Nominal (0.27 mV)	0.9 mV (A) 0.3 mV (V)	0.3 mV (A) 0.3 mV (V)	-0.4 mV (A) 0.4 mV (V)	-0.6 mV (A) 1 mV (V)	-0.15 mV (rV) 0.3 mV (rV)	-Nominal (0.27 mV) (0.27 mV)	0.4 mV (rV) 0.4 mV (rV)	(rA) -0.3 mV (rV) 0.9 mV (A) 0.3 mV (V)	0.9 mV (A) 0.3 mV (V)	-0.3 mV 1 mV (IV)	0.6 mV (rV) 1 mV (IV)	-0.4 mV (rV) 1 mV (IV)
	FV	210 bpm	194 bpm	182 bpm	200 bpm	200 bpm	188 bpm	210 bpm	180 bpm	214 bpm	180 bpm	188 bpm	200 bpm	190 bpm
	TV	190 bpm	154 bpm	x	120 (Slow TV) -170 bpm 160 (TV) bpm	x	x	190 bpm	160 bpm	182 (FVT) - 156160 bpm (TV) bpm	156160 bpm	150 bpm	170 bpm	160 bpm

Table 2. Results of AICD control after CE

		Patients (1–14)
AICD parameters	Changes in device parameters	Absent
	Inappropriate shocks	Absent
	Inappropriate ATP	Absent
	Inappropriate sensing	Absent
	Inappropriate pacing	Absent
	Noise detected	Absent
	Device reset	Absent
	Programming changes	Absent
	Permanent electrical damages	Absent

an absolute contraindication,⁷ the Food and Drug Administration and capsule manufacturers (Given Imaging, Israel and Olympus, Japan) recommend to avoid CE in patients with PM or AICD, because of a very limited clinical experience. In this study we report the use of CE in patients with 10 different types of AICD. Some of them were never been tested before for possible EMI. These devices were technically very heterogeneous in terms of models and polarity of ventricular and atrial leads, and bradycardia/tachycardia parameters. The mainstay of this series is the electrophysiological study performed during the whole duration of CE. In fact, the design of this ‘in vivo’ study allowed the ability to record every eventual EMI-induced AICD malfunction or EMI-related changes in devices parameters related to CE. The deactivation of the AICD electrical therapies during CE did not influence its ability to recognize EMI. In fact, this configuration (‘monitor only’) enables ventricular tachyarrhythmia detection but does not automatically deliver electrical therapy to the patient. The choice to set the AICD to the ‘monitor only’ mode was due to the intention of avoiding possible EMI-related inappropriate shocks. In order to ensure their safety, the patients were placed in Cardiac Care Unit and continuously monitored with telemetry during the endoscopic procedure. We opted for Mortara X12 as the monitoring patient system because we did not observe any interference of the ECG wireless transmission during CE in our previous clinical experience with this type of device.

In all the cases no EMI between CE and AICD were observed, irrespectively to the AICD properties. The outcome was the same even when the distance between the two devices was very short and the electromagnetic fields generated from capsule and AICD could more easily overlap (especially during the oesophageal capsule transit). The radiofrequency wave originated by the capsule is a pulsed signal of about 434 MHz, composed of an active signal of transmission of 250 ms followed by a pause of 250 ms, too. A possible explanation

of the absence of mutual EMI in this situation is the low power of this signal (1 μ W). In fact, on the basis of studies on mobile phones, it has been argued that the power of electromagnetic signal from the capsule should be 1mW in order to generate EMI in this situation.⁸

Data regarding possible interferences between CE and AICD are very limited, although abnormal EMI-induced functioning of these devices could lead to potentially life-threatening clinical injuries. Bandorski et al. tested in a laboratory setting eventual interactions between 45 AICDs and three different types of capsules (Pillcam SB and Pillcam Colon, Given Imaging; Endocapsule, Olympus):⁸ no interferences were observed even the devices were placed in close proximity. Dubner et al. reported the first case of EMI between CE and AICD in an ‘in vitro’ study performed with a reusable external testing device (Test Cap, Given Imaging Ltd, Yoqneam, Israel) that reproduces,⁹ at the same electromagnetic frequency, the data transmission of Pillcam capsule: an over-sensing (heart signals are seen, though do not exist) was recorded, potentially leading to inappropriate electric therapies delivery. However, no interferences were reported by the author when the Test Cap was used in a series of six AICD patients. In a recent retrospective multicentre investigation, Bandorski et al. reported the use of CE in 51 patients with PM and 11 patients with eight different types of AICD:¹⁰ no impairment in cardiac devices function nor clinical adverse events were observed. However, cardiac telemetry was not performed in all the cases and specific data regarding AICD during CE are not available. Analogue limits are present in a retrospective series from Cuschieri et al.:¹¹ five patients with AICD undergoing CE were monitored with telemetry. However, it was not possible to verify concomitant interferences between the devices because in all the patients the cardiac device detection capability was switched off during the endoscopic procedure. Except for our preliminary findings,¹² complete data on AICD function during CE are available only in a few very small clinical studies,^{13–15} and in a case report involving a total number of 13 patients.¹⁶ In all these studies, neither was cardiac telemetry abnormal functioning recorded during CE nor AICD damage reported at the post-procedural device checks.

In light of previous studies and our results, at present we perform CE in persons with AICD as outpatients, without requirements of preventive changes in AICD settings. We are still performing and strongly suggest AICD technical checks before and after CE, because of the high number of different AICD available on the market and the extreme variability of their functioning parameters. This is in order to verify the AICD stability and to collect, in an internal registry, as many

data as possible regarding this field. In case of abnormalities at the AICD check prior to CE we propose the execution of CE as in-patient, with cardiac telemetry. We also perform an AICD control after CE in case of image corruptions during the view of CE video.

Conclusions

This study is the largest prospective series ever presented in order to investigate eventual EMI between CE and AICD. We studied 10 different types of AICD in a specifically designed clinical setting, instructed to perform a complete AICD control before, during and after CE. The results confirm the absence of mutual EMI between CE and AICD. In fact, in all the patients no AICD dysfunctions, interferences in sensing or pacing or dysrhythmias were found. Moreover, no electrical permanent injuries or changes in device setting were recorded. Conversely, the review of CE videos did not reveal interruptions, disturbances or loss of endoscopic images. This study suggests that CE can be safely performed in patients with different types of AICD. However, the small number of patients reported in the published data and the high heterogeneity of cardiac devices do not consent, in our opinion, to suggest definitive recommendations for managing CE in these patients.

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Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

References

1. Lin OS. Breaching the final frontier: the future of small-intestinal capsule endoscopy. *Gastrointest Endosc* 2008; 68: 495–498.
2. Guyomar Y, Vandeville I, Heuls S, et al. Interference between pacemaker and video capsule endoscopy. *Pacing Clin Electrophysiol* 2004; 27: 1329–1330.
3. Ginsber GG, Barkun A, Bosco J, et al. Wireless capsule endoscopy. *Gastrointest Endosc* 2002; 56: 621–624.
4. Allen M. Pacemakers and implantable cardioverter defibrillators. *Anaesthesia* 2006; 61: 883–890.
5. Morris ML, Tucker RD, Baron TH, et al. Electrosurgery in gastrointestinal endoscopy: principles to practice. *Am J Gastroenterol* 2009; 104: 1563–1574.
6. Petersen BT, Hussain N, Marine JT, et al. American Society of Gastrointestinal Endoscopy (ASGE) technology status evaluation report. *Endoscopy in patients with implanted electronic devices*. *Gastrointest Endosc* 2007; 65: 561–568.
7. Ladas SD, Triantafyllou K, Spada C, et al. European Society of Gastrointestinal Endoscopy (ESGE): recommendations (2009) on clinical use of video capsule endoscopy to investigate small-bowel, esophageal and colonic diseases. *Endoscopy* 2010; 42: 220–227.
8. Bandorski D, Irnich W, Brück M, et al. Do endoscopy capsules interfere with implantable cardioverter-defibrillators? *Endoscopy* 2009; 41: 457–461.
9. Dubner S, Dubner Y, Rubio H, et al. Electromagnetic interference from wireless video-capsule endoscopy on implantable cardioverter-defibrillators. *Pacing Clin Electrophysiol* 2007; 30: 472–475.
10. Bandorski D, Lotterer E, Hartmann D, et al. Capsule endoscopy in patients with cardiac pacemakers and implantable cardioverter-defibrillators – a retrospective multicenter investigation. *J Gastrointest Liver Dis* 2011; 20: 33–37.
11. Cuschieri JR, Osman MN, Wong RCK, et al. Small bowel capsule endoscopy in patients with cardiac pacemakers and implantable cardioverter defibrillators: outcome analysis using telemetry review. *World J Gastrointest Endosc* 2012; 4: 87–93.
12. Moneghini D, Lipari A, Missale G, et al. Absence of mutual interference between capsule endoscopy and implantable cardiac defibrillators: a clinical electrophysiological study. *Gastrointest Endosc* 2011; 73: 4S, AB454.
13. Leighton JA, Srivathsan K, Carey EJ, et al. Safety of wireless capsule endoscopy in patients with implantable cardiac defibrillators. *Am J Gastroenterol* 2005; 100: 1728–1731.
14. Elias G and Toubia N. Safety of capsule endoscopy in the setting of implanted cardiac defibrillators: a brief report. *Am J Gastroenterol* 2009; 104: 1856–1857.
15. Chung JW, Hwang HJ, Chung MJ, et al. Safety of capsule endoscopy using human body communication in patients with cardiac devices. *Dig Dis Sci* 2012; 57: 1719–1723.
16. Pelargonio G, Dello Russo A, Pace M, et al. Use of video capsule endoscopy in a patient with an implantable cardiac defibrillator. *Europace* 2006; 8: 1062–1063.