

Capsule Endoscopy in Patients with Cardiac Pacemakers and Implantable Cardioverter-Defibrillators – a Retrospective Multicenter Investigation

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Abstract

Background & Aims. Capsule endoscopy (CE) is an established tool for the investigation of the small intestine. The Food and Drug Administration, Given Imaging and Olympus have not recommended the use of capsule endoscopy in patients with cardiac pacemakers and implantable cardioverter defibrillators (ICDs). The aim of this retrospective study was to investigate the safety of capsule endoscopy systems (Given Imaging and Olympus) when applied in patients with different types of pacemakers/ICDs in vivo. **Methods.** A standardized questionnaire was sent to high volume centers in Germany and in Austria. The questionnaire covered the age and gender of the examined patients, indication of CE, brand and type of CE, brand and model of pacemaker/ICD, check of the devices before and after CE, monitoring during CE, possible interference between CE and cardiac pacemakers/ICDs and possible adverse events during CE. **Results.** Data from 62 patients were retrieved for this study. Capsules used were Given Imaging (n=58; M2A, M2Aplus, PillCam SB2), Olympus EndoCapsule (n=3), Given PillCam Colon (n=1). The collective included patients with pacemakers/ICDs from seven brands (Biotronik, Medtronic, St. Jude Medical, Guidant, Boston Scientific, Ela Sorin, Vitatron) with a total of 19/8 (pacemaker/ICD) different types. In two patients interference between capsule endoscopy and telemetry (loss of images/gaps in video) was recorded. None of the cardiac pacemakers or ICDs was impaired in function. No clinically evident event was observed in any of these patients. **Conclusions.** Clinical use of these CE types is safe in patients with cardiac pacemakers and ICDs. Interference can occur between CE and ECG-telemetry leading to loss of images or impaired quality of video.

Key words

Capsule endoscopy – cardiac pacemakers – implantable cardioverter defibrillators – safety.

Introduction

Capsule endoscopy (CE) is an established tool for the investigation of the small intestine. Because of limited clinical experience with CE in patients with cardiac pacemakers/implantable cardioverter-defibrillators (ICDs), the Food and Drug Administration, Given Imaging and Olympus have recommended not using CE in these patients. Our in vitro investigations did not reveal any interference between capsule endoscopy with PillCam SB, PillCam Colon (Given Imaging Ltd., Yoqneam, Israel), EndoCapsule (Olympus Medical Systems Corp., Tokyo, Japan), and several types of cardiac pacemakers and ICDs [1, 2]. The aim of this study was to investigate the safety of these CE systems when applied in patients with different types of pacemakers/ICDs in vivo.

Patients and Methods

We carried out a retrospective data survey of patients with cardiac pacemakers and ICD who underwent CE in hospitals and outpatient clinics. A standardized questionnaire was sent to high volume centers in Germany and in Austria. The questionnaire covered the age and gender of the examined patients, indication of CE, brand and type of CE, brand and model of pacemaker/ICD, check of the devices before and after CE, monitoring during CE, possible interference between CE and cardiac pacemakers/ICDs and possible adverse events during CE. All data were submitted anonymously from the hospitals and clinics for our evaluation.

Pacemakers and ICDs investigated

Medical records were retrieved to find out the brand and model of the devices. In the case of missing specifications the patients, their cardiologist or the device implanting hospital was contacted.

Received: 19.11.2010 Accepted: 08.02.2011

J Gastrointestin Liver Dis

March 2011 Vol. 20 No 1, 33-37

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We directed our attention to the checking of the devices before and after, arrhythmias during CE or interference behaviour of the cardiac pacemakers/ICDs.

Video capsules investigated

Corresponding to the cardiac pacemakers/ICDs we also obtained an incidental collection of capsules. With regard to CE we directed our intention to the interference during CE (impairment of the quality of the picture or failure of sending pictures). Three devices, PillCam SB, EndoCapsule and PillCam Colon were used in the study.

The first capsule produced by Given Imaging Ltd., Yoqneam, Israel was marked as a M2A capsule. It has a length of 26 mm, a diameter of 11 mm. The weight is 3.7 g including internal batteries, a lens, a CMOS chip-camera, a radio transmitter with 434.09 MHz carrier frequency and 2Hz pulse trains (250 ms on, 250 ms off), and an antenna. Two pictures per second are emitted from the gastrointestinal tract with four light-emitting diodes (LEDs) flashing for internal illumination by the device at each picture. Modifications of the M2A capsule (later called M2Aplus, PillCam SB, PillCam SB2) were improvements in optical resolution, illumination control, reducing of LEDs from six to four, an increase of the viewing angle of the camera amounts from 140° to 156°. The initial working time of the capsule from 6 to 8 hours was increased over time. Presently, there is a working capacity of 8h:59min based on a pre-programmed termination of image transmission, resulting in an increase of transmitted images from approximately 50,000 to 65,000. The emitted pictures are detected by eight external electrodes attached to the body. The detected information is passed to a recorder and from there to a workstation. The data can be evaluated with the software "RAPID" (Reporting and Processing of Images and Data) at the workstation. The software offers the possibility to view the pictures in real time or in quick motion.

The initial EndoCapsule 1 (Olympus Medical Systems Corp., Tokyo, Japan) is still in use [3]. The size is identical to the M2A/PillCam SB comprising 26 mm in length, 11 mm in diameter, and weighing 3.8 g. Frequency for radio transmission is 433.8 MHz and the range of vision of the camera amounts to 145°. A CCD chip is used. Guaranteed working time of the EndoCapsule is 8 hours, but may be up to 11 hours, as there is no pre-programmed time limitation. The real time viewing device allows either wired access to the recorder during the procedure or direct wireless image acquisition from the capsule when held close to the patient's body.

The "PillCam COLON1" (Given Imaging Ltd., Israel) features 31 mm in length, 11.4 mm in diameter and weighs 2.9 g including internal batteries and at each side a lens, a chip-camera at each side, a high frequency transmitter with 434.1 MHz, with an antenna incorporated, and four light-emitting diodes. While active, the capsule transmits images at a rate of 4 images per second (2 images per second per side). For each image, an illuminating light flash is applied with LEDs. The capsule goes into a standby mode ("delay mode") and stops transmission of images 3 minutes post

activation to preserve battery energy and turns automatically on approximately 1h:45min later, typically before entering the colon [4]. It stops its operation when the batteries are depleted. In the course of the 9±1 hours duration of function, approximately 130000 single-shot pictures are provided. The emitted pictures are detected by eight electrodes and information is passed via a recorder to a workstation too. Evaluation of the data is done with the RAPID-Software mentioned above.

Results

Data from 62 patients were retrieved for this study. Mean age of patients was 73 years, indication for CE was obscure GI bleeding or anemia in 57 patients (91%).

Capsules used were Given Imaging (n=58; M2A, M2Aplus, PillCam SB2), Olympus EndoCapsule (n=3), Given PillCam Colon (n=1). The collective included patients with pacemakers/ICDs from seven brands (Biotronik, Medtronic, St. Jude Medical, Guidant, Boston Scientific, Ela Sorin, Vitatron) with a total of 19/8 (pacemaker/ICD) different types. Forty nine patients had a cardiac pacemaker and 11 patients an ICD. Twenty three patients had a single lead device, 35 had two leads, while 2 patients had three leads. In 2 patients there was no information available, concerning brand/model of the cardiac pacemaker/ICD. Details are shown in Table I. All pacemakers/ICDs were implanted intrathoracally. The devices were tested for function/interference before and after CE in 4 patients, in 2 patients before CE, in 3 patients after CE and in 51 patients not tested before or after CE. In one patient with an ICD, a „Berlin Heart“ (left heart device) [5] was implanted additionally. ECG-Monitoring during CE was performed in 13 patients while 49 patients were not monitored during CE. In 2 of the 13 patients a wireless ECG-monitoring device was used during CE. In one patient, telemetry (Telegard 7, Danica Biomedical, Roedovre, Denmark) was installed prior to the initiation of CE with M2Aplus, resulting in an impossibility to document CE images. A repeated M2A plus CE without telemetry was recorded without disturbance. A second patient swallowed the PillCam SB1 capsule in the endoscopy suite and was equipped with a telemetry (Apex Pro, GE Medical, Munich, Germany) when arriving back at the referring hospital. At this time interference between CE and wireless monitoring device (loss of image with gaps in video) was recorded as shown in Fig. 1. In all other patients capsule endoscopic images were not impaired.

None of the cardiac pacemakers or ICDs was impaired in function. No clinically evident event was observed in any of these patients.

Discussion

Corresponding to the results of our in vitro investigations [1, 2], the present study did not verify any interference between capsule endoscopy and cardiac pacemaker/ICD in patients monitored during CE. No clinically evident interference was revealed in patients without monitoring

Table I. Details of pacemaker/implanted cardioverter defibrillators. Chamber: 1=one lead, 2= two leads, 3 = three leads

Brand PM	Model PM	Chamber	Comment
Biotronik	Philos DR-T	2	
Medtronic	InSyncIII Marquise	1	ICD, Berlin Heart
Biotronik	Actros SLR	2	
St. Jude	Identity	1	
St. Jude	Verity	2	
St. Jude	Verity	1	
Guidant	CPI Discovery DR 1274	2	
Medtronic	Kappa 900 DR	2	
St.Jude	Verity	1	
Medtronic	Sensia DR	2	
St. Jude	EPIC HF	3	
St. Jude	Identity 5376	2	
Boston Scientific	Cognis 100	2	
Boston Scientific	Vitality 2 EL T177	2	ICD
Medtronic	Insync III	1	
Vitatron	C60DR	2	
Guidant	Insignia	1	
Guidant	Insignia AVT SR	1	
Medtronic	Kappa KDR 703	2	
St.Jude	Identity Adx SR 5180	1	
Boston Scientific	Teligen100 F110	2	ICD
Guidant	Ventak Prizm 2DR 1861	2	ICD
Guidant	Vitality AVT DR A 135	2	ICD
SJM	Atlas + VR V193	1	ICD
Biotronik	Philos SR-B	1	
Guidant	Insignia Plus DR	2	
St. Jude	Promote RF 3213-36	3	
St. Jude	Atlas II + VR V-168	1	ICD
Ela Sorin	Rhapsody SR 2210	2	
Ela Sorin	Symphony DR 2550	2	
Biotronik	Philos II SR	1	
Medtronic	Kappa KSR 401	1	
Medtronic	Kappa KSR 401	1	
Biotronik	TIR 60-BP	1	
Medtronic	Kappa KDR 703	2	
St. Jude	Atlas DR V-240	2	Interference with telemetry, ICD
Medtronic	Kappa KDR 703	2	
Medtronic	EnPulse E2 DR31	2	
Medtronic	EnPulse E2 DR31	2	
St. Jude	Current DR RF 2207-36	2	
Vitatron	T70 DR	2	

Table I (continued)

Guidant	Insignia	1	
Medtronic	EnPulse E2 DR 31	2	
Medtronic	Kappa KSR 703	1	Interference with telemetry
Medtronic	Kappa KSR 703	1	
Biotronik	Philos II DR	2	
Medtronic	Kappa DR 701	2	
Biotronik	Lumax 340 DR-T	2	ICD
Biotronik	Philos II DR	2	
Biotronik	Philos SR	1	
St. Jude	Identity DR	2	
St. Jude	Victory SR 5816	2	
St. Jude	Identity	1	
Medtronic	Kappa KSR 401	2	
Medtronic	Kappa KDR 703	2	
St. Jude	Current VR	1	ICD
Vitatron	Clarity SSIR	1	
St. Jude	PromoteAccel RF 3215-36	1	
Boston Scientific	Renewal	2	ICD

during CE. In an actually retrospective study including patients with cardiac pacemakers or ICDs who underwent small bowel capsule endoscopy no clinical relevant adverse effects were seen too [6]. Cuschieri et al conducted this retrospective study of 20 patients with either a cardiac pacemaker or an ICD who underwent CE. During CE a continuous ECG monitoring (telemetry) was performed. The devices were checked for function/interference before and after CE. In most of the patients (n=17) no adverse events were reported. Two patients revealed episodes of undersensing. Similar episodes were documented outside the time frame of CE and caused by a low amplitude atrial fibrillatory activity. In another patient a low signal encountered from CE resulting in lack of localization without loss of images, was observed.

In contrast to our study, all patients underwent continuous wireless electrocardiographic monitoring (telemetry) for the duration of CE. In our study, 11 patients were monitored for the whole time of CE (ECG-Monitor), 2 patients with a telemetry system, whereas 49 patients were not monitored during CE. Additionally, Cuschieri et al checked all devices before and after CE and turned off prior to the procedure detections of ICDs: cardiac pacemaker sensing and pacing configuration were either kept the same or changed to optimize patient comfort and safety. The study of Cuschieri is a monocentric study and represents the clinical pathways for CE in patients with cardiac pacemakers and ICDs in this center. Our study is a retrospective multicentric study which caused different clinical practice in patients with cardiac pacemakers and ICDs who underwent CE. Our study seems to represent the prevailing actual clinical pathway of CE in 11

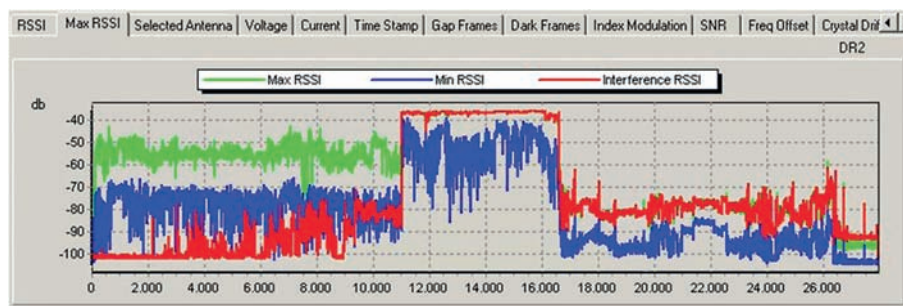


Fig 1. Received Signal Strength Indicator (RSSI) as recorded during a capsule procedure. Green: Highest RSSI of the 8 antennas. Blue: Lowest RSSI of the 8 antennas. The red curve is recorded during the transmission pauses of the capsule and represents the RSSI of external signals received by the DataRecorder. When the red curve reaches or exceeds the green curve a loss of image data will occur. The actual graph shows the influence of a wireless monitoring device transmitting on the capsule's frequency. The resulting video has gaps (Courtesy of Konstantin Ackers, GivenImaging, Hamburg, Germany).

high volume centers performing CE in patients with cardiac pacemakers/ICDs. Most of the patients had no continuous ECG monitoring during CE, whereas continuous monitoring was only done in the initial phase of establishing the CE method. All patients were observed clinically during the working time of CE battery and no adverse events occurred. Because of the different clinical practice relating to a check of the devices in our study (4 patients before and after CE, 2 patients before CE, 3 patients after CE, 51 patients none) the evaluation of possible electrophysiological interference was possible only in a minority of patients, but did not show any disturbance. It should be mentioned that CE was tolerated well, although the cohort represents a selection of elderly patients (mean age 73 years, all with at least cardiac comorbidity and additionally suffering from GI bleeding/anemia).

According to our results in the study of Cuschieri et al, interference between telemetry and CE was observed. In one patient a low signal encountered from the capsule resulting in lack of localisation was documented, but no images were lost. In contrast, in our study a loss of data occurred as shown in Fig. 1. For the first time we could document the analysis of the raw data received by the DataRecorder from capsule and from the interfering external signal (kindly performed by the capsule producer with a dedicated software tool). This demonstrates that the stronger signal of a wireless ECG-monitoring device transmitting suppresses processing of the weaker capsule signal, leading to gaps in the capsule video. Interference between telemetry and CE could possibly explain loss of images e.g. reported by Guyomar et al and Bandorski et al [7, 8].

Previous studies included patients with pacemakers/ICDs who underwent CE with the Given small bowel capsules. These patients account for the vast majority of our study population as well, while additionally, 3 patients undergoing Olympus EndoCapsule or GivenPillCam Colon1 investigation could be included. In concordance with the in vitro studies using these capsule types, no clinical

adverse events were observed, nor was electrophysiological interference detected in those patients.

In our retrospective study, most of the patients underwent CE with the PillCam. Both types of CE (Given Imaging and Olympus) are nearly completely identical in their technical properties (emitted frequency, radiated power). Despite the vast majority of PillCam we conclude that this fact does not have an influence on the interpretation of our results relating to interference between CE, cardiac pacemakers and ICDs.

Limitations of this study are its retrospective protocol, the fact that only a minority of patients underwent cardiac monitoring during CE and analysis of pacemaker protocols and that the study does not represent a complete register of all pacemaker/ICD patients. However, based on previous systematic in vitro investigations, nationwide surveys and smaller case series, this study includes a larger number of patients, mainly from high volume centers, further capsule types and additional kinds of pacemakers/ICDs. Again no adverse events caused by capsule endoscopy in these patients could be observed, giving further support to the suggestion of omitting the presence of pacemakers/ICDs as a contraindication for CE. Nevertheless, patients with pacemakers/ICDs should be informed about the still existing formal contraindication to perform CE. The results of this study further demonstrate that in clinical practice, cardiac monitoring as well as pacemaker control is infrequently performed due to the physicians' confidence in the safety of this procedure.

Although Leighton et al already suggested performing CE as an ambulatory procedure in his first patients with clinical observation of these patients on a ward or in an outpatient clinic during the life of the capsule battery [10], this may be a compromise. Cardiac monitoring might be dispensable. Furthermore, based on our observations, wireless ECG-monitoring with telemetry should be avoided because of the risk of losing endoscopy images due to interference.

The number of included patients in our study represents

an extensive collective of devices. In most of the other studies a smaller number of patients was included [6, 7, 9-11]. A few devices were investigated in other studies: Medtronic Kappa [9,12], Boston Scientific Vitality [11], Guidant Ventac PRIZM2 [10], Medtronic InSync [10]. According to our results, no clinically relevant interference was noticed. The results of these studies confirmed our results of the in vitro investigations [1, 2].

Conclusion

No clinically evident interference was observed between Given Imaging small bowel CE, the Given PillCam ColonI and the Olympus EndoCapsule (technically identical for emitted frequency and radiated power) on one hand, and cardiac pacemakers and ICDs in vivo. The results confirm our in vitro investigations which suggest that clinical use of these CE types is safe in patients with cardiac pacemakers and ICDs. Interference can occur between CE and ECG-telemetry leading to loss of images or impaired quality of video. Different applications of monitoring were performed during CE whereas continuous monitoring was only done in the initial phase of establishing the CE method.

Conflicts of interest

None to declare.

Acknowledgments

We are grateful for the data submission from the following colleagues: Prof. Dr. D. Jaspersen (Fulda), Dr. H. Fensterer and Dr. G. P. Horn (Marburg), Dr. C. Duecker (Hamburg-Barmbeck), Dr. C. Schulz (Magdeburg), PD Dr. M. Farnbacher (Fuerth), Dr. T. Pachofszky (Vienna), PD Dr. J. Albert (Frankfurt), PD Dr. A. J. Dormann (Cologne), Dr. T. Rath and Dr. M. Goedecke (Giessen), Dr. R. Koelble (Dusseldorf).

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