

Capsule endoscopy in patients with cardiac pacemakers, implantable cardioverter defibrillators and left heart assist devices

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Abstract

According to the recommendations of the US Food and Drug Administration and manufacturers, capsule endoscopy should not be used in patients carrying implanted cardiac devices. For this review we considered studies indexed (until 30.06.2013) in Medline [keywords: capsule endoscopy, small bowel endoscopy, cardiac pacemaker, implantable cardioverter defibrillator, interference, left heart assist device], technical information from Given Imaging and one own publication (not listed in Medline). Several *in vitro* and *in vivo* studies included patients with implanted cardiac devices who underwent capsule endoscopy. No clinically relevant interference was noticed. Initial reports on interference with a simulating device were not reproduced. Furthermore technical data of PillCam (Given Imaging) demonstrate that the maximum transmission power is below the permitted limits for cardiac devices. Hence, impairment of cardiac pacemaker, defibrillator or left ventricular heart assist device function by capsule endoscopy is not expected. However, wireless telemetry can cause dysfunction of capsule endoscopy recording. Application of capsule endoscopy is feasible and safe in patients with implanted cardiac devices such as pacemakers, cardioverter defibrillators, and left heart assist devices. Development of new technologies warrants future re-evaluation.

Keywords Capsule endoscopy, cardiac pacemakers, implantable cardioverter defibrillator, interference, left heart assist device

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Introduction

Capsule endoscopy (CE) for the small bowel has emerged as the first line diagnostic tool for patients with mid gastrointestinal (GI) bleeding. Many of these patients with mid GI bleeding are elderly and suffering from cardiovascular

co-morbidity with the necessity of thrombocyte aggregation inhibition and / or oral anticoagulation. In consequence it is not unusual that these patients requiring CE for mid GI bleeding have an implanted cardiac device. The US Food and Drug Administration (FDA) and the manufacturers Given Imaging and Olympus recommend not using CE in these patients. Nevertheless, patients with implanted cardiac pacemakers (PM) and implantable cardioverter defibrillators (ICD) have undergone CE without clinical sequel. The endoscopy section of the German Society of Digestive and Metabolic Diseases (DGVS) recommends informed consent about the formal contraindication [1]. According to the guidelines of the European Society for Gastrointestinal Endoscopy (ESGE) CE is not contraindicated in patients with PMs or ICDs [2].

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Methods

This review summarizes the current evidence from the literature. For this review we considered studies indexed (until 30.06.2013) in Medline (keywords: CE, small bowel endoscopy, PM, ICD, interference, left heart assist device),

technical information of Given Imaging and one own publication (not listed in Medline).

CE in patients with PM

Up to date potential interference between CE and PM has been investigated in 12 studies (Table 1).

A recent study by Harris *et al* reports about 118 CE in 108 patients [3]. The CE was repeated in 8 patients because of recurrent bleeding episodes. Sixty eight patients (63%) had a PM, 25% an ICD and 12% a left ventricular assist device (LVAD; LVAD=8 patients, LVAD+PM=2 patients, LVAD+ICD=4 patients). Functionality of the PM was checked before and after CE and did not reveal any significant arrhythmias. Monitoring of cardiac rhythm during CE was performed via Holter analyses or telemetry, again without evidence for significant arrhythmias. There was no alteration of device function or programmed parameters.

Cuschieri *et al* included 20 patients (PM: 14 patients) in

their study who underwent ECG telemetry monitoring during CE [4]. In 4 patients the data of the PM/ICD and in 2 patients the telemetry report were not available. The programmed parameters of the PM/ICD were preserved. Premature ventricular beats were found before, during and after CE, however, they were not ascribed to the capsule endoscope.

Our retrospective multicenter investigation included 62 patients, with a total of 19/8 different types of PM/ICD from seven brands [5]. Applied capsule types were PillCam SB 1 and SB2, PillCam Colon 1 (Given Imaging, Yoqneam, Israel) and EndoCapsule EC1 (Olympus, Tokyo, Japan). In 2 patients there was no information available, concerning brand/model of the PM/ICD. None of the tested PM/ICD was impaired in function. None of the patients had a clinically evident event.

Two of five PM patients undergoing CE in a Canadian series had an abdominal pacemaker [6]. Additionally, relevant interference was excluded in these patients by holding the capsule close to the abdominal PM. All patients underwent CE without interference.

As there is a wide variety of PMs, 21 types from seven manufacturers were included in an *in vitro* study [7]. In

Table 1 Studies investigating patients with cardiac pacemakers who underwent capsule endoscopy

Author	Year	Number of patients/ cardiac pacemakers (n)	Brand of cardiac pacemaker	Kind of study	Interference	Brand of capsule endoscopy
Harris [3]	2013	76	Medtronic, Guidant and others	<i>In vivo</i>	No	Given Imaging
Bandorski [12]	2012	300	No specification	<i>In vivo</i>	No	Given Imaging Olympus
Cushieri [4]	2012	14	Medtronic, St. Jude Medical, Ela	<i>In vivo</i>	No	Given Imaging
Bandorski [5]	2011	49	Medtronic, Vitatron, Ela, Guidant, St. Jude Medical, Biotronik, Boston Scientific	<i>In vivo</i>	No	Given Imaging+ Olympus
Dirks [6]	2008	5	No specification	<i>In vivo</i>	No	Given Imaging
Bandorski [7]	2008	21	Medtronic, Osypka, Siemens, Vitatron, Ela, Guidant, St. Jude Medical	<i>In vitro</i>	No	Given Imaging+ Olympus
Bandorski [9]	2006	1	Biotronik	<i>In vitro</i>	No	Given Imaging
Payeras [10]	2005	20	No specification	<i>In vitro</i> <i>In vivo</i>	No No	Given Imaging (Test Cap)
Bandorski [11]	2005	45	No specification	<i>In vivo</i>	No	Given Imaging
Dubner [15]	2005	100	St. Jude Medical, Medtronic, Guidant, Biotronik, Sorin	<i>In vivo</i>	Yes (n=4, noise mode)	Given Imaging (Test Cap)
Guyomar [13]	2004	1	ELA	<i>In vivo</i>	No	Given Imaging
Leighton [14]	2004	5	No specification	<i>In vivo</i>	No	Given Imaging
Chung [27]	2012	3	St. Jude Medical, Medtronic	<i>In vivo</i>	No	Intramedic

brief, a PM and its electrodes were placed into a saline bath. Resistivity of this solution corresponded to lower frequency range of muscle tissue as described previously by Irnich and co-workers when investigating the effect of cell phones on PM [8]. The PM pulses were made visible by an oscilloscope. Customized sensitivity settings as well as maximal sensitivity were applied in the test while using unsynchronized impulse. For one minute each, the capsule endoscope was placed in different positions and different directions as close as possible to the PM. After this procedure a CENELEC standard test signal was performed and the measurements were repeated. Functionally of the capsule was documented during the manoeuvre by recording the transmitted images. No interference from PillCam on any of the PM could be detected. Additionally, an endoscopic capsule (Given Imaging) in a porcine intestine did not influence a PM in DDD-/VVI- mode (Philos DR, Biotronik, Berlin, Germany) in spite of proximity for 10 min [9].

Payeras and colleagues used a simulation Test cap (Given Imaging) for their studies instead of a regular capsule endoscope. This device transmits identical signals without having any optical features [10]. Interference between Test cap and PM (Kappa KD 701, Medtronic, Minneapolis, MN, USA) was assessed for 1 min. This experiment was performed first in air, and then with the PM immersed into a container with a solution, similar to that applied in our investigation. After using a unipolar mode, the experiment was repeated with the PM in bipolar mode. Additionally, the test was continued in vivo with the Test Cap placed close to the patient's thorax. Finally, patients ingested the endoscopic capsule under ECG monitoring. No interference of the CE or PM was observed.

A German survey in 2004 retrospectively evaluated the clinical practice concerning CE in patients with PM or ICD with a standardized questionnaire [11]. Patients from 28 centers with a PM (n=45) or ICD (n=8) were reported having undergone CE without complications.

A follow up of this survey performed in 2010 in Germany, Austria and Switzerland revealed that 51% of responding physicians performing CE in hospitals or in an office provided this service also for patients with implanted cardiac devices. 300 uneventful CE procedures were reported in patients with PMs, the majority without specific cardiac monitoring [12].

However, multiple gaps in the recording of a video CE were reported in a patient with a PM implanted in the abdominal wall. The VVI PM with an unipolar epicardial electrode was not influenced, even if the capsule was held at various abdominal sites close to the aggregate [13].

In our latest survey, impairment of CE videos was observed in two patients, which could be attributed to application of wireless telemetry during the procedure [12].

In Leighton's study 5 patients underwent CE with a Holter ECG monitoring [14]. PM testing before and after CE revealed atrial and ventricular extrasystoles in three cases. One patient had a non-sustained ventricular tachycardia of 3 beats. No interference of CE/PM was observed.

Dubner's study investigated patients with a PM (n=100) [15]. For this evaluation the Test Cap was used under con-

tinuous electrocardiographic monitoring. After placing the Test Cap above the pulse generator it was moved following the estimated course of the leads to their tip in atrium and ventricle. The test was repeated twice and re-evaluated in patients with interference one week later, each time with the Test Cap at various distances: close (2 cm), approximately 10 cm from the skin and more than 10 cm from the surface at intervals of 10, 30 and 60 sec. Interference in 4 patients could be reproduced again after one week. This interference was observed with the Test Cap localized within 10 cm of the body surface close to generator and electrodes (Biotronik, Berlin, Germany: Actros SR and Logos, St. Jude Medical, St. Paul, MN, USA: two Affinity DR) causing the PM to switch to noise-mode function (VOO- or DOO-mode). The authors conclude this interference in a "worst case scenario" setting not to have clinical relevance.

To assess the possibility of interference between CE and PM/ICD, technical data of PillCam and remote transmitting DR3 data-recorder were made available by Given Imaging to two of the authors (D.B. and D.S.). Based on the maximum effective radiated power and transmitter frequency the maximum electromagnetic radiation in close proximity (5 mm) was calculated. The maximum radiation does not reach the limits for PMs/ICDs specified in the standard E DIN VDE 0848-3-1 [24]. Hence interference of PillCam and DR3 recorder (Given Imaging)/with PM/ICD is not to be expected. EndoCapsule EC-1 (Olympus, Tokyo, Japan) did not show interference *in vitro* and in a small number of patients.

Two other types of video capsules with real time data transmission are on the market. OMOM capsule (Jinshan, Chongqing, China) uses similar image transmission by radio frequency [25]. However, no data on the potential interference of this system in patients with PM/ICD are available yet. Human body communication is applied for image transfer of MiRoCam (Intromedic, Seoul, Korea). A modulated 3V current is tapped by standard ECG electrodes that are attached to the patient's abdomen [26]. Although this principle might be more critical for PM/ICDs than radiotransmission, no interference was observed with MiRoCam and PM/ICD in a recent small series with six patients [27]. No disturbances in cardiac devices or arrhythmias were detected on telemetry monitoring during CE. No significant changes in the programmed parameters of the cardiac devices were noted after CE. There were no imaging disturbances from the cardiac devices on CE.

Developments of wireless CE systems include remote control of the capsule imaging rate/sec via the recorder. Initially, the OMOM system (Jinshan, Chongqing, Cina) provided the option of manual remote switching between different image acquisition rates. Especially during gastric passage, power saving mode can preserve battery power [28]. The automatic frame rate control depending on capsule speed in the intestine as represented by the alteration of images from PillCam Colon2 (4 vs. 35 images/sec) [29] and PillCam SB 3 (2 vs. 6 images/sec) is realized by transmitting a reverse signal from the recorder (DR3) to the capsule. Theoretical considerations based on the data of Given Imaging support that there is also no risk of interference.

A new CE system CapsoCam (Capsovision, Saratoga, CA, USA) uses an internal chip to store acquired images. Hence, emission of current or radiofrequency waves, potentially influencing cardiac devices is completely avoided. On the other hand, this capsule has to be retrieved to download the images.

CE in patients with ICD

Nine studies investigated possible interference between ICD and CE (Table 2). The study of Harris *et al* included 34 patients with an ICD [3]. The ICDs were tested before and after CE and the patients were monitored by Holter monitor or telemetry. No interference was observed. In one patient with an ICD, loss of capsule endoscopic images for a 25-min period was attributed to a defect of the data recorder, as this problem could be fixed by replacing the recorder.

The study of Cuschieri *et al* including 5 patients with an ICD [4] and our retrospective multicenter investigations of 2011/2012 showed that 8/80 patients [5,12] did not detect any interference between ICDs and CE too.

In analogy to our *in vitro* study on potential interference between the Given capsule and PM, the next trial tested susceptibility of ICD [16]. Forty five ICDs, three capsule types (PillCam SB2, PillCam Colon1, Given Imaging) and EndoCapsule (Olympus) were tested in this study [16]. Again ICDs and electrodes were placed in a 0.9% saline solution simulating resistivity of low frequency range in muscle tissue. Pacing pulses of the

ICDs were observed by an oscilloscope. The setting included variable distances between capsule and ICD including different positions and directions for 1 min each. Finally capsules were placed on the case of the ICD and close to coil, ring and tip of the leads for 1 min. Neither interference with ICD function nor with acquisition of capsule images was observed.

No interference was detected during a CE in patient an ICD (GEM III 7275, Medtronic, Minneapolis, MN, USA) [18].

Our survey in 2004 in Germany reports about eight ICD patients without any clinically evident events due to CE [11].

Leighton *et al* report about five patients with an ICD who underwent CE (Given Imaging) monitored by telemetry [19]. A pre- and post-procedure ICD interrogation revealed no interference and the CE images were not disturbed.

Dubner and co-worker extended their initial study that had shown interference between CE simulation kit and PM to ICDs [20]. Again interference between the capsule endoscope Test Cap and ICDs was reported. During the *in vitro* part ICD and its lead were placed in a saline gel bath and the Test Cap was positioned 1 to 15 cm from the ICD, ring and coil for 10 to 60 sec. ICDs at nominal setting and at highest sensitivity were tested with specific programmers before and after the challenge. The tests were repeated after a week. Reproducible interference (triggering delivery of inappropriate electric shock) occurred when placing the Test Cap over ring and coil but not over the pulse generator of a Belos DR (Biotronik, Berlin, Germany). This interference was not eliminated even at 30 cm distance from the ICD system. Six patients with ICDs that had not shown interference during the laboratory

Table 2 Studies investigating patients with implantable cardioverter defibrillators who underwent capsule endoscopy

Author	Year	Number of patients/ ICD (n)	Brand of ICD	Kind of study	Interference	Brand of CE
Harris [3]	2013	34	n.a.	<i>In vivo</i>	No	Given Imaging
Bandorski [12]	2012	30	No specification	<i>In vivo</i>	No	Given Imaging Olympus
Cushieri [4]	2012	5	Medtronic, St. Jude Medical	<i>In vivo</i>	No	Given Imaging
Bandorski [5]	2011	11	Biotronik, Guidant, Medtronic, St. Jude Medical, Boston Scientific	<i>In vivo</i>	No	Given Imaging+ Olympus
Bandorski [16]	2009	45	Biotronik, Guidant, Medtronic, St. Jude Medical	<i>In vitro</i>	No	Given Imaging+ Olympus
Dubner [20]	2008	6 (<i>In vitro</i>) 6 (<i>In vivo</i>)	Medtronic, St. Jude Medical, Guidant, Biotronik	<i>In vitro</i> <i>In vivo</i>	Yes (oversensing with inappropriate shock delivery) No	Given Imaging Test Cap
Pelargonio [18]	2005	1	Medtronic	<i>In vivo</i>	No	Given Imaging
Bandorski [11]	2005	8	No specification	<i>In vivo</i>	No	Given Imaging
Leighton [19]	2005	5	Guidant, Medtronic, St. Jude Medical	<i>In vivo</i>	No	Given Imaging
Chung [27]	2012	3	St. Jude Medical, Medtronic	<i>In vivo</i>	No	Intromedic

n.a., not available; ICD, implantable cardioverter defibrillator; CE, capsule endoscopy

Table 3 Studies investigating patients with ventricular assist devices who underwent capsule endoscopy

Author	Year	Number of patients (n)	Brand of LVAD	Kind of study	Interference	Brand of CE
Harris [3]	2013	14	n.a.	<i>In vivo</i>	Yes (2 capsule videos impaired)	Given Imaging
Bandorski [5]	2011	1	Berlin Heart AG	<i>In vivo</i>	No	Given Imaging
Girelli [21]	2006	1	Berlin Heart AG	<i>In vivo</i>	No	Given Imaging
Garatti [22]	2006	1	Berlin Heart AG	<i>In vivo</i>	No	Given Imaging

n.a., not available; *n.a.*, not available; LVAD, left heart assist device; CE, capsule endoscopy

study were evaluated similar to the *in vitro* part. For safety reasons, the 60 sec period was excluded. None of these ICDs tested showed *in vivo* interference.

A recent study with the MiRoCam (Intromedic, Seoul, Korea) capsule system revealed no interference in 3 patients with an ICD.

CE in patients with LVAD

Few reports are available on CE in patients with LVAD (Table 3). The study of Harris et al. investigated 14 patients with a LVAD [3]. The type and manufacturer of the LVAD are not specified. Two patients had interference with capsule image acquisition while the CE was in the small bowel (<2 min), the LVAD was unaffected.

The patient with a Berlin Heart and an ICD included in our multicenter series underwent CE without any interference [5].

Two additional case reports on patients with a left ventricular assist device (LVAD; INCOR; Berlin Heart AG, Berlin, Germany) who underwent uneventful CE are listed in Medline [21,22].

Discussion

With the advent of wireless video CE concerns arose that radio transmission from capsule to recorder might disturb PM or ICD stability. Furthermore, initial reports from one group described interference of a test cap, simulating capsule transmission with PM [15] and later also on ICD [20]. However, these interferences on PM were considered by the authors not be harmful to patients, even assuming a worst case scenario. Additionally, interference with ICD was not observed in the *in vivo* part of the study and other groups could not reproduce these findings with regular video capsules either *in vivo* or *in vitro* [3-5,11,12,16,18].

Following initial reports on uneventful CE in patients with PM and later also with ICDs, numerous physicians started applying CE in these patients in spite of still existing formal contraindication.

CE in PM and ICD patients seems to be safe, considering

technical data provided by one of the manufacturers (Given Imaging) on the power of capsule signals, *in vivo* studies with the Given and Olympus system with PM and ICD, and several series reporting uneventful clinical application. These clinical observations included several different types of PM and ICD. In addition, few cases have been reported without interference between CE and left heart assist devices [3,5,11,12].

With regard to different capsule types, PillCam SB1, SB2, PillCam Colon1, and Olympus EndoCapsule1 have been studied. Additionally, few clinical applications of MiroCam in patients with PM or ICD have been conducted without problems [27]. No reports are as yet available for OMOM capsule. For the new PillCam SB3 and PillCam Colon2 with additional remote signals from the recorder to the capsule in order to adapt frame rates, studies are still warranted. However, interference with cardiac devices is not to be expected, as the signal power from the recorder is too low to interfere with PMs/ICDs. For capsules systems (as CapsoCam) with on board storage of images without transmission, interference with cardiac devices is not possible *a priori*.

Relevant interference of wireless telemetry, however, has been observed. In some cases, CE videos had been corrupted [5,12,13]. If cardiac monitoring is necessary during CE, wired systems should be used.

In conclusion CE seems to be safe in patients with PM, ICD and left heart assist devices. This is to be expected for new capsule types as well but has yet to be confirmed. However, wireless telemetry can impair recording of video capsule images.

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