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REVIEW

### Contraindications for video capsule endoscopy

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#### Abstract

Video capsule endoscopy (VCE) has been applied in the last 15 years in an increasing field of applications. Although many contraindications have been put into perspective, some precautions still have to be considered. Known stenosis of the gastrointestinal tract is a clear contraindication for VCE unless surgery is already scheduled or at least has been considered as an optional treatment modality. In patients with a higher incidence of stenosis, as in an established diagnosis of Crohn's disease, clinical signs of obstruction, prior radiation or surgical small bowel resection, a preceding test with the self-dissolving patency capsule can override this contraindication. Endoscopic placement of the capsule should be considered in patients with swallowing disorders to avoid aspiration. Esophageal or gastric motility disorders may require endoscopic capsule transport or application of prokinetics if the real-time viewer proofs delayed transit. In pregnant women, VCE should be restricted to urgent cases where diagnosis cannot be postponed after delivery, as data on safety are missing. There is theoretical and clinical evidence that patients with implanted cardiac devices such as a pacemaker, cardioverters or left heart assist devices, can safely undergo VCE in spite of still existing contraindication by manufacturers. Children from the age of 2 years have safely undergone VCE. Although video capsules are not proven safe with magnetic resonance imaging (MRI), first single cases of patients incidentally undergoing MRI with an incorporated capsule have been reported, showing susceptibility artifacts but no signs of clinical harm.

Key words: Video capsule endoscopy; Contraindications; Stenosis; Pacemaker; Aspiration; Pregnancy; Magnetic



resonance imaging

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Core tip: Video capsule endoscopy has emerged as a first line diagnostic tool for small bowel visualization. The few existing contraindications are discussed in this review and put into perspective. Special situations are to be considered for patients with gastrointestinal stenosis, swallowing and motility disorders, or implanted electromagnetic cardiac devices, pregnant women, young children, and magnetic resonance imaging for patients with a retained capsule. Appropriate precautions are discussed in this paper.

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#### INTRODUCTION

Video capsule endoscopy (VCE) was introduced in 2001 as a well-tolerated, non-invasive, radiation free, disruptive method to visualize the gastrointestinal (GI) tract, in particular the small bowel. The wireless video capsule consists of one or more cameras with a corresponding lens and light source, batteries, a video chip, and an electronic circuit to either store or transmit the captured images. Depending on the manufacturer, the capsule measures 24-32 mm in length and 11-13 mm in diameter. The capsule is swallowed by the patient and then progresses through the gastrointestinal tract by peristalsis until it is excreted naturally. Only the colon capsule endoscopy needs an additional booster-solution during the procedure. The most commonly used VCE systems transmit the captured images in real-time to an external sensor array and recorder. The transmission technique is based on radiofrequency (Pillcam, Medtronic plc, Dublin, Ireland; EndoCapsule, Olympus Medical Systems Corp., Tokyo, Japan; OMOM capsule, Jinshan Science and Technology Co. Ltd., Chongging, China) or electrical current via Human Body Communication (MiRoCam, IntroMedic Co. Ltd., Seoul, South Korea). Images captured by the CapsoCam capsule (CapsoVision Inc., Saratoga, CA, United States) are stored on-board in an integrated flashdrive, thus obviating the need for an external recorder, but requiring retrieval of the capsule to download the data[1].

Based on these properties of VCE systems and the modality of the procedure, contraindications were established by the manufacturers. Up to today, millions of VCE studies have been performed worldwide. For example, Covidien/Medtronic announced that more than 1.5 million PillCam capsules were used by the end of 2014. With this vast clinical experience, many of the initially pronounced contraindications can now be put into perspective.

This review summarizes the contraindications to VCE provided by the manufacturers and critically analyzes the theoretical reasons, the existing clinical evidence in the literature and technical data, as well as statements and guidelines of national or international societies.

### CONTRAINDICATIONS FOR VCE BASED ON MANUFACTURERS' RECOMMENDATIONS

Listed below (Table 1) are the contraindications and relative contraindications for VCE as stated by the manufacturers. Detailed contraindications are summarized based on the underlying pathophysiology (*i.e.*, radiation enteritis, large small bowel tumor, extensive abdominal surgery, extensive small bowel or colon diverticulosis, GI perforation and fistulas are summarized under GI obstruction/obstacles).

## VCE IN PATIENTS AT RISK FOR GASTROINTESTINAL STENOSIS

Known or suspected obstruction of the gastrointestinal tract bears the risk of capsule retention and consecutive complications. Intestinal obstacles like extensive diverticulosis or fistulas can have a similar effect. Capsule retention is defined by consensus as having a capsule endoscope remaining in the GI tract for a minimum of 14 d or if a directed medical, endoscopic or surgical intervention has to be implemented to retrieve the capsule<sup>[2]</sup>. The consequences of capsule retention can be a total or subtotal obstruction<sup>[3]</sup>, gastrointestinal perforation<sup>[4,5]</sup>, or capsule disintegration<sup>[6]</sup>. As these rare complications may occur late in previously asymptomatic patients, retrieval of a retained capsule should be considered. A case report has documented asymptomatic retention for up to 12 years. This 43-year-old patient underwent procto-colectomy for familial adenomatous polyposis (FAP) in 2000 and capsule endoscopy in a pilot study in 2004. The patient was lost at follow-up. In 2016 an abdominal computed tomography (CT) detected the capsule proximal of an anastomotic stricture. After failed endoscopic retrieval, the capsule was recovered surgically<sup>[7]</sup>. This very rare necessity of surgery for retrieval is the reason that some manufacturers include the inability to undergo surgery as a contraindication for VCE.

In a systematic review of 22840 VCE procedures, the overall retention rate was as low as 1.4% (CI:



Table 1 Contraindications by manufacturer

Product Condition	Medtronic Patency capsule	Medtronic PillCam	Olympus EndoCapsule	IntroMedic Mirocam	Capsovision CapsoCam	Jinshan Science OMOM capsule
Known or suspected GI obstruction/obstacles, Fistulae,		С	С	С	С	RC
relevant (small bowel) diverticulosis						
Motility disorder incl. indigestion or slow gastric emptying			C	C	C	
Cardiac pacemakers or other implanted electromedical devices		C	C	C		RC
Swallowing disorder (dysphagia)	C	C	C	C	C	RC
Pregnancy		RC	C	C	C	RC
Children under the age of (yr)	2	2 (SB3)		2		
		18 (Colon, Eso)				
Strong electromagnetic fields i.e., MRI			C	C	C	
Inability to endure capsule retrieval surgery			C			C
Inability to communicate sufficiently				C		
Concomitant heart disease or epilepsy (due to electromagnetic				C		
radiation)						

PillCam Rapid 8 User Manual (DOC-2051-02) http://www.medtronic.com/content/dam/covidien/library/us/en/product/diagnostic-testing/rapid-v83-user-manual.pdf; Olympus EC 10 System User Manual (DE-8602257); IntroMedic Mirocam User Manual v3.9 (MM1100-U-1511); Capsovision CapsoCam SV1 Manual (Doc. No. 1151, Rev. G, ECO 11-0098; OMOM User's Manual Version 1 (ZSSM-OM00-002). C: Contraindication; GI: Gastrointestinal; MRI: Magnetic resonance imaging; RC: Relative contraindication.

1.2-1.6). Categorized by indication, retention rates in obscure gastro-intestinal bleeding (OGIB) were 1.2% (CI: 0.9-1.6), in Crohn's disease (definite or suspected) 2.6% (CI: 1.6-3.9) and in the neoplastic lesions subgroup 2.1% (CI: 0.7-4.3). Out of 104 reported capsule retentions, 88 were asymptomatic (85%) and 16 had signs of partial or total intestinal obstruction. Of the retained capsules 58.7% were removed surgically, 12.5% endoscopically, or passed either spontaneously or after medical treatment in 15.8%, others were not reported in detail. In 136 cases a cause for retention was reported: Crohn's disease 35.3%, neoplastic lesions 22.1%, NSAID-induced enteropathy 18.4%, postsurgical stenosis 7.4%, ulceration 3.7%, intestinal adhesion 2.9%, tuberculosis or radiation enteritis each 2.2%, ischemia-induced stenosis, Meckel's diverticulum or pouch each 1.5%, peptic ulcer scar with stricture or cryptogenic multifocal ulcerous stenosing enteritis each 0.7%<sup>[8]</sup>. In addition, case reports documented capsule retention in a Zenker's diverticulum<sup>[9]</sup>, a duodenal diverticulum<sup>[10]</sup>, in an ileorectal fistula<sup>[11]</sup>, in a epiphrenic diverticulum<sup>[12]</sup>, and the appendix  $orifice^{[13]}$ .

An analysis of 5428 VCE procedures in Spain came to a similar conclusion. The overall retention rate was 1.9%, and 1.5% in the OGIB subgroup and 3.3% in the inflammatory bowel disease subgroup. Retention rate raised to 5.7%-30% if at least two of these clinical symptoms were present prior to the VCE study: abdominal pain, distension and nausea/vomiting<sup>[14]</sup>.

In patients with suspected GI obstruction a patency test capsule can be administered prior to the actual VCE study. If the capsule is excreted intact within 30 h, GI patency is presumed. After 30 h the lactose body of the patency capsule dissolves, leaving only a slim cellophane coating and a small tag<sup>[15]</sup>. Passage of an intact patency capsule predicts uneventful VCE<sup>[16]</sup>.

Established Crohn's disease is an indication for capsule endoscopy with an increased rate of capsule retention. A Swedish analysis found an odds ratio of 9.39 (95%CI: 3.32-26.54, P < 0.001) for capsule retention in patients with known Crohn's disease compared to bleeding indication<sup>[17]</sup>. Even if current studies could not confirm retention rates of 13% as reported in the era before the advent of the patency capsule<sup>[18]</sup>, a retention rate of 2%-3% seems to be realistic<sup>[19]</sup>. Clinical assessment, MR-enteroclysis and the use of a patency capsule can help to identify highrisk patients.

In a retrospective study 134 patients with known Crohn's disease underwent VCE. Patients with obstructive symptoms, a history of bowel obstruction and NSAID/aspirin medication were previously excluded and 1/3 had prior small bowel follow through. Although no patency capsule test was performed on this selected group of patients, no cases of a capsule retention were observed<sup>[20]</sup>. This is in accordance with a recent retrospective multicenter study including 406 patients with known Crohn's disease. A patency capsule test in every patient with Crohn's disease did not show a reduction in the capsule retention rate compared to a selective use of the patency capsule in high risk patients with clinical signs of obstruction, or prior abdominal surgery[19]. In a prospective study, 57 patients with known Crohn's disease and mild symptoms or in remission, who underwent MRenteroclysis evaluated by two radiologists, had a good sensitivity (92.3% and 100%, respectively) and a negative predictive value (96.3% and 100%, respectively) for retention of the patency capsule as a predictor for functional stenosis test<sup>[21]</sup>.

In 2009 the joint consensus of the Organisation Mondiale d'Endoscopie Digestive and the European Crohn's and Colitis Organization recommended using



imaging techniques before VCE in suspected Crohn's disease<sup>[22]</sup>. However, in 2015 based on broader evidence, the European Society for Gastrointestinal Endoscopy (ESGE) recommended not using cross sectional imaging or patency capsule before VCE in patients with suspected Crohn's disease in the absence of obstructive symptoms. In contrast, in established Crohn's disease, imaging techniques and patency capsule are recommended to precede VCE<sup>[23]</sup>.

Patients with a small bowel (SB) tumor seem to have a slightly higher risk of retention. A suspected tumor as an indication for VCE was associated with an odds ratio of 3.9 (95%CI: 1.2-12.8, P = 0.026)<sup>[17]</sup>. However, clinical symptoms of such tumors are typically bleeding or iron deficiency anemia. As tumors only present in a small subgroup of patients presenting with bleeding/anemia, retention even in this subgroup is rare, mostly asymptomatic, and diagnostic rather than a complication, ESGE recommends against routine precautious tests before VCE in bleeding patients. However, if a tumor is suspected by imaging techniques, device assisted enteroscopy with the option of obtaining histology is preferred over VCE<sup>[23]</sup>.

In sum, suspected or known GI stenosis is a contraindication unless intestinal patency is proven, best by the passage of an intact patency capsule. The risk for capsule retention should be assumed in patients with known Crohn's disease, clinical or radiologic signs of obstruction, a history of abomino-pelvic radiation, and after small bowel resection. Patients undergoing VCE for mid-GI bleeding without the above risks do not require preceding radiology or a patency capsule.

# VCE IN PATIENTS WITH MOTILITY DISORDERS

VCE is not indicated for the diagnosis of GI motility disorders. For this purpose, a specifically designed, non-imaging wireless motility capsule (SmartPill, Medtronic plc, Dublin, Ireland) has been developed. Data from sensors measuring pH, pressure, and temperature are transmitted wirelessly for up to 5 d allowing diagnosis of gastroparesis, and prolonged transit times in the small bowel, colon or combined disorders<sup>[24-27]</sup>.

Nevertheless, standard video capsule was applied in 18 patients with chronic intestinal dysmotility in the search for associated mucosal lesions. Three capsules were retained in the stomach for > 2 h, one of them during the entire recording time. However, no permanent retention, symptoms, or need for interventional treatment occurred [28]. Another study included 36 patients with severe symptomatic intestinal motor disorders for analysis of VCE image patterns compared with controls. No adverse events were mentioned in this report [29].

Although indication of VCE for diagnosis of GI motility disorders has yet to be considered as

experimental, known or yet undiagnosed motility disorders may jeopardize routine VCE performed for other indications. Prolonged esophageal or gastric passage may lead to incomplete visualization of the small bowel, *i.e.*, the cecum is not reached during working capacity of the batteries. Moderate prolongation seems to be compensated by longer battery life span in newer capsule generation<sup>[30]</sup>.

VCE systems using an external recorder have the ability to display transmitted images in real-time during the procedure<sup>[31-33]</sup>. Significantly prolonged gastric transit time can be identified by this real-time viewer and a prokinetic agent can be administered<sup>[34]</sup>. A single center study reported a higher completion rate and diagnostic yield when a real time viewer was used and the capsule was placed endoscopically into the duodenum in the case of prolonged gastric transit time (> 60 min)[35]. The unselected primary endoscopic placement of the capsule into the duodenum to circumvent possible gastroparesis had no effect on complete small bowel visualization in a single center analysis of 687 hospitalized or out-patients compared to swallowing the capsule<sup>[36]</sup>. In a prospective singlecenter study including 100 VCE studies, a pathologic Gastroparesis Cardinal Symptoms Index questionnaire could not predict a prolonged gastric transit time nor did a delayed gastric passage have any clinical significance<sup>[37]</sup>.

GI motility disorders are no contraindication for VCE. The routine use of a real time viewer directly after swallowing the capsule and after an hour enables detection of aspiration (see below) and esophageal or gastric retention and consecutive intervention.

# VCE IN PATIENTS WITH IMPLANTABLE CARDIAC DEVICES

The radio transmitters of the first capsule endoscopes work with a carrier frequency of 434.1 MHz in PillCam and 433.8 MHz in EndoCapsule, similar to the C-Net mobile cellular system (450 MHz). The frequency in the newly available OMOM Capsule is 2.4 GHz. Two studies revealed electromagnetic interference (EMI) between cardiac pacemakers (PM) and the C-Net mobile cellular system in 22.4%-30.7% of the tested pacemakers<sup>[38,39]</sup>. However, the radiated power of C-Net mobile phones with 2 W is several factors higher than that of VCE with max. 100 nW. EMI with implantable cardiac devices at 2.4 GHz was also investigated in two studies<sup>[40,41]</sup> showing no risk of interference. Nevertheless, users of VCE estimated EMI between capsules and cardiac devices possibly being lifethreatening for patients. Since the introduction of VCE, several in vitro and in vivo studies analyzed EMI between VCE (PillCam and EndoCapsule) and PMs (in vitro: [42-44]; in vivo: [44-54]), implantable cardioverter defibrillators (ICD) (in vitro:[55,56]; in vivo:[45-48,54,56-59]) and left ventricular assist devices (LVAD) (in vitro:

none, in vivo:[52,60-68]).

In order to simulate electrical interactions under physiological conditions in patients, the authors of in vitro studies positioned PMs<sup>[43,44]</sup> or ICDs in a saline solution with a resistivity corresponding to that of muscle tissue. No interference with any of the PMs was observed. In Dubner's study in one ICD (Belos DR, Biotronik), interference occurred reproducible when placing a test cap (technical data corresponding to first generation PillCam SB1 video capsule) over the ring and the shock coil electrode, but not over the pulse generator itself. This could still be verified even at 30 cm distance from the ICD system<sup>[56]</sup>. However, the reason for EMI remained unclear, and in vivo validation was missing. This observation is in contrast to our results. We tested five Belos ICDs and found no interference by the capsules at all, even though the devices were investigated in the most sensitive setting<sup>[54]</sup>. Furthermore, there are several in vivo studies investigating interference between VCE and PMs and ICDs. Interrogation of the devices (in all or some patients) either before and/or after VCE was performed in some studies (PM:[44,46-48,52-54]; ICD:[48,52,54,57-59]) whereas (all or some) patients in other studies were monitored with ECG monitor, telemetry or clinically (PM:[44-54] ICD:[44-49,52,54,57-59]). No interference with any of the PMs or ICDs in in vivo studies was observed. Relevant interference of wireless telemetry has been observed. In some cases, VCE videos had been corrupted<sup>[46,47,51]</sup>. If cardiac monitoring is necessary during VCE, wired systems should be used.

With regard to different capsule types, PillCam SB1, SB2, PillCam Colon1, and Olympus EndoCapsule have been studied. For the new PillCam SB3 and PillCam Colon2 with additional remote signals from the DR3 recorder to the capsule in order to adapt frame rates<sup>[69]</sup>, studies are still warranted.

Only one study investigated EMI between the MiroCam endoscope that uses human body communication to transmit data and PMs (n=3) and ICDs (n=3)<sup>[70]</sup>. VCE was safely performed in patients with PMs and ICDs, and images from capsule endoscopy were not affected by cardiac devices. Studies relating to EMI between OMOM-Capsule and cardiac devices are lacking. For CapsoCam with on board storage of images without transmission, interference with cardiac devices is not possible.

EMI between VCE and LVAD was investigated in 10 in-vivo studies<sup>[52,60-68]</sup>. No interference was observed in any of the studies.

The United States Food and Drug Administration (FDA) and the manufacturers of transmitting capsules (Medtronic GI solutions, Olympus, IntroMedic, and Jinshan) recommend not using VCE in patients with cardiac devices. For CapsoCam without transmission technology there is no such formal contraindication.

Guidelines of the ESGE state that VCE is not contraindicated in patients with PM or ICD<sup>[71]</sup>, whereas

the American Society of Gastrointestinal Endoscopy guidelines consider cardiac devices as a relative contraindication for VCE<sup>[72]</sup>. The German Society of Gastroenterology, Digestive and Metabolic diseases recommends not withholding VCE in patients with a proper indication regardless of implanted cardiac devices<sup>[73]</sup>.

In accordance with the recommendations of the Biotronik and Medtronic Cardio vascular group, VCE can be used in patients with cardiac devices [74,75], whereas statements from other manufacturers are not available. Technical data (maximum effective radiated power or output current and transmitter frequency) of VCE (Medtronic, Olympus, Jinshan, IntroMedic) and of the remote transmitting PillCam recorder DR3 were made available to two of the authors (Bandorski D, Stunder D). Based on this data, the maximum electromagnetic radiation in close proximity (5 mm) was calculated for VCE of Medtronic, Olympus, Jinshan as well as for Medtronic recorder DR3. Likewise, for VCE of IntroMedic the maximum obtainable interference voltage at the input of cardiac devices due to the human body communication was evaluated. The determined values are below the safety objectives set by the international product standard for cardiac devices (ISO 14117)[76] by a factor of 8 to 85.

In conclusion, VCE is safe in patients with PMs/ICDs based on technical data and *in vitro/in vivo* studies. The automatic frame rate control by transmitting a reverse signal from the recorder (DR3) to the capsule also remains without interference. Technical data of manual remote switching between different image acquisition rates in OMOM capsules are lacking. Wireless telemetry can impair recording of VCE images. Regarding patients with LVAD VCE seems to be safe according to *in vivo* results.

## VCE IN PATIENTS WITH SWALLOWING DISORDERS

Capsule aspiration is a rare complication of VCE with a presumed incidence of 1 in 600-700<sup>[77,78]</sup>. Oral ingestion of the capsule is therefore contraindicated in patients with known swallowing disorder. Yet it is difficult to predict the patient's ability to swallow the capsule safely. Aspiration was reported even if a patency capsule had been administered successfully prior to the procedure<sup>[79]</sup> or a barium swallow was uneventful<sup>[78]</sup>. In a series of 15 well-documented cases of capsule aspiration, only three patients had a history of dysphagia. The leading symptom during the aspiration was coughing (12/15)<sup>[80]</sup>, which can stop even if the capsule is still within the trachea<sup>[81]</sup>. The aspiration resolved spontaneously by coughing (9/15) or *via* endoscopic retrieval (6/15)<sup>[80]</sup>.

In one case, asymptomatic retention of a capsule for 6 d within in a bronchus and consecutive spontaneous passage through the GI tract was reported<sup>[82]</sup>. However,



one patient with capsule aspiration experienced fatal extensive intracerebral hemorrhage, either provoked by initial coughing or during consecutive endoscopy for retrieval<sup>[83]</sup>.

In case of an increased risk of aspiration, the capsule should be placed endoscopically directly into the duodenum<sup>[73]</sup>. This can be achieved *via* an overtube<sup>[84]</sup> or a special endoscopic delivery device (AdvanCE, US Endoscopy, Mentor, OH, United States)<sup>[85]</sup>. Endoscopic placement with a Roth net is another alternative, but is more frequently associated with mucosal trauma in children than application with the dedicated delivery device<sup>[86]</sup>.

In conclusion, swallowing disorders with the inability to safely swallow the capsule are a contraindication for standard procedure. However, if endoscopic placement is applied, VCE can be safely performed. The clinical challenge is the identification of patients at risk. Older patients, a history of cerebral stroke, bleeding or trauma, require a thorough history, and test for swallowing function. Children may have a test with swallowing a marshmallow.

#### VCE IN PREGNANCY

During pregnancy the growing uterus compresses the GI tract. Additionally, gastrointestinal transit is prolonged in the second and third trimester<sup>[87]</sup>, which theoretically may jeopardize VCE procedure. There are only two published cases of VCE studies about pregnant women. Both reported no adverse events including no retention. The first case was a 30-yearold woman with extensive GI bleeding. A conventional upper endoscopy was uneventful. Lower endoscopy showed fresh blood coming out of the ileocecal valve. VCE revealed an ulcerated jejunal neuroendocrine tumor. Emergency surgery was successful and mother and child were alive and well<sup>[88]</sup>. The second case was a 20-year-old woman with a history of cavernous transformation of the portal vein with secondary thrombosis after omphalitis at the age of two. Esophageal varices were treated with sclerotherapy and banding at age 13 and 15. Due to the high risk of upper GI bleeding during pregnancy, the esophagus was examined through the PillCam ESO capsule. No esophageal or gastric varices were detected. The VCE study was uneventful with mother and child alive and well<sup>[89]</sup>. The theoretical short-term risk of retention due to altered GI motility in advanced pregnancy was not observed in either of these two cases.

However, there is no data on whether the electromagnetic field of the capsule-recorder-system could harm the unborn child. For comparison, mobile phones seem to have no negative effect<sup>[90]</sup>. In contrast, pregnancies of mothers reporting microwave use 6 mo prior to the pregnancy or during the first trimester were more likely to result in miscarriage (OR = 1.28, 95%CI: 1.02-1.59). The odds ratio was raised with an increasing level of exposure with an odds ratio of 1.59

for the highest exposure group (20 or more exposures/month)<sup>[91]</sup>. Although microwaves have a higher frequency - from 300 to 3000 MHz - than radio waves, the radio waves used by endoscopic capsules (*e.g.*, 434 MHz for PillCam and EndoCapsule) are within the lower range of microwaves. Another comparator are effects caused by mobile phones with a much higher power than video capsules but not reaching proximity to the unborn as an intra-abdominal source of radio waves. This risk is not relevant for CapsoCam without electro-magnetic emission.

In conclusion, elective capsule endoscopy should be postponed after delivery due to missing data. Nevertheless, VCE may be considered in indications related to maternal symptoms not allowing delay of diagnosis as in relevant small bowel bleeding. Accordingly, the FDA assesses pregnancy only as a relative contraindication to VCE<sup>[92]</sup>.

#### **VCE IN CHILDREN**

There has been an increased use of VCE in the pediatric population due to the possibility of avoiding ionizing radiation, deep sedation and general anesthesia $^{[93]}$ . The main issue of VCE in children seems to be the ability to voluntarily swallow the capsule and the fear of the capsule not being able to pass the narrow GI tract $^{[94]}$ .

Since it was introduced, the minimum age of VCE has been lowered by the manufacturers and the FDA. In 2009 the FDA approved VCE for children of 2 years or older. The youngest age of a child undergoing a VCE study was 8 mo<sup>[95]</sup>, and the lowest weight was 7.9 kg<sup>[96]</sup>. Voluntary ingestion seems feasible at an age older than 6-8 years<sup>[94]</sup>, and has already been reported in a child of 4 years<sup>[86]</sup>. However, the manufacturer of PillCam recommends not letting children under the age of 8 years swallow the capsule. If endoscopic delivery is necessary, the AdvanCE delivery device was superior to the Roth-net, which caused significant mucosal trauma in 50% in a multicenter trial<sup>[86]</sup>.

There have been no reports of a capsule aspiration, perforation or complete small bowel obstruction in the studies and meta-analyses of more than 1000 VCE studies with children [86,93,95-98]. In the largest metaanalysis, the retention rate was 2.3%. The risk for retention was higher in known inflammatory bowel disease (IBD 5.2%), a small bowel follow through suggestive of Crohn's disease (CD 35.7%), and the combination of a body-mass-index below the 5th percentile and known IBD (43%). Retention rates by indication were 1.2% for OGIB, 2.6% for CD, and 2.1% for neoplastic lesions<sup>[93]</sup>. In patients with an increased risk of small bowel obstruction, a patency capsule test may reduce the risk of retention[97,98]. Guidelines of the Spanish Societies for Pediatric Gastroenterology, Hepatology, and Nutrition (SEGHNP) and for Digestive Diseases (SEPD) recommend that in suspected or established Crohn's disease, magnetic resonance

enterography or patency capsule should precede VCE in cases of obstruction symptoms<sup>[94]</sup>.

# MAGNETIC RESONANCE IMAGING IN PATIENTS WITH INCORPORATED CAPSULE

As no testing on magnetic resonance (MR) compatibility of VCEs has been conducted, the FDA requested a warning that a patient should not undergo magnetic resonance imaging (MRI) until excretion of the capsule has been verified<sup>[99]</sup>. The feared theoretical complication of performing an MRI scan while a capsule is still within the GI tract is migration of the capsule and the potential for bowel injury or perforation due to heat or high forces<sup>[100]</sup>. There are only few reported cases of MRI scans in patients with retained video capsules. In one case, an emergency MRI of the lumbar spine was ordered due to acute lumbar radiculopathy. The localizing sequence showed a focal susceptibility and the MRI was terminated, the capsule was excreted two days later<sup>[100]</sup>. In another case, an MRI was performed in a patient with a recurring Crohn's disease. The MRI revealed a capsule that had been retained for two years due to a stenosis. The capsule was retrieved endoscopically with prior dilatation of the stenosis<sup>[101]</sup>. The third case was also a patient with symptoms of recurring Crohn's disease. An MRI was performed shortly after VCE with the capsule still lying in the colon[102]. None of the three cases reported adverse events. Due to the interference of the MRI scan, VCE had no diagnostic value. Unpublished personal experience with three other patients incidentally undergoing abdominal MRI with an incorporated VCE confirms these initial reports.

# COLON CAPSULE ENDOSCOPY IN PATIENTS WITH CONTRAINDICATION FOR SODIUM PHOSPHATE

The standard colon preparation prior to a colon capsule endoscopy consists of a PEG solution. In addition, sodium phosphate is used as the standard booster solution during the procedure to ensure that the capsule passes through the entire colon within the lifespan of the capsule's battery. The ESGE guidelines for colon capsule endoscopy recommend the use of sodium phosphate as a booster for all patients with no contraindication<sup>[103]</sup>. However, sodium phosphate can cause severe complications like phosphate nephropathy, acute renal failure, hypertension, or mineral imbalance.

In the search for an alternate procedure, a pilot study showed feasibility of a low volume cleansing procedure for colon capsule endoscopy using PEG with ascorbic acid for bowel cleansing and as a boost after swallowing the capsule. CCE could be completed in 37/49 patients (76%)<sup>[104]</sup>. Another pilot trial from Japan, where sodium phosphate is contraindicated in hypertensive patients older than 63 years, proposed a diluted Gastrografin solution as an alternative booster based on a capsule excretion rate during recording of 97% (28/29 patients)<sup>[105]</sup>.

#### CONCLUSION

Non-invasive VCE is safe, and formal contraindications can be put into perspective when observing some precautions. Based on uneventful clinical application in children, the minimum age has been lowered to 2 years. There is positive in vitro and in vivo evidence that cardiac pacemakers and defibrillators are no contraindication to VCE. Due to missing data, VCE in pregnancy should only be performed in very limited indications in cases where a delay of diagnosis until after delivery may put the mother or the unborn at risk. MRI with retained video capsule should be avoided, although the first reports describe only artifacts prohibiting proper image analysis but no harm to the patient. Suspected, known, or likely GI stenosis is a contraindication to VCE unless patency has been proven, or surgery is scheduled and preceding VCE might provide additional relevant information.

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9905

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