Impact of reimbursement policy in Belgium on the referral pattern and diagnostic yield of capsule endoscopy. A single-centre study

S. De Rouck[1], P. Hindryckx[2], M. De Vos[2], D. De Looze[2]

(1) Department of Internal Medicine and (2) Department of Gastroenterology, Ghent University Hospital, Ghent, Belgium.

Abstract

Introduction : **Since the first of July 2008, capsule endoscopy (CE) is partially reimbursed for patients with obscure gastrointestinal bleeding (OGIB).**

Objective : **To evaluate the impact of reimbursement of CE on the referral pattern and the diagnostic yield of CE.**

Methods : **We retrospectively selected data from patients who underwent a CE in the University Hospital of Ghent between July 2002 and June 2009. Following data were analysed : number of CEs, indication, number of transfusion-dependent patients, haemoglobin level and relevance of the CE findings.**

Results : **There was an increase in the number of patients referred for CE after the first of July 2008. Simultaneously, the number of relevant findings was decreasing. Between July 2002 and June 2003, 66.7% of the capsule endoscopies showed relevant bowel lesions. Over the last 2 years, the diagnostic yield has been decreasing to 40.5% in the period July 2007-June 2008 and only 30.2% in the period July 2008-June 2009. Transfusion need and haemoglobin level at the moment of CE had a significant influence on the diagnostic yield (P<0.001 for both parameters).**

Conclusions : **The number of patients referred for CE has risen since the reimbursement of CE. However, there is a trend towards referral of less severe bleeders, with less transfusion need and a higher haemoglobin level. This significantly lowers the diagnostic yield of CE.** (Acta gastroenterol. belg., **2010**, 73, **437-440**).

Key words : capsule endoscopy, obscure bleeding, reimbursement, diagnostic yield.

Introduction

Capsule endoscopy (CE) is a relatively new method for direct visualisation of the small bowel. The most important indication for CE is obscure gastrointestinal bleeding (OGIB) (1,2). OGIB, which is defined as suspected digestive bleeding that persists or recurs after negative routine endoscopic examination of the upper and lower GI tract, can be divided into overt GI bleeding (melena, hematochezia or hematemesis) and occult GI bleeding (iron-deficiency anemia with or without a positive fecal occult blood test) (3,4). OGIB is a common problem encountered by gastroenterologists, and accounts for approximately 5% of all GI bleeding complications (4,5).

Several studies showed that CE is highly effective in detecting small-bowel lesions in patients with OGIB. With a diagnostic yield of 45-67%, CE is superior to push enteroscopy, small bowel series, CT enteroclysis, mesenteric angiography, small bowel MRI and nuclear studies (5-8). As a consequence, current guidelines propose CE as the first-line examination in OGIB (2). Only since the first of July 2008, partial reimbursement of CE has also been implemented by the Belgian authorities for patients with suspected OGIB and a documented iron deficiency anemia, unexplained by conventional upper and lower GI endoscopy. We questioned whether the introduction of reimbursement had an impact on the referral pattern of physicians and the diagnostic yield of CE.

Methods

Patients

We retrospectively selected data from all patients with OGIB who underwent a CE in the University Hospital of Ghent (Belgium) between July 2002 and June 2009. The patients were referred by gastroenterologists after endoscopic work-up with at least 1 upper-GI endoscopy and at least 1 ileocolonoscopy. The referring physicians had to complete a datasheet detailing the indication for CE, the lowest haemoglobin (Hb) level, transfusion requirements and results of previous investigations. This study was approved by the Ethical Committee.

Equipment

The Pill Cam videocapsule (Given Imaging, Yoqneam, Israel) was used in all patients. This wireless capsule endoscope acquires high quality images from the GI tract. Sensor arrays, fixed by tape on the patient's abdomen, transmit the images to a data recorder, carried by the patient on a belt. After eight hours, the data recorder is connected to the computer workstation. The data are downloaded, processed and finally viewed on a monitor (9).

Procedure

The patients were requested to clean the bowel with 2 litters polyethylene glycol in the evening before capsule ingestion and to remain fasted from midnight onwards.

Correspondence to : Prof. Dr. Danny De Looze, Department of Gastroenterology, De Pintelaan 185, 1K12-IE, 9000 Ghent, Belgium.
E-mail : Pieter.Hindryckx@UGent.be

Submission date : 28/02/2010
Acceptance date : 26/08/2010

Between 8:30 AM and 10:00 AM the capsule was swallowed with a glass of water. Patients were allowed to eat 4 hours after ingestion. After eight hours, the sensor arrays and the data recorder were removed. The capsule is expulsed naturally.

One gastroenterologist (D.D.L.) with extensive enteroscopy experience interpreted all the capsule videos.

The viewing method was identical before and after reimbursement of CE, except for regular software upgrades. Findings were considered relevant if an active bleeding or significant lesions that could explain the bleeding were present.

Data analysis

For analysis, the data were divided into 7 periods of 1 year. A more detailed sub-analysis was performed on 2 periods : July 2007 till June 2008 and July 2008 till June 2009, the latter being the year after change in reimbursement policy. Following data were analysed : number of CEs, indication, number of transfusion-dependent patients, Hb level and relevance of the findings.

Statistics

The data were analysed by using SPSS version 15.0 for windows (SPSS Inc, Chicago). Continuous variables were expressed by mean, and were compared by using the Mann-Whitney-U test. Statistical analysis of categorical values was conducted by using the χ^2 test. Significance was accepted at a value of $P < 0.05$.

Results

Number of capsule endoscopies

In total, 236 CEs were performed between July 2002 and June 2009. As shown in Figure 1, the first two years, the number of CEs increased steadily. Between July 2004 and June 2008, the number of CEs stabilized, with the exception of the period between July 2006 and June 2007, in which we saw a notable decrease. The year after the introduction of reimbursement of CE, there were 63 CEs performed, whereas in the year before merely 37 CEs were performed.

Patients

A total of 236 patients referred for OGIB were included in this study. Looking at the entire cohort, 125 patients were referred for occult GI bleeding and 111 for overt GI bleeding (Table 1).

Data regarding patient demographics (age and gender) and clinical parameters of bleeding history (transfusion need and Hb level) are found in Table 1. No differences in age and gender were noted in any analysed group. Analysis of the transfusion requirements did show some differences in patient selection. The first year all patients required transfusion of packed red cells. Also the following years, the percentage of patients who needed transfusion remained more than 80%. The last two years, there is a trend toward less transfusion need. In the period July 2007 - June 2008 the percentage of transfusion need is 72.2% and in the period July 2008 - June 2009, the year after the introduction of the reimbursement, this percentage is only 60.7% ($p = 0.249$). After the introduction of reimbursement of CE, we also notice a significant increase in the mean Hb value before CE. In the period July 2007 - June 2008, the mean Hb value was 7.63 g/dL, whereas between July 2008-June 2009, the mean Hb value was 8.50 g/dL ($p = 0.038$).

Findings

A significant lesion in the small bowel was detected in 113 of the 236 patients (47.9%) who underwent a CE for OGIB between July 2002 and June 2009. In the first year, there was a relevant finding in 66.7% of the capsule endoscopies. Between July 2006 and June 2007 this percentage was still 64.7%. As shown in Figure 2, we see this percentage is decreasing over the last 2 years, with a

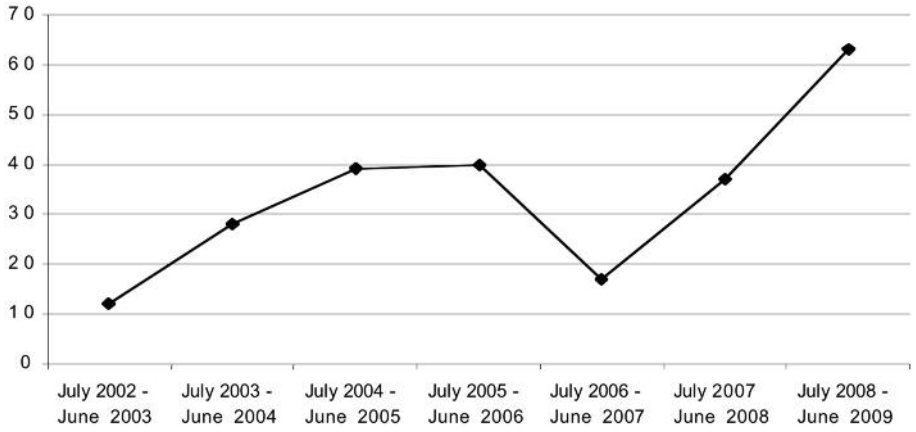

Fig. 1. — Number of capsule endoscopies

Table 1. — **Patient demographics and clinical parameters of bleeding**

	No. patients	M/F	Mean age (range) (y)	Transfusion need (yes) %*	Mean lowest Hb value (range) (g/dL)**	Indication (overt/occult)
July 2002 – June 2003	12	4/8	66.5 (19-85)	100	7.67 (6.6-9.0)	5/7
July 2003 – July 2004	28	13/15	63.5 (27-87)	82.1	7.78 (4.4-12.5)	15/13
July 2004 – June 2005	39	17/22	66.6 (28-86)	84.6	8.11 (4.4-12.1)	25/14
July 2005 – June 2006	40	11/29	61.7 (34-86)	84.2	7.97 (4.0-12.9)	17/23
July 2006 – June 2007	17	10/7	65.0 (41-84)	75.0	8.46 (5.8-12.6)	7/10
July 2007 – June 2008	37	14/23	62.2 (36-92)	72.2	7.63 (4.3-11.3)	21/16
July 2008 – June 2009	63	27/36	59.3 (16-84)	60.7	8.50 (2.8-13.1)	35/28
Total	236	96/140	62.6 (16-92)	75.9	8.08 (2.8-13.1)	125/111

(* 7 missing values, ** 22 missing values).

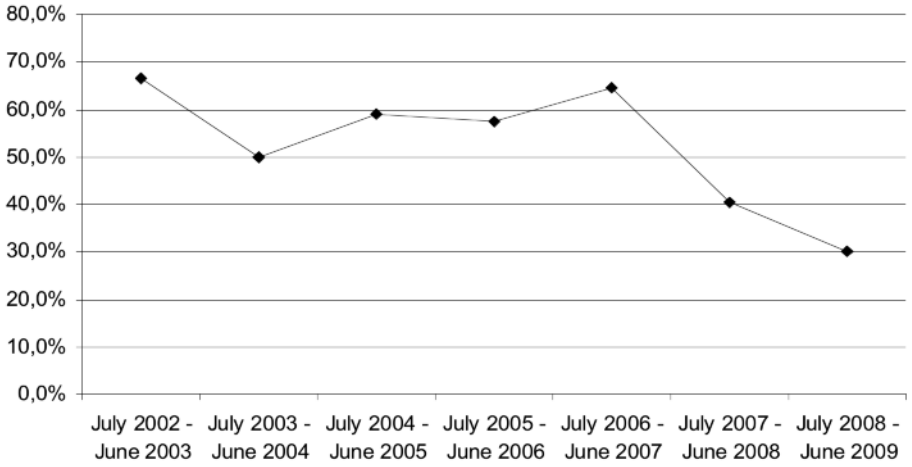

Fig. 2. — Relevant CE findings

percentage of 40.5% in the period July 2007-June 2008 and only 30.2% in the period July 2008-June 2009. Although there clearly is a trend towards less relevant CE findings since the introduction of reimbursement, the difference in diagnostic yield between the year before and after this reimbursement was not significant ($p = 0.290$).

The type of lesions reported on CE is reported in Table 2. In 43 patients (38.1%), an active bleeding was detected. Small bowel angiodysplasia was the most common lesion detected on CE, comprising 35.4% of all relevant findings. The second most common finding was small bowel erosion or ulceration, which was seen in 30 of the 113 patients with a positive capsule result (26.5%). A tumour was found in 11 of these 113 patients (9.7%). Other relevant findings were venous ectasias, varices, inflammatory polyps or abnormal mucosal pattern.

Analysis of factors possibly affecting the yield of CE in patients with OGIB revealed that transfusion need and a low Hb level before CE were associated with an increased yield on CE. A markedly higher diagnostic yield (53.8%) was found in patients with transfusion requirements, compared with 25.5% in the patients without transfusion requirements ($p < 0.001$). The mean Hb value in the patients with relevant findings was 7.62 g/dL and 8.51 g/dL in the patients without relevant findings. Once more, this difference is significant ($p < 0.001$). There was no significant difference in diagnostic yield between the patients with overt bleeding and those with occult bleeding (51.4% vs. 44.8%, $p = 0.315$).

Table 2. — **Most common findings on capsule endoscopy in 236 patients with obscure GI bleeding**

Total number of relevant findings	113
Active bleeding	43 (38.1%)
Angiodysplasia	40 (35.4%)
Erosions / ulcerations	30 (26.5%)
Tumour	11 (9.7%)

Discussion

In this study, we evaluated the impact of the partial reimbursement of CE in Belgium on the referral pattern and the diagnostic yield of CE.

There is a biphasic increase in the number of patients referred for OGIB since the introduction of the CE for clinical use. The first years after the introduction of CE,

there was an increase in the number of patients referred for CE. This is explained by the increasing knowledge and the increasing number of publications about CE. In the following years, the number of patients referred for CE was relatively stable. Only after the first of July 2008, we observed a second increase in the number of CEs. This phenomenon could be explained by the new reimbursement policy in Belgium since that date.

Simultaneously with an increasing number of investigations, the number of relevant findings on CE decreased, with a historically low diagnostic yield since implementation of partial reimbursement. As no fundamental changes were made in the capsule viewing procedure after reimbursement, we hypothesized that a different patient selection explained this drop in diagnostic yield.

Since the first of July 2008, we saw a trend towards less transfusion dependent patients and patients with a significantly higher Hb value before CE. Analysis of these parameters in all patients, showed that the diagnostic yield was significantly lower in patients without transfusion requirements and that the group of patients without relevant findings on CE had a significantly higher mean Hb value before CE. Hence it appears that transfusion need and Hb level have a significant impact on the diagnostic yield. These results confirm earlier literature data. May *et al*. stated that patient selection plays a significant role in the high diagnostic yield of CE, and therefore transfusion requirements and Hb value must be regarded as two decisive parameters (10).

No significant difference was found in the diagnostic yield between the obscure-overt and the obscure-occult bleeders. According to Pennazio *et al*., the time span between overt bleeding episodes and performing a CE does have a significant influence on the diagnostic yield (4). In their study, the diagnostic yield of CE in patients with an ongoing overt bleeding was significantly higher than the diagnostic yield in patients with previous obscure-overt bleeding. Unfortunately, we did not collect data concerning these time spans.

We did not collect data concerning the duration of the OGIB. May *et al*. on the other hand did include this parameter in their study (10). Although the duration of OGIB did not show to be a significant parameter, analysis of the data showed that it was usually only in patients with a OGIB period of six months and more that a positive capsule result was obtained. When the period was shorter, positive capsule results were only seen when there were high transfusion requirements.

As a result of the observed trend toward less transfusion-dependent patients and patients with a higher Hb level before CE, we hypothesize that gastroenterologists nowadays refer their patients with OGIB sooner, thereby adding a group of less severe and spontaneously resolving obscure bleeders, a phenomenon described by Hindryckx *et al*. (11).

In summary, we conclude that, despite the fact that the current referral pattern is consistent with existing guidelines and Belgian reimbursement conditions, an increase in the number of CE's is accompanied by a lower number of relevant findings. This is due to earlier patient referral with less severe bleeding, defined as lower transfusion need and less haemoglobin fall.

References

1. GUPTA A., REDDY D.N. Capsule endoscopy : current status in obscure gastrointestinal bleeding. *World J. Gastroenterol*., 2007, **13** : 4551-4553.
2. MOREELS T.G. History of endoscopic devices for the exploration of the small bowel. *Acta Gastroenterol. Belg*., 2009, **72** : 335-7.
3. American Gastroenterological Association (AGA) Institute technical review on obscure gastrointestinal bleeding. *Gastroenterology*, 2007, **133** : 1697-1717.
4. PENNAZIO M., SANTUCCI R., RONDONOTTI E., ABBIATI C., BECCARI G., ROSSINI F.P., DE FRANCHIS R. Outcome of patients with obscure gastrointestinal bleeding after capsule endoscopy : Report of 100 consecutive cases. *Gastroenterology*, 2004, **126** : 643-53.
5. CAREY E.J., LEIGHTON J.A., HEIGH R.I., SHIFF A.D., SHARMA V.K., POST J.K., FLEISCHER D.E. A single-center experience of 260 consecutive patients undergoing capsule endoscopy for obscure gastrointestinal bleeding. *Am. J. Gastroenterol*., 2007, **102** : 89-95.
6. ELL C., REMKE S., MAY A., HELOU L., HENRICH R., MAYER G. The first prospective controlled trial comparing wireless capsule endoscopy with push enteroscopy in chronic gastrointestinal bleeding. *Endoscopy*, 2002, **34** : 685-689.
7. ELIAKIM R. Wireless capsule video endoscopy : three years of experience. *World J. Gastroenterol*., 2004, **10** : 1238-1239.
8. TRIESTER S.L., LEIGHTON J.A., LEONTIADIS G.I., GURUDU S.R., FLEISCHER D.E., HARA A.K., HEIGH R.I., SHIFF A.D., SHARMA V.K. A meta-analysis of the yield of capsule endoscopy compared to other diagnostic modalities in patients with obscure gastrointestinal bleeding. *Am. J. Gastroenterol*., 2005, **100** : 2407-2418.
9. DELVAUX M., GAY G. Capsule endoscopy in 2005 : facts and perspectives. *Best Pract. Res. Clin. Gastroenterol*., 2006, **1** : 23-39.
10. MAY A., WARDAK A., NACHBAR L., REMKE S., ELL C. Influence of patient selection on the outcome of capsule endoscopy in patients with chronic gastrointestinal bleeding. *J. Clin. Gastroenterol*., 2005, **39** : 684-688.
11. HINDRYCKX P., BOTELBERGE T., DE VOS M., DE LOOZE D. Clinical impact of capsule endoscopy on further strategy and long-term clinical outcome in patients with obscure bleeding. *Gastrointest. Endosc*., 2008, **68** : 98-104.