Int J Clin Exp Med 2015;8(8):13482-13490
www.ijcem.com /ISSN:1940-5901/IJCEM0011735

*Original Article*

# The clinical characteristic and risk of capsule incomplete and retention in Crohn's disease

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Received June 21, 2015; Accepted August 6, 2015; Epub August 15, 2015; Published August 30, 2015

**Abstract:** Objective: To evaluate capsule endoscopy in terms of incomplete examinations and capsule retentions, to describe the characteristic of these events and to find risk factors for these events. Methods: This retrospective and consecutive case-control study includes data of 204 capsule enteroscopy examinations in patients with Crohn's Disease, performed at the first hospital affiliated to zhejiang university medical school from June 2003 to April 2014. Results: The frequency of complete examinations was 56.9%. Male gender (OR=2.48, P=0.026), abdominal pain (OR=2.88, P=0.002), melena/bloody stools/OB+ (OR=3.34, P=0.009) were risk factors for an incomplete examination. Capsule retention occurred in 8.33% (n=17). The ratio of male and female was 12:5. While the average age of these patients was 42.2±16.2, and the average course of disease was 52.5±46.6 months. Of the seventeen cases of retained capsules, four patients chose to undergo surgery to remove the capsule for occurring symptoms of intestinal obstruction, spontaneous passage occurred in twelve patients after medical treatment, and one patient still have the capsule retained after 16 months of expectation. The longest capsule retained time in patients was four years. Risk factors for capsule retention was abdominal distention (OR=8.45, P=0.006). Conclusions: The majority of capsule endoscopy retention develops into spontaneous passage after medical treatment. Therefore capsule endoscopy is considered a safe procedure, although obstructive symptoms and serious complications due to capsule retention can be found in patients with known Crohn's disease.

**Keywords:** Crohn's disease, capsule endoscopy, retention, risk factors

## Introduction

Crohn's disease (CD) is a chronic idiopathic inflammatory disease, mainly affecting the gastrointestinal tract, from the month cavity to anus. However, isolated involvement of the proximal small intestine can occur in as many as one third of cases [1]. Currently, no matter in western countries or in Asia, the incidence and prevalence of CD are both increasing. In Western countries, the incidence rates for CD ranges from 14.6 to 17.4 per 100,000 person-years and the prevalence is from 155.2 to 279.2 per 100,000 people. A rising incidence and prevalence of CD also has been reported in Asia. For example, In Taiwan, The prevalence of CD increased from 0.19 per 100,000 people in 1998 to 1.78 per 100,000 people in 2008. [2].

Capsule endoscopy, offering enhanced direct visualization of the small-bowel mucosa in a relatively noninvasive manner, was quickly applied to the diagnosis and evaluation of the small intestinal diseases, especially in obscure gastrointestinal tract bleeding (OGIB), Crohn's disease, neoplastic lesions and so on. Some research have showed that capsule endoscopy has great advantage in finding lesions in small intestine, comparing with other imaging examination [3-7]. As what has mentioned above, as many as one third of cases isolated involved of the proximal small intestine, then capsule endoscopy is more and more frequently used in Crohn's disease.

Capsule retention is the feared major complication of capsule endoscopy [11], mostly because of small intestinal stricture. So it is necessary to complete the evaluation of small intestine by imaging examinations to exclude the situation of small intestinal stricture. 25% of CD patients have had at least one small bowel stricture [8].

Therefore patients with CD are at increased risk of capsule retention. Capsule retention rates as high as 13% have been reported in patients with known CD [9]. Then the safety of capsule endoscopy in CD is not sure.

In this retrospective and consecutive case-control study, we mainly study to evaluate capsule endoscopy in terms of incomplete examinations and capsule retentions, to describe the characteristic of these events and to find risk factors for these events.

## Material and methods

### *Patients*

This study comprised 204 capsule enteroscopy examinations in patients with Crohn's Disease (146 men, 58 women, mean age 34.1±15.3 y, range: 9 to 79 y, mean course 29.5±43.6 m), performed at the first hospital affiliated to zhejiang university medical school from June 2003 to April 2014. The diagnosis of CD remains a clinical one and is based on the combination of clinical, radiologic, endoscopic, and histologic findings, which based on the guideline of inflammatory bowel disease (IBD) in China 2012 [10].

### *Given patency system, bowel preparation and the examination*

The Given Patency System consists of a PillCam capsule, Given data recorder and the Reporting and Processing of Images and Data (RAPID) workstation. The size of the capsule is 11.0 mm × 26 mm, which is single camera, can see 156°.

All the subjects were fed a semi-liquid diet for 24 hours (h) and received complete colonic irrigation 12 h prior to the examination. They were deprived of water for 4 h and then given a defoamer orally 30 minutes (min) prior to the examination. Then, they were allowed to consume light beverages from 4 h after the capsule ingestion. During the examination, subjects were allowed to move freely, but were requested to avoid exposure to any strong electromagnetic field. Digital video image streams of the examination were downloaded to the Reporting and Processing of Images and Data (RAPID) workstation for graphic analysis.

### *Capsule retention and capsule incomplete*

Capsule retention was defined as a capsule endoscope remaining in the digestive tract for a minimum of 2 weeks or one that required directed intervention or therapy to aid its passage [11]. The incomplete CE examination means that there was failure of the capsule to reach the caecum during the recording time.

### *Statistical analysis*

We mass survey and follow up the patients with Crohn's disease. Statistical analysis was carried out with SPSS 18.0 (SPSS, USA) software. Categorical variables were analyzed with $\chi^2$ test, Fisher's exact test was applied to the values predicted ≤5. Continuous variables with normal distribution and homogeneity was analyzed with T test, while the others were analyzed with Wilcoxon rank sum test. We used logistic regression analysis for multi-factor regression analysis. P≤0.5 was considered as statistical significant.

## Results

### *Basic information for incomplete examinations*

A total of 88 (43.1%) patients were incomplete, meaning that there was failure of the capsule to reach the caeum during the recording time. The completion rate of capsule endoscopy examination was 56.9%. In the incomplete patients, mean age was 38.6±14.5 y (range 11 to 69 y), mean course was 35.8±43.7 m. Clinical manifestation of these patients were abdominal pain (n=54, 61.4%), abdominal distention (n=10, 11.4%), diarrhea (n=21, 23.9%), melena/bloody stools/occult blood (OB)+(n=25, 28.4%), poor appetite or weight loss (n=12, 13.6%) (**Table 1**).

### *Risk factors of incomplete examination*

According to the CE examination completion situation, we divided the patients with CD who accepted the capsule endoscopy examination into two groups, one was the incompletion (n=88), the other is completion (n=116). We performed the analysis correlative analysis including the factors which possibly related to the incompletion (the gender, the age, the disease course, the BMI, the passage time, the clinical features, such as abdominal pain, abdominal distention, diarrhea, melena, bloody stools and OB+) (for details, **Table 1**). The results demonstrated that the average age for the incompletion group was older than the completion one and the difference was significant

**Table 1.** Basic information of CE completion and incompletion

| | Incompletion n=88 | Complete n=116 | P |
|---|---|---|---|
| Man | 73.9% (65/88) | 69.8% (81/116) | 0.6339 |
| Mean age (y) | 38.6±14.5 | 30.7±15.0 | **0.0002** |
| Mean course (m) | 35.8±43.7 | 24.7±43.1 | 0.0710 |
| BMI | 19.43±3.1 | 19.68±3.3 | 0.3449 |
| The passage time of the stomach | 44.4±67.8 | 36.4±42.5 | 0.2450 |
| Clinical manifestation | | | |
| Abdominal pain | 61.4 % (54/88) | 36.2% (42/116) | **0.0002** |
| Abdominal distension | 11.4% (10/88) | 8.6% (10/116) | 0.0672 |
| Diarrhea | 23.9% (21/88) | 31.0% (36/116) | 0.3306 |
| Melena/bloody stools/OB+ | 28.4% (25/88) | 12.9% (15/116) | **0.0099** |
| Poor appetite/weight loss | 13.6% (12/88) | 12.9% (15/116) | 1.0000 |

CE: capsule endoscopy. BMI: body mass index. OB: occult blood test. P: *P* Value. The bold numbers mean that the *p* values are significant.

**Table 2.** The risk factors of CE incompletion

| Factor | OR | 95% CI | *Adjusted OR | 95% CI | P |
|---|---|---|---|---|---|
| Age | 1.03 | 1.01, 1.06 | 3.78 | 0.62, 3.19 | 0.151 |
| Man | 1.25 | 0.66, 2.35 | 2.48 | 1.11, 5.53 | **0.026** |
| Course | 1 | 1, 1.01 | 0.9 | 0.77, 1.05 | 0.169 |
| BMI | 0.97 | 0.9, 1.04 | 0.93 | 0.85, 1.03 | 0.16 |
| Abdominal pain | 2.57 | 1.44, 4.6 | 2.88 | 1.47, 5.65 | **0.002** |
| Abdominal distension | 1.32 | 0.52, 3.32 | 2.13 | 0.73, 6.16 | 0.165 |
| Melena/bloody stools/OB+ | 2.89 | 1.37, 6.09 | 3.34 | 1.36, 8.22 | **0.009** |

*Adjusted with the gender, the age, the disease course, the BMI, the clinical features, such as abdominal pain, abdominal distention, diarrhea, melena, bloody stools and OB+ *P<0.05. CE: capsule endoscopy. CI: confidence interval. BMI: body mass index. OB: occult blood test. P: *P* Value. The bold numbers mean that the *p* values are significant.

(P=0.0002). Additionally, the incompletion group showed abdominal pain, which was significantly more than the completion group (P=0.0002), and the incompletion group also showed more melena/bloody stools/(OB)+, which was significantly different (P=0.009). Combined those factors mentioned above, multi-factor regression analysis indicated that male gender (OR=2.48, P=0.026), abdominal pain (OR=2.88, P=0.002), melena/bloody stools/(OB)+(OR=3.34, P=0.009) before examination was the high risk factor for the incomplete examination occurred (**Table 2**).

*Basic information for retention*

Capsule retention was found in 17 patients. The retention rate of CE examination was 8.33%. The ratio of male and female was 12:5. While the mean age of these patients was 42.2±16.2 y (range 18 to 67 y), and the average course of disease was 52.5±46.6 months. Clinical manifestation of these patients were abdominal pain (n=11, 64.7%), abdominal distention (n=5, 29.4%), melena/bloody stools/occult blood (OB)+(n=6, 35.3%), poor appetite or weight loss (n=3, 17.6%), and no one show diarrhea (**Table 4**). Of the seventeen cases of retained capsules, abdominal CT showing the thickening of small intestine before CE examinations occurs in seven patients. The longest capsule retained time in patients was four years (**Figure 1**), while four patients chose to undergo surgery to remove the capsule for occurring symptoms of intestinal obstruction, spontaneous passage occurred in twelve patients after medical treatment (**Figure 2**), which six patients were by using Methylprednisolone, two patients were by using azathioprine, and four patients were by using mesalazine. And one of the patients still have the capsule retained after 16 months of expectation (**Table 3**).

*Risk factors of retention*

According to the retention situation, we divided the patients with Crohn's disease who accepted the capsule endoscopy examination into two groups, one was the retention (n=17), the other is no retention (n=187). We performed the analysis correlative analysis including the factors which possibly related to the retention (the gender, the age, the disease course, the BMI, the passage time, the clinical features, such as abdominal pain, abdominal distention, diarrhea, melena, bloody stools and OB+) (for details, **Table 4**). The results demonstrated that the average age for the retention group was older than the no retention one and the differ-

**Table 3.** Patients of CE retention

| Case number | Gender/ Age | Chief complaint | Finding in CT before CE examination | Anal fistula (Y or N) | Ileus (Y or N) | Reteniton time | Treatment after CE retention |
|---|---|---|---|---|---|---|---|
| 1 | F/43 | Repeat melena for 3 years | Normal | N | N | Since December, 2013 | Still Retention |
| 2 | M/33 | Abdominal distention and fever for 3 days | Normal | N | N | 20 dys | Using azathioprine |
| 3 | F/60 | Repeat abdominal distention and poor appetite for 2 years | Segmental small bowel and sigmoid colon wall thickening | N | N | 4 months | Using mesalazine |
| 4 | M/60 | Repeat anemia for 10 years, aggravate for 1 month | Segmental small bowel wall thickening | N | N | 2 years and 7 months | Using Methylpredn-isolone |
| 5 | M/27 | Abdominal pain for 10 years, melena for 1 day | Segmental small bowel wall thickening | Y | N | 1 year | Using Methylpredn-isolone |
| 6 | M/55 | Abdominal pain for 9 years | Segmental small bowel wall thickening | N | N | 1 month | Using Methylpredn-isolone |
| 7 | M/18 | Abdominal pain for 7 years | Normal | Y | N | 4 weeks | Using azathioprine |
| 8 | M/28 | Repeat melena for 2 months with feeble | Normal | N | N | 4 months | Using Methylpredn-isolone |
| 9 | M/28 | Repeat abdominal pain, distention, and stop the Defecation for 7 years, relapse for 4 days | Normal | Y | N | 4 years | Using mesalazine |
| 10 | M/39 | Repeat melena for 7 years, relapse for 2 months | Normal | N | N | 3 years | Using mesalazine |
| 11 | M/31 | Abdominal pain for 7 years | Normal | N | N | 1 year | Using Methylpredn-isolone |
| 12 | M/41 | Right lower-abdominal pain for 2 months | No | N | N | 50 days+ | Using Methylpredn-isolone |
| 13 | M/26 | Repeat abdominal pain, distention, and fever for 3 years and 5 months | Segmental small bowel wall thickening | N | N | 2 months | Using mesalazine |
| 14 | F/33 | Abdominal pain for 8 years | No | N | Y | 3 years | By surgery |
| 15 | F/65 | Repeat abdominal distention for 1 month | Partial ileum wall thickening and stenosis, complicated by incomplete intestinal obstruction | N | Y | 2 weeks | By surgery |
| 16 | F/67 | Periumbilical pain for 6 months, with OB(+) | No | N | Y | 50 days+ | By surgery |
| 17 | M/64 | Repeat right lower-abdominal pain for 6 days | Segmental ileum wall thickening and complicated by incomplete intestinal obstruction | N | Y | 7 months | By surgery |

CE: capsule endoscopy. CT: computed tomography.

**Table 4.** Basic information of CE retention and no retention

| | Retention n=17 | No retention n=187 | P |
|---|---|---|---|
| Man | 70.6% (12/17) | 71.7% (134/187) | 1.0000 |
| Mean age (y) | 42.2±16.2 | 33.3±15.0 | **0.0424** |
| Mean course (m) | 52.5±46.6 | 27.4±42.9 | **0.0455** |
| BMI | 19.4±2.8 | 19.6±3.3 | 0.9358 |
| The passage time of the stomach (minute) | 21.3±23.6 | 42±56.4 | 0.1471 |
| Clinical manifestation | | | |
| Abdominal pain | 64.7% (11/17) | 45.5% (85/187) | 0.1379 |
| Abdominal distension | 29.4% (5/17) | 12.7% (15/187) | 0.1556 |
| Diarrhea | 0.0% (0/17) | 48.3% (57/187) | **0.0039** |
| Melena/bloody stools/OB+ | 35.3% (6/17) | 28.8% (34/187) | 0.1091 |
| Poor appetite/weight loss | 17.6% (3/17) | 20.3% (24/187) | 0.4769 |

CE: capsule endoscopy. BMI: body mass index. OB: occult blood test. P: *P* Value. The bold numbers mean that the *p* values are significant.

ence was significant (P=0.0424). Additionally, the average disease course for the retention group was markedly longer than the no retention one (P=0.0455). However, the retention group manifested no diarrhea, which was significant different from the no retention one (P=0.0039). Although the patients from the retention group showed abdominal pain, abdominal distention, melena, bloody stools and OB+, the difference between these two groups was not significant (P>0.5). Combined those factors mentioned above, multi-factor regression analysis indicated that abdominal distention (OR=8.45, P=0.006) before examination was the high risk factor for the retention occurred (**Table 5**).

## Discussion

Capsule endoscopy has gradually been becoming the primary choose for examination of disease of small intestine. Considering 1/3 patients with Crohn's disease only involving proximal small intestine, the examination for small intestine is of necessary in recent years during the diagnosis and evaluation of the disease. The Capsule endoscopy is employed frequently for patients with Crohn's disease for its non-invasive as well as comprehensive and direct evaluation of villous coat of small intestine. However, at the mean time with application of capsule endoscopy, there unavoidably occurs the complication of capsule endoscopy retention elicited by this evaluation method. Accumulating evidence suggests Crohn's disease is the high risk factor for capsule endoscopy retention. The occurring rate of normal people is 1% to 2.5% reported in several studies [12-15]. However, the people with Crohn's disease displayed capsule endoscopy retention with the highest rate being 13% [13]. Moreover, it is reported that 4%-6.7% patients with Crohn's disease displaying negative symptoms shown by CT have capsule endoscopy retention.

This study included 204 patients of Crohn's disease, with the average age being 34.1 years old, which was near the age of high incidence of Crohn's disease. The completion rate of capsule endoscopy for patients of Crohn's disease was 56.9%, which was in accordance with the previous reports from literatures showing the rate being 53-61% [20-23]. Due to chronic inflammation bringing about impaired gastrointestinal motility, the completion rate for patients of Crohn's disease is markedly reduced compared to other patients. In present study, we had shown that the gender of male, abdominal pain and gastrointestinal bleeding were the three primary risk factors for incompletion for capsule endoscopy examination. Therefore, before capsule endoscopy, application of prokinetic agents should raise the completion rate of capsule endoscopy for patients of Crohn's disease.

With the logistic regression analysis for multifactor regression analysis, we proposed that the gender of male, abdominal pain, melena, bloody stools and OB+ were the primary risk factors for incompletion of capsule endoscopy

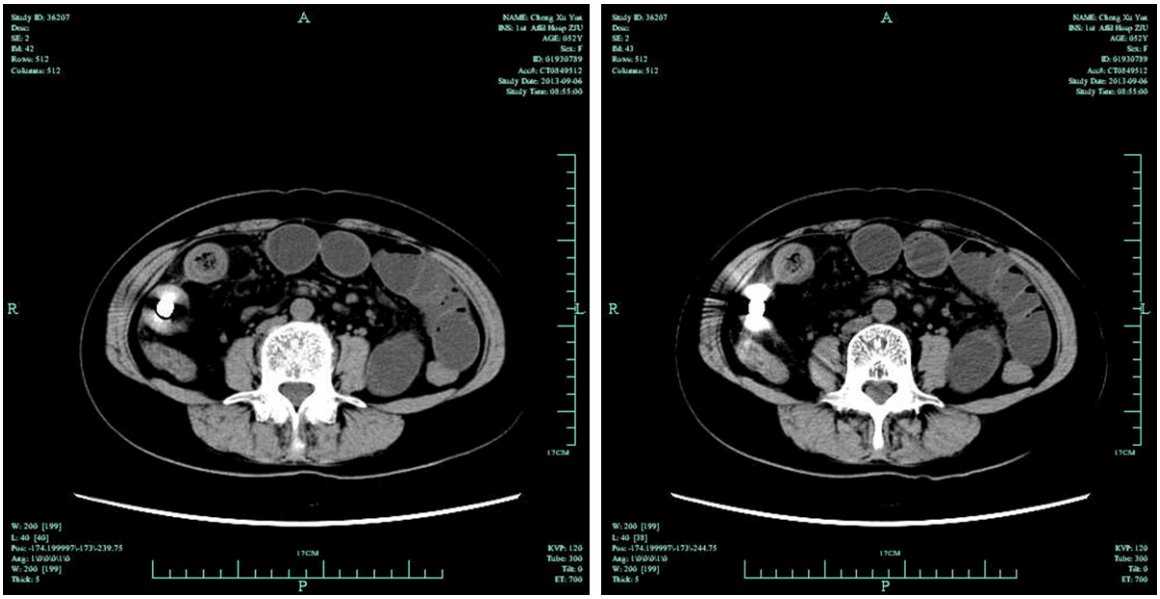

**Figure 1.** CE retention in CT.

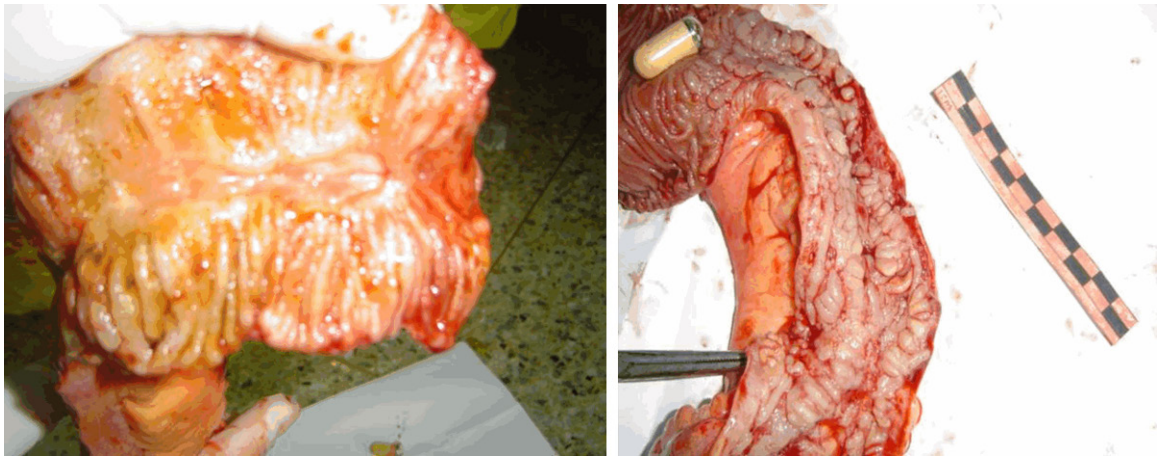

**Figure 2.** The surgery of CE retention.

examination. It is reported that deep ulcer of villous coat of small intestine of patients of Crohn's disease is the prognosis element for the development of intestinal stricture [24]. Additionally, deep ulcer prolongs the passage time of capsule endoscopy through intestine. Besides, it is worth to note that the clinical features of deep ulcer mostly manifest abdominal pain, melena, bloody stools and OB+. Thus, it is rational that all those features mentioned above are the primary risk factors for incompletion of the examination. Therefore, our study raised the suggestion that examination for intestinal stricture with CTE should precede capsule endoscopy in those patients with abdominal pain and gastrointestinal bleeding.

The capsule endoscopy retention rate is 8.3% in 204 patients of Crohn's disease in this study, which is consistent with previous study [16-19]. Analyzing the high risk factor for capsule endoscopy retention with multi-factor regression analysis, we proposed abdominal distention was the risk factor for retention. Given intestine obstruction is usually accompanied with abdominal distention, imaging examination should precede capsule endoscopy in patients with abdominal distention. Although capsule

**Table 5.** The risk factors of CE retention

| Factor | OR | 95% CI | *Adjusted OR | 95% CI | P |
|---|---|---|---|---|---|
| Age | 1.03 | 1, 1.06 | 12.55 | 0.04, 4124.11 | 0.392 |
| Man | 1.21 | 0.37, 3.92 | 1.71 | 0.4, 7.36 | 0.473 |
| Course | 1.01 | 1, 1.02 | 0.82 | 0.51, 1.33 | 0.423 |
| BMI | 1.00 | 0.88, 1.15 | 0.98 | 0.85, 1.14 | 0.823 |
| Abdominal pain | 1.97 | 0.69, 5.64 | 2.67 | 0.72, 9.85 | 0.14 |
| Abdominal distension | 5.03 | 1.54, 16.4 | 8.45 | 1.85, 38.56 | **0.006** |
| Melena/bloody stools/OB+ | 2.12 | 0.69, 6.51 | 1.87 | 0.45, 7.83 | 0.39 |

*Adjusted with the gender, the age, the disease course, the BMI, the clinical features, such as abdominal pain, abdominal distention, diarrhea, melena, bloody stools and OB+
*P<0.05. CE: capsule endoscopy. BMI: body mass index. OB: occult blood test. P: *P* Value. The bold numbers mean that the *p* values are significant.

endoscopy demonstrates great advantage in early diagnosis for Crohn's disease and other diseases, such as small intestinal ulcer, our study illustrated that incompletion rates of capsule endoscopy and its retention were substantially elevated among patients with Crohn's disease. Hence, before capsule endoscopy examination for patients with Crohn's disease, imaging examination should be performed in advance for avoiding capsule endoscopy retention. According to our results, more attention must be paid to the male patients with abdominal distention, abdominal pain and gastrointestinal bleeding.

Of the 17 patients with capsule endoscopy retention, only 4 of them had obstruction. After receiving the medical conservative treatment, they still required surgical intervention to take out the capsule endoscopy. However, the other 12 patients got rid of the capsule endoscopy by themselves with the help of medical conservative treatment. There is remaining one patient retains the capsule endoscopy without obstruction. Notably, the 4 patients receiving the surgery were rather selective operation but not emergency surgery for serious complications. Besides, one patient of the 4 with surgery displayed symptoms after 3 years of retention. Moreover, it is worth to note the longest time for retention of capsule endoscopy in our study is 4 years, while the record for retention is 6 years and 10 months, implying the retention of capsule endoscopy in human body being relatively safe [25]. Thus, it is reasonable to increase the medical conservative observation time. Especially for patients of Crohn's disease, the risk of surgery is relatively high for a proportion of the patients who have the inflammation. Nevertheless, after medical conservative treatment, the inflammation subsides and the capsule endoscopy is excreted spontaneously. Therefore, if patients with Crohn's disease have the retention, the primary choose for them can be medical conservative treatment. There is no need for surgery until obstruction occurs. Otherwise, endoscopic balloon dilation or capsule endoscopy removement is alternative method for surgery.

## Conclusion

Our study shows that the completion rate for the patients with Crohn's disease is 56.9%, while the retention rate is 8.33%. Male, abdominal pain, melena, bloody stools and OB+ are the primary cause for the retention of capsule endoscopy. Additionally, abdominal distention is another risk factor for the capsule endoscopy retention. To improve the completion rate of capsule endoscopy, except for promoting Gastric Dynamics drugs treatment, we proposed application of prokinetic agents for the patients with high risk factors as well. At the meantime, imaging examination for abdominal distention and obstruction should reduce the retention rate. The majority of the patients with retention can excreted the capsule endoscopy after medical conservative treatment by themselves, showing no need for emergency surgery due to serious complications. These results suggest the retention of capsule endoscopy is relatively safe. Furthermore, stenosis expansion or surgical removes of capsule endoscopy under intestinal endoscopy is alternative method for surgery. In general, capsule endoscopy is quite safe for the patients with Crohn's disease.

## Acknowledgements

This study was funded by the Zhejiang Provincial Natural Science Foundation of China, No. LQ13H030002; Medical and Health Science Fund of Health Bureau of Zhejiang Province, China, No. 2013KYB089.

## Disclosure of conflict of interest

None.

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