

Digital single-operator cholangioscope for endoscopic retrograde appendicitis therapy

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submitted 10.1.2021

accepted after revision 23.4.2021

published online 23.4.2021

Bibliography

Endoscopy 2022; 54: 396–400

DOI 10.1055/a-1490-0434

ISSN 0013-726X

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Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

 Fig. 1s

Supplementary material is available under

<https://doi.org/10.1055/a-1490-0434>

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ABSTRACT

Background This study aimed to investigate the diagnostic and therapeutic value of a digital single-operator cholangioscope (SOC) system for endoscopic management of acute appendicitis.

Methods 14 patients with acute uncomplicated simple or supportive appendicitis were evaluated between November 2018 and September 2020. The diagnosis of acute appendicitis was confirmed by direct colonoscopy imaging and cholangioscope. The success rate of digital SOC-assisted endoscopic retrograde appendicitis therapy (ERAT), the procedure time, postoperative length of hospital stay, complications, and recurrence rate were recorded.

Results Technical success rate was 100%, with high quality imaging of the appendiceal cavity achieved using SOC in all 14 patients. The mean procedure time was 37.8 (standard deviation [SD] 22) minutes. All patients experienced immediate relief from abdominal pain after the procedure. Mean postoperative hospitalization was 1.9 (SD 0.7) days. No recurrence occurred during 2–24 months of follow-up.

Conclusion Digital SOC-assisted ERAT provided a feasible, safe, and effective alternative approach for diagnosis and management of acute uncomplicated appendicitis without the need for X-ray or ultrasonic guidance.

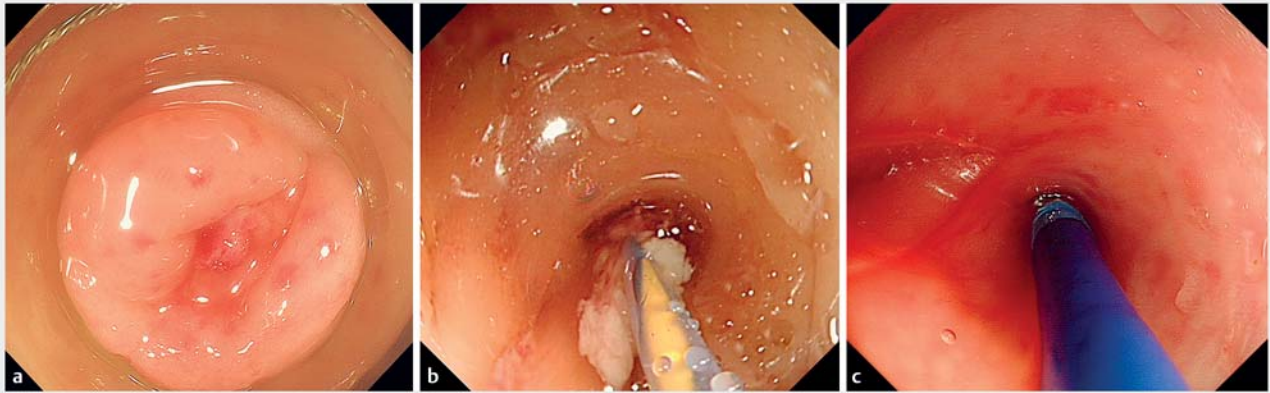
Introduction

Acute appendicitis is the most common abdominal emergency in all age groups. Endoscopic retrograde appendicitis therapy (ERAT) is a new and minimally invasive alternative method for the diagnosis and treatment of acute appendicitis [1,2], the effectiveness of which has been confirmed in a multicenter retrospective trial [3]. The technique requires direct endoscopic imaging or fluoroscopic endoscopic retrograde appendicography to separate suspected acute appendicitis from actual acute appendicitis. For patients with appendicitis, the ERAT procedure is performed to relieve the appendiceal lumen obstruction. ERAT includes appendiceal luminal irrigation, appendiceal stone removal, and stenting for drainage, when necessary [3,4]. One limitation of ERAT has been the inability to

directly visualize the appendiceal cavity to exclude other conditions and to accurately guide therapy [5,6].

The digital single-operator cholangioscope (SOC) system (SpyGlass DS; Boston Scientific, Marlborough, Massachusetts, USA) is a fiberoptic direct vision system typically used during endoscopic retrograde cholangiopancreatography for the treatment of bile duct stones and in the differential diagnosis of biliary stricture. The outer diameter of the cholangioscope is 3.3 mm, which is small enough to enter the appendiceal lumen. In this study, we used digital SOC in ERAT to allow direct vision of the appendiceal cavity for observation, directed irrigation and, if necessary, lithotripsy. The instrument was introduced via the biopsy port of the colonoscope. The purpose of the study was to investigate the diagnostic and therapeutic advantages of using digital SOC for ERAT in acute appendicitis.

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► **Fig. 1** Endoscopic view. **a** Appendiceal edema. **b** Pus extraction. **c** Insertion of the digital single-operator cholangioscope.

Patients and methods

Study design and protocol

Patients with acute uncomplicated appendicitis (acute simple appendicitis and acute supportive appendicitis) admitted to The First Affiliated Hospital of Zhengzhou University from November 2018 and September 2020 were eligible for inclusion in the study.

The following inclusion criteria were applied.

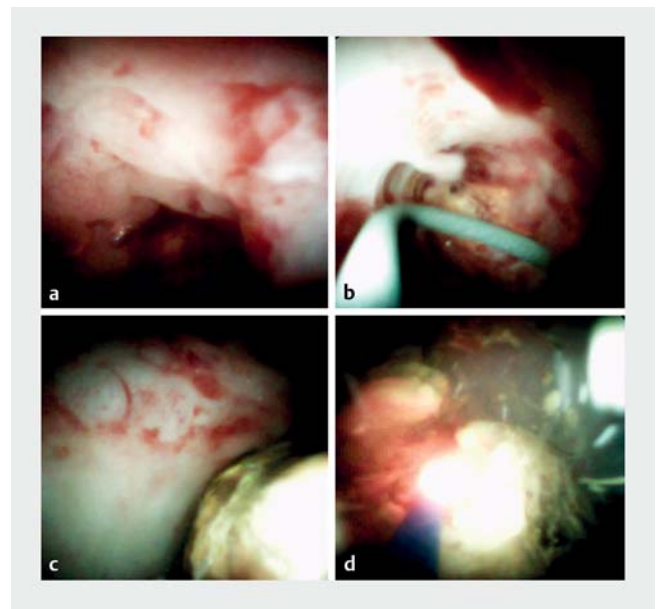
1. Patients with acute appendicitis diagnosed by abdominal computed tomography (CT) or ultrasound; criteria for diagnosis were presence of an inflammatory reaction or fecal stone on CT.
2. Patients with suspected appendicitis were diagnosed by clinical symptoms and signs (i.e. an Alvarado score ≥ 5).
3. In patients such as pregnant women, children, and couples planning a pregnancy who rejected CT, the diagnosis was confirmed by colonoscopy based on the findings of edema at the opening of the appendix or pus flowing out of the appendiceal cavity.

Patients with complicated appendicitis such as periappendiceal inflammation, appendiceal perforation, or acute gangrene were excluded.

Description of technique

Preparation for ERAT included bowel cleansing using either 2L polyethylene glycol electrolyte solution or low-pressure cleansing enemas (300–500 mL per enema) given five times. For patients with mild or moderate symptoms, the oral preparation was given 4–6 hours before the procedure. For clinically severe cases or patients with anorexia or nausea/vomiting, low-pressure cleansing enemas (300–500 mL per enema) were given approximately 30 minutes prior to endoscopy so as not to delay treatment of appendicitis.

All patients were offered general anesthesia; however, only 20% of patients received anesthesia. The procedure was performed with patients in the supine position. For the main procedure, a colonoscope (CF-HQ290I, 3.7 mm channel diameter;



► **Fig. 2** Cholangioscopic view. **a** Edema of the inner wall of the appendix. **b** End of the appendix. **c** Fecal stones in the appendix. **d** Laser lithotripsy.

Olympus, Tokyo, Japan) with a conical transparent cap was inserted into the cecum. After observing the opening of the appendix (► **Fig. 1a**), a guidewire was inserted into the appendiceal cavity (see **Fig. 1s-a**, in the online-only Supplementary material) and the cholangioscope was introduced into the appendiceal cavity along the guidewire (► **Fig. 1b,c**). The appendiceal cavity was observed and treatment such as removal of fecal stones, washing, and biopsy were performed where needed (► **Fig. 2**, ► **Video 1**).

Antibiotics were given to all patients (except pregnant patients) for no more than 3 days after the procedure. The patients underwent physical examination after the operation and were followed up by telephone.



▶ Video 1 Digital single-operator cholangioscope-assisted endoscopic retrograde appendicitis therapy. Online content viewable at: <https://doi.org/10.1055/a-1490-0434>

Statistical analysis

The statistical analyses were performed using SPSS Statistics v23.0 (IBM Corp., Armonk, New York, USA). The mean and standard deviation (SD) were calculated for quantitative variables and frequency (%) was used for qualitative variables.

Results

A total of 14 patients (5 males and 9 females) with a mean age of 32.9 (SD 12) years were included in the study. The Alvarado score ranged from 3 to 6 points (mean 4.6 points). Clinical symptoms included metastatic right lower abdominal pain in 14 patients (100%), right lower abdomen tenderness in 8 (57.1%), rebound tenderness in 10 (71.4%), anorexia in 9 (64.3%), and vomiting in 5 (35.7%) (▶ **Table 1**). ERAT was performed within 12–24 hours after admission. The technical success rate was 100%. No patients required transfer to surgery. The mean procedure time (defined as the time from the beginning of colonoscopy to the end of treatment) was 37.8 (SD 22) minutes, the mean hospital stay after the operation was 1.9 (SD 0.7) days, and the mean leukocyte recovery time was 1.3 (range 1–3) days (▶ **Table 1**).

The digital-SOC diagnoses of the patients were: congestion and edema in six (42.9%), fecal stones in seven (50.0%), purulent discharge adhesion in nine (64.3%), and tortuous, dilated, or narrow lumen in four (28.6%) (▶ **Table 2**). In four patients (with strictures in the appendix caused by inflammation), metronidazole mixed with normal saline solution was used to irrigate the lumen by direct view and a stent was placed, which was removed 1 month after the procedure. Extraction of the appendiceal stone was achieved in seven patients (by washing in four and by basket in two); one patient with a giant appendiceal stone underwent laser lithotripsy (▶ **Table 2**). One of the

▶ Table 1 Baseline characteristics of study patients.

Patients, n	14
Sex, n (%)	
▪ Male	5 (35.7)
▪ Female	9 (64.3)
Age, mean (SD), [range], years	32.9 (12) [15–52]
Clinical symptoms, n (%)	
▪ Metastatic right lower abdominal pain	14 (100)
▪ Right lower abdomen tenderness	8 (57.1)
▪ Rebound pain	10 (71.4)
▪ Anorexia	9 (64.3)
▪ Vomiting	5 (35.7)
Body temperature on admission, n (%)	
▪ >37.3 °C	4 (28.6)
▪ ≤37.3 °C	10 (71.4)
Leukocyte, n (%)	
▪ >10 × 10 ⁹ /L	3 (21.4)
▪ ≤10 × 10 ⁹ /L	11 (78.6)
Percentage of neutrophils, n (%)	
▪ >75 %	3 (21.4)
▪ ≤75 %	11 (78.6)
Alvarado score, n (%)	
▪ 3	1 (7.1)
▪ 4	5 (35.7)
▪ 5	6 (42.9)
▪ 6	2 (14.3)
Mode of diagnosis, n (%)	
▪ Abdominal CT	11 (78.6)
▪ Abdominal ultrasound	1 (7.1)
▪ Colonoscopy ¹	2 (14.3)
Delay between admission and ERAT, mean (SD) [range], hours	17.7 (3.5) [12–24]
Procedure time, mean (SD) [range], minutes	37.8 (22) [12–100]
Time to disappearance of rebound pain, mean (SD) [range], hours	5.1 (3.4) [1–12]
Hospital stay post-procedure, mean (SD) [range], days	1.9 (0.7) [1–3]
Follow-up ² time, mean (SD) [range], months	12.4 (7.3) [2–24]

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► **Table 1** (Continuation)

Patients, n	14
Postoperative complications, n	0

SD, standard deviation; CT, computed tomography; ERAT, endoscopic retrograde appendicitis therapy.

¹ Patients were pregnant women or were planning for pregnancy and refused to undergo radiological examination. They underwent ultrasound followed by colonoscopy with digital single-operator cholangioscope-assisted ERAT upon confirmation.

² Follow-up was by telephone call, which all patients answered.

► **Table 2** Endoscopic characteristics of study patients (n = 14).

Endoscopic manifestations, n (%)	
▪ Congestion and edema of appendiceal orifice	10 (71.4)
▪ Fecal stone and its incarceration	9 (64.3)
▪ Pus and feces at appendiceal orifice	8 (57.1)
Cholangioscopic manifestations, n (%)	
▪ Congestion and edema of inner wall	6 (42.9)
▪ Fecal stone in cavity	7 (50.0)
▪ Intraluminal pus	9 (64.3)
▪ Abnormal lumen	4 (28.6)
Treatment conducted during ERAT, n (%)	
▪ Lavage	14 (100)
▪ Laser lithotripsy	1 (7.1)

ERAT, endoscopic retrograde appendicitis therapy.

patients was a pregnant woman who underwent successful digital SOC-assisted ERAT with no use of X-rays (► **Table 2**).

Abdominal pain was relieved immediately after ERAT in all the patients and did not recur. Rebound pain disappeared in 5.1 hours (SD 3.4; range 1–12) after the procedure, and the white blood cell counts returned to normal within 24 hours. There were no complications during or after the operation, and no recurrence or other adverse event was noted over 12.4 months (SD 7.3, range 2–24) of telephone follow-up.

Discussion

The main cause of acute appendicitis is the obstruction of the appendix lumen. The formation of fecal stones and the stenosis of the appendix lumen are common factors leading to the obstruction [6]. The shape of the appendix varies greatly; the lumen is long and thin, and the external diameter of the appendix occasionally expands. Because of this variation, some studies have shown that simply relying on CT and abdominal ultrasound is not always sufficient to make a reliable diagnosis of appendicitis [6, 7]. The reported negative appendectomy rate is as high as 15% [8–10]. There is no gold standard for the preoperative diagnosis of appendicitis, and the clinical manifestations (e.g. Alvarado score) are still used for diagnosis. Recent

studies and analyses have shown that using endoscopy with appendiceal cavity imaging to observe the internal orifice and surrounding mucosa of the appendix, along with data obtained by X-ray or ultrasound, can accurately diagnose acute appendicitis [2, 3, 11]. However, despite the progress in endoscopic technology, there is still little evidence that appendiceal cavity imaging can accurately exclude appendiceal disease. Although ERAT is effective, and appendiceal fecal stones can be diagnosed by endoscopic retrograde appendicography, there is no assurance that all stones have been removed.

In recent years, there has been growing evidence that acute uncomplicated appendicitis can be treated without urgent appendectomy. However, the most appropriate nonsurgical treatment is still a matter of debate: intravenous inpatient antibiotic therapy, oral ambulatory antibiotic treatment, or more recently, ERAT. Although conservative treatment can avoid postoperative complications and has a high success rate and short hospital stay, patients remain at risk of recurrent appendicitis and may eventually need appendectomy [11, 12]. Direct endoscopic retrograde appendiceal imaging is greatly improved by the use of the digital SOC system, which allows a detailed view of the appendiceal cavity during colonoscopy. Use of the cholangioscope allows a clear view of feces, pus, and pus adhesions in the appendiceal cavity, inner wall congestion and edema of the appendiceal cavity, and the tortuosity, expansion, and stenosis of the lumen. Direct vision also obviates the need for X-rays and the use of contrast media, which is especially important in pregnant women. The method cannot only overcome the need for X-ray guidance for appendix cleansing and stenting but also allows the examination of the entire appendiceal cavity, which plays an important role in the selection of a suitable appendix stent. Moreover, the visual control allows the use of lithotripsy for appendiceal stones that are often considered causal factors of the disease. Another advantage is that an experienced endoscopist can confirm the diagnosis of appendicitis and complete the treatment. One limitation is that the current digital SOC system (SpyGlass) is an expensive single-use instrument. Further development of inexpensive disposable or multiuse instruments would make the technique even more attractive.

This study has some limitations, including characterization of the new technique, retrospective design, small cohort, and absence of a control group. Larger randomized comparative trials will be needed to understand the future for this innovative new approach to the treatment of acute uncomplicated appendicitis.

In conclusion, digital SOC-assisted ERAT may be a better option than conventional ERAT as it potentially allows for the detection and removal of fecal stones. Digital SOC not only allows a direct view of the appendiceal cavity but also allows targeted treatment, similarly to its application in the biliary tract. In addition, some patients (pregnant women, children, and couples planning pregnancy, etc.) who are not suitable for radiation and/or who do not wish to undergo X-ray or other radiological examination, are suitable candidates for digital SOC-assisted ERAT, as cholangioscope does not involve radiation.

Competing interests

The authors declare that they have no conflict of interest.

Funding

Henan province innovation talents of science and technology plan
184200510020
Natural science foundation of China 818704540

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