

Title:

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Efficacy of cap-assisted forward-viewing endoscopy as a method for evaluation of ampulla of Vater

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Abbreviations:

- Ampulla of Vater: AV
- Familial adenomatous polyposis: FAP
- Endoscopic retrograde cholangiopancreatography: ERCP

Conflict of interest. Authors claim no conflict of interest.

Abstract

Endoscopic evaluation of ampulla of Vater, although routinely recommended, is not always possible due to its anatomic configuration that can hide it from the visual field of the forward-viewing endoscope. Cap-assisted forward-viewing endoscopy has been proposed as a useful alternative to facilitate the examination of this structure.

Objectives: Assess the efficacy of cap-assisted forward-viewing endoscopy for the complete evaluation of the ampulla of Vater (AV). Secondary outcomes were to assess AV morphology, search and total procedure times, and technique safety.

Methods: Prospective, single-arm study. We included patients who were selected for elective upper endoscopy. We excluded patients with advanced neoplasia, modified anatomy, upper gastrointestinal stenosis, or obstructions.

Outcomes: We included 90 patients, 36 men (40%) and 54 women (60%). Fifteen percent had a history of hereditary colon cancer syndrome. Technical success of cap-assisted, forward-viewing endoscopy was 98.8%. AV was classified as type 1 (classic) in 49.4%, type 2 (small) in 16.8%, type 3 (protruding) in 11.2% and type 4 (ridged) in 22.4%. Mean search time was 37.7 s (SD \pm 31.6) and total procedure time was 487.4 s (SD \pm 206.2). No adverse events were reported.

Conclusions: Cap-assisted forward-viewing endoscopy is an effective and safe technique for complete visualization and morphologic characterization of the ampulla of Vater.

Introduction

The ampulla of Vater (AV) was first described in 1720 by the anatomist Abraham Vater. (1) It is an anatomic structure conformed by the junction of the distal segment of both choledochal and main pancreatic ducts, which in most cases (75%), merge into the medial wall of the second portion of the duodenum. (2)

AV visible segment during endoscopic examination is the major papilla and it is conformed by the papillary orifice surrounded by intraductal mucosa, the infundibulum, proximal transverse fold and a distal longitudinal duodenal fold. The terms major papilla and AV are often used interchangeably; from here on we will refer as AV to the endoscopic evaluated segment of this structure.

Interest into endoscopic examination of AV is mainly based on the possibility to early detection of neoplastic lesions. Although AV neoplasms are rare in general population (about 6 cases per million of habitants), there is a group of high-risk patients, such as those with familial adenomatous polyposis (FAP), who present an incidence up to 300 times higher. (3,4) AV neoplasms proposed carcinogenesis follows an accumulation of mutations like the one described in colonic neoplasms. (5) This adenoma-carcinoma sequence favors potential screening. That is why it becomes relevant to know the endoscopic characteristics of the VA, as well as the appropriate techniques for its evaluation.

In 2017, Haraldson et al, proposed a classification for morphological description of the AV. This workgroup validated four endoscopic types of AV: type 1 (regular or classic), type 2 (small), type 3 (protruding) and type 4 (ridged). (6) This way to describe the AV was later used as a standard in a multicenter study. (7)

Examination of AV and duodenal second portion are proposed as quality indicators in upper endoscopy. (8) Previous studies have reported a sensitivity that ranges from 50% to 80.8% for AV examination with a forward-viewing endoscope, not being greater mainly due to its location on the medial wall of the duodenum. (9,10,11) Therefore, it is currently advised to examine the AV using a duodenoscope. (12,13)

Alternatives have been searched that allow the use of the gastroscope for an adequate AV examination, since using a duodenoscope not only implies a second procedure, but also requires a special training for its management.

In 2013, Choi et al., reported the use of a plastic cap placed in the distal tip of the forward-viewing endoscope to examine the AV in 23 patients in whom proper complete visualization was not possible using a forward-viewing endoscope; efficacy of this

combination was 91.3%. (14) In 2017, Kallenberg et al, reported the use of this technique in 40 patients with FAP, with an efficacy of 95% and without any adverse events. (15) The 2019 European Society of Gastrointestinal Endoscopy guideline for the management of patients with polyposis hereditary syndromes recommends the latter technique as an alternative to duodenoscopes for screening of duodenal and periampullary lesions. (16)

We find ourselves in front of an emergent technique that is postulated as effective for the assessment of AV. The aim of this study is to assess the feasibility and efficacy of cap-assisted forward-viewing endoscopy for the complete examination of the AV. Secondly, we evaluate AV morphology, time to assess its location, total procedure time and related adverse events.

Material and methods.

Study design. Prospective, single-arm study, conducted at the Gastrointestinal Endoscopy Department at Mexico's National Institute of Cancer (INCan) from August 2019 to February 2020. The protocol was authorized for the local ethics committee.

Inclusion criteria. Patients were consecutively included if they were >18 years old and had an indication for performing an elective upper gastrointestinal endoscopy at our department during the established period.

Exclusion criteria. Patients were excluded if they presented any of the following: advanced neoplasia, surgically modified anatomy, confirmed or probable diagnosis of esophageal or gastric outlet obstruction by clinical, endoscopic and/or image study.

Procedure. Patients must have given their written informed consent prior to enrollment. Patients were placed in left lateral decubitus and under conscious sedation administered by a certified anesthesiologist. Demographic data (sex, age, history of hereditary colon

cancer syndrome), as well as the indication for the endoscopic procedure and endoscopic diagnosis were recorded.

Upper endoscopy was performed with a forward-viewing gastroscope (GIF-HQ190 Olympus Optical Co, Tokyo, Japan) with placement of a transparent, 4 mm length, plastic cap (Reveal® US endoscopy Ohio, EUA) on its distal tip. Procedures were performed by certified endoscopists or by trainees under their supervision.

Procedure photodocumentation was performed, as well as total procedure time, recording it in seconds (s) from oral intubation to endoscope withdrawal.

To locate the AV, the gastroscope was advanced to the second or third portion of the duodenum, reaching as further as possible; after that, the gastroscope was withdrawn and duodenal examination was performed until the longitudinal duodenal fold and the AV were identified, this was done paying special attention to the visual field between 09 and 01 hours. Once the longitudinal fold distally located to the AV was identified, it was followed by the endoscopist by further withdrawal of the gastroscope with short movements (2 to 3 mm each) and by flattening of each mucosal fold with the aid of the plastic cap; if the infundibulum was observed or the duodenal bulb was reached, the gastroscope was reintroduced to the second duodenal portion and the procedure was repeated as many times as needed in order to observe the AV. Once the AV was located, it was centered in the gastroscope's vision field by maintaining stability with its distal tip and applying slight pressure to observe it completely and detect any related alteration. Rest of duodenal mucosa was examined in a standard fashion with rotatory movements. Video.

AV search time was recorded in seconds from intubation of the duodenal second portion to the complete visualization of the AV (papillary orifice and external edges of intraductal mucosa).

Visualization was categorized into complete, incomplete, or null. AV morphology was catalogued as one of the four types described by Haraldson et al. (6) in their study. Ampullary or periampullary neoplastic suggestive features were recorded. Biopsies were performed as endoscopist criteria. Spiegelman classification (Table 1) was used if duodenal polyposis was identified. Immediate and delayed (up to 72 hours after procedure) adverse events were recorded by patient consultation or by phone call.

Statistical analysis. Statistical analysis was performed using SPSS V.23 (IBM Corp., Armonk, NY, USA). Continuous variables were described as means, medians and standard deviation. Categorical variables were described as relative frequencies.

Results.

A total of 90 patients were included in this study during the established period; 36 were men (40%) and 54 women (60%), mean age was 52.4 years (SD \pm 16.2). Fourteen patients (15.5%) had a history of hereditary colon cancer syndrome: 8 patients had Lynch syndrome, 5 had FAP and 1 patient was carrier of MUTYH mutation. Procedure indications were screening for upper gastrointestinal cancer (38.9%), refractory gastroesophageal reflux disease (11.1%), history of gastrointestinal bleeding or chronic anemia (10%), gastrointestinal premalignant lesions follow-up, either on surveillance or previously treated (7.8%) or any other (32.2%). Final endoscopic diagnosis was as follow: normal study (27.8%), erosive or congestive gastropathy (22.2%), chronic – atrophic gastritis (14.4%), gastric and/or duodenal polyposis (11.1%), probable Kaposi sarcoma (7.8%), erosive esophagitis graded from A to D according to Los Angeles classification (4.4%) and any other diagnosis (12.3%).

AV was completely visible in 98.8% (89 out of 90 patients); it was not possible to identify it in one patient despite several attempts and a second examination by another endoscopist.

AV was classified as type 1 (classic) in 49.4%, type 2 (small) in 16.8%, type 3 (protruding) in 11.2% and type 4 (ridged) in 22.4%; no neoplastic features were identified.

Figure 1. One patient with Lynch syndrome was diagnosed with duodenal polyps with advanced features; these polyps were resected in a later procedure and classified as a stage IV according to Spigelman classification. No AV neoplastic features were identified in this patient. Figure 2.

Mean procedure time was 37.7 s (SD \pm 31.6), with a total procedure time of 487.4 s (SD \pm 206.2). Table 2.

No adverse events related to cap-assisted forward-viewing endoscopy were reported.

Discussion.

We determined in our study that plastic cap-assisted forward-viewing endoscopy is technically feasible and effective for complete visualization of the AV (edges and orifice) in 98.8% of the times. This is consistent with an efficacy greater than 90% reported by Choi (14) and Kallenberg (15) in 2013 and 2017, respectively.

We observed that cap-assisted forward-viewing endoscopy allowed to place the AV in front of the gastroscope, to pull the folds that might hide it and maintain an adequate distance between the AV and the gastroscope. Using a plastic cap allowed an 18% increase (80% vs 98%) in AV visualization when compared to previous studies in which this accessory was not used. (14)

We proved that cap-assisted forward-viewing endoscopy allows an adequate examination of ampullary morphology. Applying the classification proposed by Haraldson (7), the most frequent AV types were type 1 (classic) and 4 (ridged), accounting for 49% and 22% of all types, respectively. Although this classification has had its major role in the field of endoscopic retrograde cholangiopancreatography (ERCP), it also allows to set a standard for terminology and agreement between endoscopists.

Neoplastic features in the AV were not found in the examined patients. Duodenal polyposis without ampullary neoplastic features was found in one patient with Lynch syndrome. Features suggestive of Kaposi sarcoma were found in 7.8% of our patients, a rare finding which was later confirmed by pathology in 66% of the cases. Figure 3.

Current endoscopes are equipped with technologies that allow to apply digital chromoendoscopy and image magnification, tools that in combination with cap-assisted endoscopy might increase detection of early gastrointestinal lesions. This could be evaluated in future protocols.

Mean time for AV localization was 37 s (± 31.6) and it was not related to a longer procedure, carrying it out in an average of 8 minutes (487.4 s). Endoscopies were performed in a training center, which implied that trainees were involved in this study; nevertheless, this was not related to any sort of difficulties for locating the AV. A comparative analysis was not performed between expert ERCP endoscopists and trainees, but no obvious differences were seen between both groups which might imply that cap-assisted forward-viewing endoscopy does not carry a significant learning curve, even in those trainees who are not familiar to duodenoscopies.

Plastic cap-assisted endoscopy was not associated with adverse events. No difficulties were reported in its use, although we noticed a slight opacification of the visual field on gastric examination; the latter was compensated by increasing luminous intensity and systematic examination.

This technique can be useful for examination in patients at high risk of ampullary pathology (i.e., FAP) as it has been recently suggested by the European Society of Gastrointestinal Endoscopy. (16) Cap-assisted endoscopy has the advantage of performing a complete examination of the upper gastrointestinal tract in one single procedure, without needing a duodenoscope, an endoscope that not only requires a special training, but also increases costs. The alternative to easily and routinely examine the AV and to take it as a quality indicator of complete endoscopic visualization of upper gastrointestinal tract (equivalent to cecal intubation in colonoscopy) seems like an attractive possibility for improving daily endoscopy practice.

The main limitation of this study is the absence of a control group to compare cap-assisted forward-viewing endoscopy vs duodenoscopy. Nevertheless, we opt for a feasibility study considering the results of previous reports (14, 15) and our findings might help to design future trials.

It is mandatory to mention that most of the patients included in our study did not had a suspicious diagnosis of ampullary disease; the presence of AV disease and related symptoms might modify its anatomy and impact the technique efficacy.

In conclusion, cap-assisted forward-viewing endoscopy is a feasible and effective technique for complete visualization and morphologic characterization of the AV, without increasing neither total procedure time nor adverse events.

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Table 1. Spigelman classification			
Variable	1 point	2 points	3 points
# polyps	1-4	5-20	>20
Size (mm)	1-4	5-10	>10
Histology	Tubular	Tubulovillous	Villous
Dysplasia	Low grade		High grade

Stage 0 = 0 points. Stage I = 1-4 points. Stage II = 5-6 points. Stage III = 7-8 points. Stage IV = 9-12 points.

Table 2. Results from cap-assited forward-viewing endoscopy for examination the ampulla of Vater (AV)

	Percentage (%)	Mean (SD)	<i>n</i> =
Complete visualization	98.8		89/90
Incomplete visualization	-		-/90
Null	1.2		1/90
Search time of AV (seconds)		37.7 (±31.6)	
Total procedure time (seconds)		487.4 (±206.2)	
AV types			89
1. Classic	49.4		44
2. Small	16.8		15
3. Protruding	11.2		10
4. Ridged	22.4		20

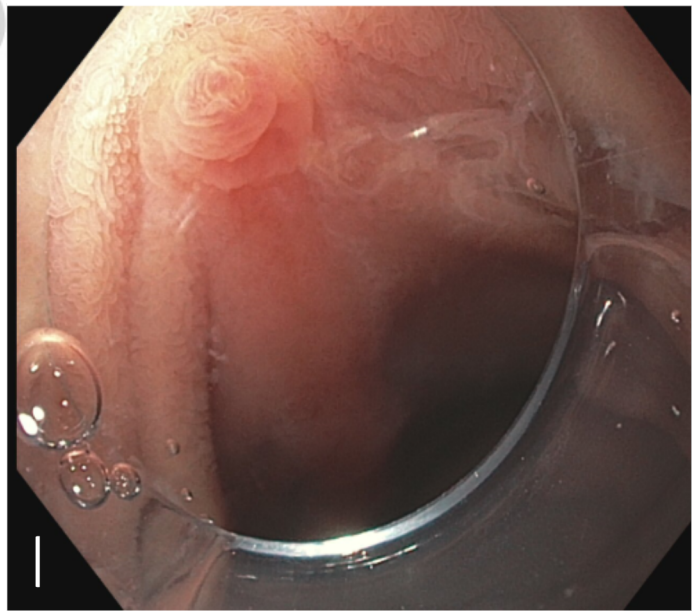
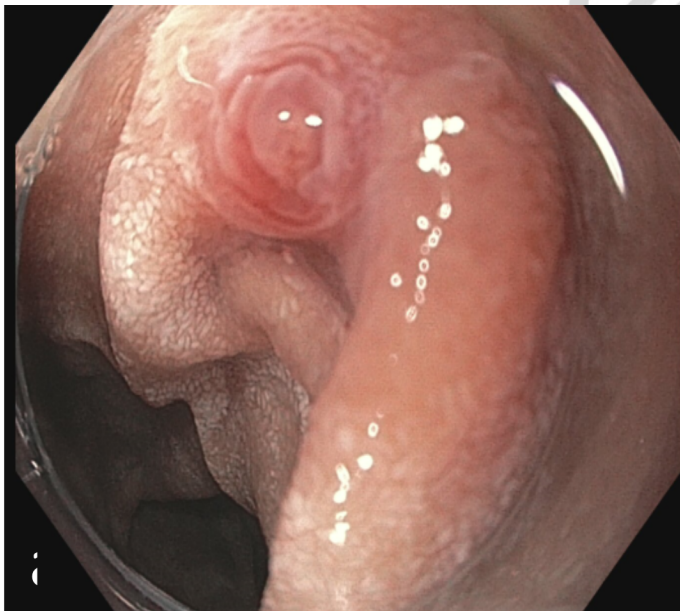


Figure 1. Ampulla of Vater morphologic features. a. Type 1 (classic). b. Type 2 (small), smaller than 3 mm. c. Type 3 (protruding) plastic cap allows a precise examination of the AV. d. AV type 4 (ridged).

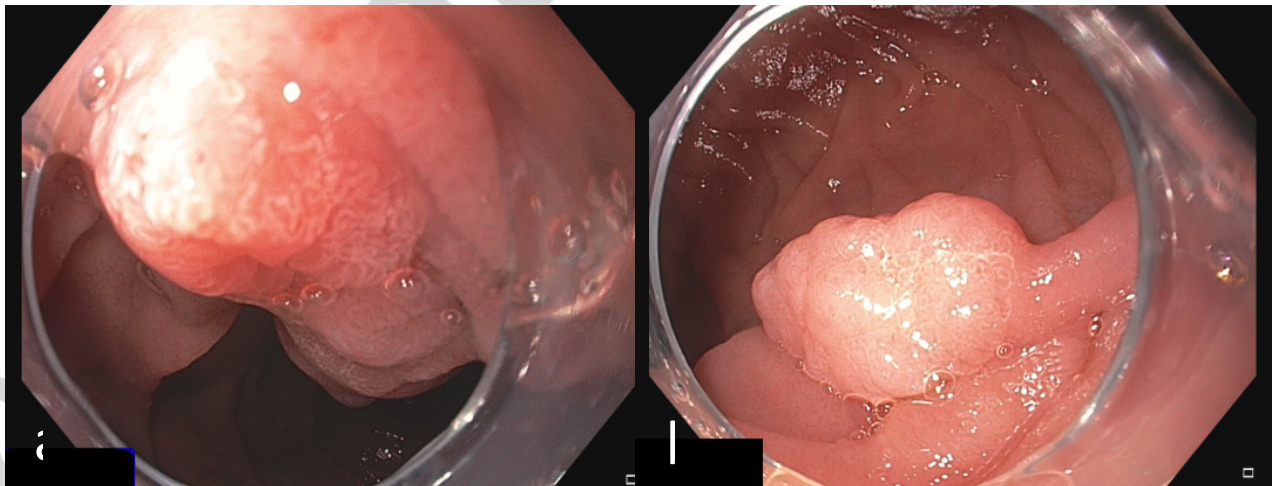


Figure 2. Duodenal polyposis in a patient with Lynch syndrome. a. Ampulla of Vater type 4. b. Pedunculated polyp in duodenal second portion.

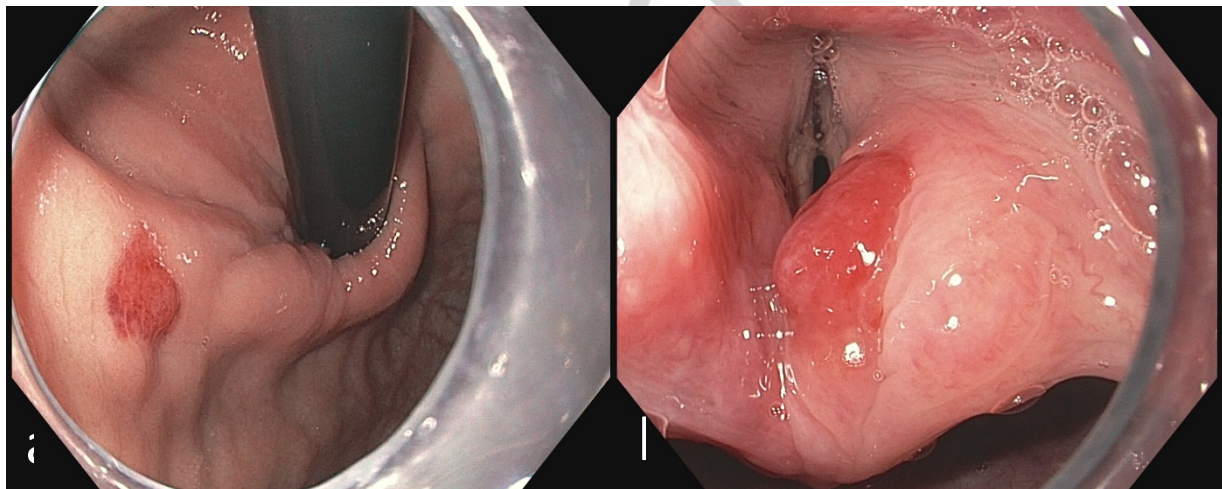


Figure 3. Kaposi sarcoma suspicious lesions. a. Erythematous nodular lesion located 1 cm distal from the cardias on the gastric lesser curvature. b. Erythematous nodular lesion located on the right arytenoid cartilage.