Comparison of Cap-Assisted vs Conventional Endoscopic Technique for Management of Food Bolus Impaction in the Esophagus: Results of a Multicenter Randomized Controlled Trial

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INTRODUCTION: **"Push" or "pull" techniques with the use of snares, forceps, baskets, and grasping devices are conventionally used to manage esophageal food bolus impaction (FBI). A novel cap-assisted technique has recently been advocated to reduce time taken for food bolus (FB) removal. This study aimed to compare the effectiveness of the cap-assisted technique against conventional methods of esophageal FB removal in a randomized controlled trial.**

METHODS: **Consecutive patients with esophageal FBI requiring endoscopic removal, from 3 Australian tertiary hospitals between 2017 and 2019, were randomized to either the cap-assisted technique or the conventional technique. Primary outcomes were technical success and FB retrieval time. Secondary outcomes were technical success rate, en bloc removal rate, procedure-related complication, length of hospital stay, and cost of consumables.**

RESULTS: **Over 24 months, 342 patients with esophageal FBI were randomized to a cap-assisted (n = 171) or conventional (n = 171) technique. Compared with the conventional approach, the cap-assisted technique was associated with (i) shorter FB retrieval time (4.5 ± 0.5 minutes vs 21.7 ± 0.9 minutes, $P <$ 0.001), (ii) shorter total procedure time (23.0 ± 0.6 minutes vs 47.0 ± 1.3 minutes, $P <$ 0.0001), (iii) higher technical success rate (170/171 vs 160/171, $P <$ 0.001), (iv) higher rate of en bloc removal (159/171 vs 48/171, $P <$ 0.001), and (v) lower rate of procedure-related mucosal tear and bleeding (0/171 vs 13/171, $P <$ 0.001). There were no major adverse events or deaths within 30 days in either group. The total cost of consumables was higher in the conventional group (A$19,644.90 vs A$6,239.90).**

DISCUSSION: **This multicenter randomized controlled trial confirmed that the cap-assisted technique is more effective and less costly than the conventional approach and should be first-line treatment for esophageal FBI.**

SUPPLEMENTARY MATERIAL accompanies this paper at http://links.lww.com/AJG/C193

Am J Gastroenterol 2021;00:1–6. https://doi.org/10.14309/ajg.0000000000001484

INTRODUCTION

Food bolus impaction (FBI) is one of the most common endoscopic emergencies in clinical practice worldwide (1–4). A food bolus (FB) can be removed by either a "push" technique with air insufflation and gentle pressure with the tip of the endoscope to push the FB into the stomach or a "pull" technique with the aid of various endoscopic devices such as snares, Dormia baskets, tripod graspers, forceps, and retrieval nets (5–10). However, endoscopic removal of FBs can be challenging because of a confined working space and impaired endoscopic visualization within the esophagus (2,8,9), leading to a risk of mucosal trauma, tears, bleeding, and even perforation (4,8,11).

A cap-assisted technique has emerged, involving the use of an endoscopic mucosal resection cap to engage the FB and provide powerful suction to remove the entire bolus en bloc (12–14). This technique has also been reported to be useful in removing other foreign bodies from the esophagus (15). In recent prospective nonrandomized studies (12,14), the cap-assisted technique was

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Received August 13, 2020; accepted June 29, 2021; published online September 20, 2021

found to have a higher technical success rate, shorter procedural time, fewer complications, and shorter length of stay compared with conventional techniques of FB removal. Given such promising observations, we aimed to compare the clinical outcomes between cap-assisted and conventional extraction of esophageal FBs in a large multicenter randomized controlled study.

METHODS

Study design

This was a randomized, multicenter study involving recruitment of patients with esophageal FBI from 3 high-volume Australian tertiary hospitals. Sample size calculations were based on our prospective nonrandomized study (14), using technical success and procedural time as the primary outcomes. A power calculation indicated that a sample of at least 170 patients in each group would be required to demonstrate a 5% difference in primary outcomes with a 2-sided significance level of 0.05 and a power of 80%. Human Research Ethics Committee and/or Institutional Review Board approval was obtained at all participating sites (HREC2017/110). All patients provided written informed consent, and the trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000290998).

Study protocol

All adult patients (18 years or older) who presented with suspected esophageal FBI that required endoscopic removal were invited to participate. Patients were excluded in the event of suspected nonfood foreign body ingestion, known or suspected pregnancy, or inability or refusal to give informed consent. Endoscopy was scheduled to be undertaken within 8 hours of consent and was performed by experienced endoscopists (more than 1,000 gastroscopies each), using Olympus endoscopes (180H and 190H; Olympus Optical, Tokyo, Japan), under general anesthesia with endotracheal intubation to minimize the risk of aspiration. The initial aim of endoscopy was to confirm the presence of esophageal FBI; patients without persisting FBI (e.g., due to spontaneous passage) were excluded from this study. In all subjects, gentle pushing of the FB into the stomach by the scope tip was attempted, and those in whom this was accomplished were excluded. Only subjects who still had the FBI after these measures were randomized to either (i) the conventional technique or (ii) the cap-assisted technique in a 1:1 ratio. The randomization, determined by random sequence generating software, was concealed using an opaque envelope system. Investigators were made aware of the treatment allocation only after the procedure had commenced. Because the allocation determined which devices were used, investigators could not be blinded, but patients were blinded to their allocation.

If the FB could not be removed within 15 minutes using the allocated technique, the endoscopists had the option to cross over to the alternative technique. All patients underwent an endoscopic assessment for procedure-related adverse event(s) immediately after the removal of the FB. A follow-up telephone interview or bedside review was performed at 24 hours and 30 days after the procedure. Data were collected by a dedicated research nurse and included patient demographics, clinical presentation(s), outcomes, type, size of the largest retrieved fragment, and location of FB, underlying esophageal pathologies, en bloc FB removal, FB retrieval time (FBRT), and total procedure time. The length of hospital stay (LOS), procedure-related adverse events, and 30-day mortality were also included in the database. Total costs of endoscopic consumables used in each group were calculated.

Conventional technique. The FB was removed by either en bloc or piecemeal extraction using 1 or more endoscopic devices including snares, retrieval nets, tripod graspers, and biopsy forceps. The selection of the devices and the use of an esophageal overtube were at the discretion of the endoscopist. Where feasible, once the majority of the impacted bolus had been extracted and fragmented, the protocol allowed the endoscopist to push the residual bolus into the stomach.

Cap-assisted technique. This approach involved attachment of an 18.1 mm disposable soft oblique transparent cap (Olympus Japan, model D-206-04) onto the tip of the endoscope, which was secured with adhesive tape (Figure 1a). After intubating the esophagus, the top of the FB was engaged into the cap and constant suction was applied, before attempting to withdraw the bolus from the esophagus en bloc. When necessary, the balloon of the endotracheal tube was deflated transiently to facilitate the transit of the cap through the upper esophageal sphincter and reinflated as soon as the tip of the scope traversed the upper esophageal sphincter.

Measured outcomes and definitions

Primary outcomes were technical success rate and FBRT. Technical success was defined as the complete removal of the foreign body at the end of the procedure without the need to cross over to the alternative technique; the latter was allowed after 15 minutes

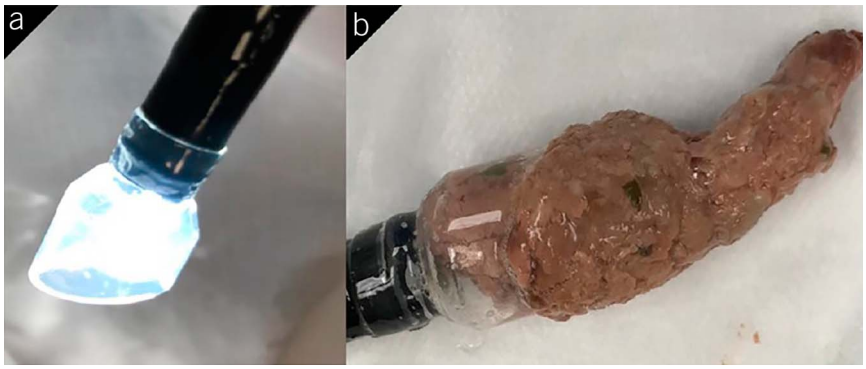

Figure 1. (**a**) A photograph of the cap device fitted onto the tip of a gastroscope. (**b**) A demonstration of en bloc removal of a food bolus using the cap-assisted technique.

but was at the discretion of the endoscopist. FBRT was taken as the time between the insertion of the allocated endoscopic device and the FB removal from the esophagus. Secondary outcomes were mean total procedure time, rate of en bloc FB removal, procedure-related adverse events, LOS, type, size, and location of FB within the esophagus, and cost related to the disposable devices used to remove the boluses. The total procedural time was measured as the time from the start of anesthetic induction to the time of endotracheal extubation at the end of the procedure and included the time to assess the mucosa and assemble endoscopic device(s).

A procedure-related adverse event was defined as any complication arising from the endoscopy, including anesthesia and endotracheal intubation. The adverse events were broadly categorized into major and minor events. Major events included perforation (evidence of extraluminal gas on cross-sectional imaging) and significant bleeding (defined as a decrease in hemoglobin concentration of >2 g/dL or a need for endoscopic intervention). Minor adverse events included chest pain, mucosal tear, or any other symptoms experienced by patients that did not require medical or surgical intervention.

Statistical analysis

Data were expressed as mean ± SD, and proportions were described as percentages. The 2 groups were compared using the Fisher exact test for dichotomous categorical variables, and the Student *t* test for continuous variables. Statistical significance was determined by a *P* value of < 0.05. Analyses were performed using GraphPad Prism statistical software, version 6 (GraphPad Software, La Jolla, CA).

RESULTS

During the study period, 507 patients met the inclusion criteria and were enrolled, and of these, 51 patients (10%) were excluded because of the absence of a FB in the esophagus. A further 114 patients (25%) were excluded after the push technique was successful in advancing the FB into the stomach. The remaining 342 patients (241M:101F, age 54.1 ± 14.9 years) were randomized to the cap-assisted technique (n = 171) or conventional technique (n = 171) (Figure 2). There were no differences in the demographic variables, type and location of FB, or the underlying esophageal pathology between the 2 groups (Tables 1 and 2). The most common FB location was distal esophagus (76.6%, n = 262), and most common FB type was beef (76.6%, n = 262). Peptic stricture (38.6%, n = 132) and eosinophilic esophagitis were the most common underlying abnormalities (Table 2).

Technical success

The success rate of FB removal was higher in the cap group than the conventional group (170/171 (99.4%) vs 160/171 (93.6%); $P < 0.001$) (Table 3). All 11 patients with failed FB removal by the conventional technique achieved successful FB removal in an en bloc fashion (Figure 1b) when crossed over. The mean duration taken to convert from the conventional technique to the cap-assisted approach was 17.6 ± 0.7 minutes. After conversion to the cap-assisted technique, a mean duration of 2.7 ± 0.4 minutes was required to remove the FB from these patients. One patient who failed the cap-assisted technique, because of the inability to advance the cap through the cricopharyngeus, had successful removal of the FB when crossed over with the use of a snare and retrieval net. In 2 patients, deflation of the endotracheal tube balloon was required to allow the insertion of the cap (n = 1) and to remove the FB (n = 1). The balloon was reinflated with minimal delay, and none of these patients sustained an aspiration event. An esophageal overtube was not adopted in any patient.

Procedural and clinical outcomes

The cap-assisted group had a shorter total procedure time (23.0 ± 0.6 minutes vs 47.0 ± 1.3 minutes, $P < 0.0001$) and FBRT (4.5 ± 0.5 minutes vs 21.7 ± 0.9 minutes, $P < 0.001$), with a higher rate of en bloc removal (159/171 [93%] vs 48/171 [28%], $P < 0.001$) (Table 3). The per-case ($115.0 ± 2.1 vs $36.5 ± 0.8; $P < 0.0001$) and total (A$19,644.90 vs A$6,239.90) cost of consumables used was significantly higher in the conventional group, as compared with the cap-assisted group (Table 2). There was no difference in LOS between the groups (cap-assisted = 1.0 ± 0.6 day vs conventional: 1.6 ± 1.4 days, $P = 0.17$).

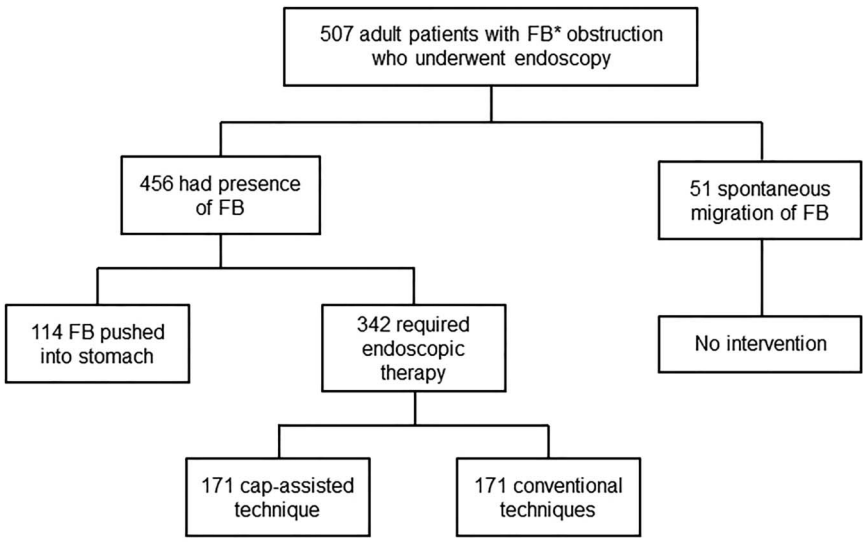

Figure 2. Outline of study recruitment.

Table 1. Patient demographics and clinical characteristics

Data	Cap-assisted group n = 171	Conventional group n = 171
Male sex, n (%)	119 (69.6)	122 (71.3)
Mean age (yr)	54.7 ± 15.2	53.6 ± 14.7
Symptoms, n (%)		
FB sensation	171 (100)	169 (99)
Chest pain	17 (9.9)	21 (12.3)
Hypersalivation	13 (7.6)	11 (6.4)
Regurgitation	4 (2.3)	3 (1.8)
Underlying disease, n (%)		
Peptic stricture	69 (40.4)	63 (36.8)
Eosinophilic esophagitis	48 (28.1)	51 (29.8)
None	40 (23.4)	44 (25.7)
Schatzki ring	8 (4.7)	9 (5.3)
Anastomotic stricture	6 (3.5)	4 (2.4)

Note some patients presented with more than 1 symptoms.
FB, food bolus.

Complications

There were no major adverse events or deaths within 30 days in either group. None of the patients had evidence of perforation or required blood transfusion or endoscopic intervention to achieve hemostasis. In the conventional group, there were more localized esophageal mucosal tears with associated minor bleeding than in the cap-assisted group (13/171 vs 0/171, $P < 0.01$). Sore throat, however, was more common with the cap-assisted technique (9/171 vs 0/171, $P = 0.003$), although this symptom resolved within 24 hours in all patients.

DISCUSSION

Although the incidence of impacted FB is increasing globally, mostly because of the increasing prevalence of eosinophilic esophagitis (7,16), the endoscopic techniques and approaches vary widely among centers. The push technique is more frequently used (31–74%) in the United States compared with Australia (17) but carries a risk of perforation. In fact, the American Society of Gastrointestinal Endoscopy cautions against the use of the push technique in cases where impaction is longer than 48 hours, EoE is suspected, or advancement is not easy (17). In these cases, a pulling technique is advocated, but extraction is often in a piecemeal fashion, requiring repeated and time consuming esophageal intubation. In practice, most endoscopists would try to dislodge the impacted bolus into the stomach with a gentle push technique, and if resistance is encountered, would change to a pulling approach. To our knowledge, this was the first randomized multicenter study that is sufficiently powered to evaluate the effectiveness of 2 available pulling approaches: a cap-assisted technique and a conventional technique. The results are consistent with our previous nonrandomized study, showing that the cap-assisted technique was associated with a higher rate of FB removal, a higher rate of en bloc removal, a shorter FBRT, and fewer procedure-related adverse events. Although any reduction in LOS with the cap-assisted technique was not statistically significant, the cost of endoscopic consumables used was approximately one-third of that in the conventional group. Given the near 100% technical success, a short procedure time, fewer complications, and lower cost, the use of the cap-assisted technique should be regarded as the first-line therapy for removing esophageal FBs after a gentle push fails to dislodge the bolus into the stomach.

Similar to the previous studies (12–14), the success rate of FB removal using a cap in this randomized controlled trial was very high (99.4% as compared with 100% in previous studies). Our single failed case occurred in an elderly woman of small stature known to have cervical osteophytes, where the cap could not be passed into the

Table 2. Differences in the type and location of impacted food bolus, type of accessory devices used, and the associated device cost between the cap-assisted group and the conventional group

Data	Transparent cap-assisted group n = 171	Conventional group n = 171	*P* value
Types of FB			
Steak	128 (74.9)	134 (78.4)	0.52
Pork	31 (18.1)	21 (12.3)	0.18
Lamb	8 (4.7)	8 (4.7)	1.0
Chicken	3 (1.8)	6 (3.5)	0.50
Others	1 (0.6)	2 (1.2)	1.0
Location of FB			
Distal	130 (76.0)	132 (77.2)	0.90
Middle	35 (20.5)	37 (21.6)	0.89
Proximal	6 (3.5)	2 (1.2)	0.29
Endoscopic devices used to extract the impacted food bolus			
Retrieval net	1[a]	98	<0.001
Snare	1[a]	47	<0.001
Rat-tooth forcep	0	68	<0.001
Tripod grasper	0	39	<0.001
Cap	171	11[a]	<0.001
Total devices	173	263	
Cost related to the endoscopic devices used (AUD $)			
Cap ($35.7 each)	$6,104.70	$35.70	
Snare ($22.0 each)	$22.0	$1,034.00	
Retrieval net ($113.20 each)	$113.20	$11,093.60	
Tripod grasper ($72.40 each)	0	$2,823.60	
Rat-tooth forcep ($68.50 each)	0	$4,658.00	
Per-case cost	$36.5 + 0.8	$115.0 + 2.1	<0.0001
Total cost	$6,239.90	$19,644.90	

In the conventional group, in some cases, more than 1 endoscopic devices were used per patient.
FB, food bolus.
[a]After failed method in the group.

Table 3. Differences in the rate of technical success, en bloc removal of impacted food bolus, retrieval time, complications, length of hospital stay, and 30-day mortality between the cap-assisted group and the conventional group

Data	Transparent cap-assisted group n = 171	Conventional group n = 171	*P* value
Technical success rate	170 (99.4%)	160 (93.6%)	<0.001
Rate of en bloc removal	159 (93.0%)	48 (28.1%)	<0.001
Length (mm)	52.3 + 20.7	26.6 + 27.5	<0.01
Width (mm)	17.6 + 2.9	8.3 + 9.2	<0.01
Bolus retrieval time (min)	4.5 ± 0.5	21.7 ± 0.9	<0.0001
Procedure time (min)	23.0 ± 0.6	7.0 ± 1.3	<0.0001
Complication			
Esophageal mucosal tear	0 (0%)	13 (7.6%)	0.01
Sore throat	9 (5.2%)		
Length of stay (d)	1.0 ± 0.6	1.6 ± 1.4	0.0017
30-day mortality	0	0	1.0

esophagus, and FB removal was ultimately achieved by switching to the conventional technique. Although the cap diameter is 18 mm, its oblique shape and soft texture usually allows passage through the upper esophageal sphincter with minimal resistance. In some case, transient deflation of the endotracheal tube balloon is necessary to facilitate insertion. It is likely that minor mucosal trauma in this region was responsible for sore throat in 9 patients, although this complication resolved rapidly in all cases. The smaller, shorter, more rigid cap used for variceal banding has been successfully used for FB extraction, but its efficacy has not reported in the literature. Further study is warranted to formally assess the role of this smaller cap for extraction of FBs.

The success rate of conventional techniques in bolus removal seemed to be lower than in previous studies (9–11). This is likely related to the study design, where switching to the cap-assisted technique was allowed when the conventional technique failed to extract the bolus after 15 minutes. Most boluses could eventually be removed by the conventional technique, often with a piecemeal approach, and this is reflected in the long procedural time (9–14). We allowed the endoscopists to switch techniques in this study; our previous retrospective report demonstrated very good outcomes with the cap, so it was ethically sound to do so (14). Not only did this allow the procedure to be completed sooner, but it may also have prevented the mucosal trauma associated with piecemeal removal using the conventional technique (14).

The major advantage of the cap-assisted technique is its ability to remove the impacted FB en bloc in most of the cases. This relates to the ability to apply strong suction through the cap to the FB surface and dislodge it from the surrounding esophageal wall. This, in turn, allows the impacted bolus to be removed rapidly as a whole, with minimal trauma to the surrounding mucosa. These findings are in keeping with previous studies that used the cap-assisted technique (14,15,18,19). As illustrated in this study, only a minority of impacted boluses can be removed en bloc by conventional techniques, leaving most to be retrieved in a piecemeal fashion. In a proportion of cases treated with the conventional technique, the fragments can be pushed or spontaneously migrate distally once the bolus is fragmented with piecemeal extraction (2,6,17). The repetitive maneuver of removal and reinsertion of the conventional device(s) and/or endoscope contributes to the longer time required for FB retrieval and a higher rate of localized esophageal mucosal trauma (14,15,18). Using a cap-assisted technique, Zhang et al. reported a similarly low rate of mucosal trauma to our study when removing esophageal foreign bodies (15,18). It is intriguing that, despites the repetitive intubation of the endoscope through the upper esophageal sphincter, sore throat was not reported in the conventional group (0% as compared with 5% in the cap-assisted technique).

In contrast to our previous nonrandomized study (14), any difference in LOS between the groups was small and not statistically significant. However, it should be noted that the LOS was short in both groups, and since a majority of patients had their procedures late in the day, most were required to stay overnight before discharge the following morning. Even if the hospital LOS did not differ, the marked reduction in cost of disposable devices used to retrieve the FB (approximately one-third of that in the conventional group) would justify the use of the cap-assisted technique as a first-line therapy for esophageal FBI.

Strengths of this study include its randomized design, which minimizes any potential selection bias, and its multicenter recruitment, which suggests that the findings can be generalized and that the cap-assisted technique is readily taken up by experienced endoscopists. Furthermore, the sample size was adequate to demonstrate a difference in the primary outcomes.

An overtube has been reported to be useful in removing foreign bodies from the esophagus, including impacted FBs (6,8,16). Its main purpose is to protect the airway. Our standard practice is for endotracheal intubation in all cases, which secures the airway from aspiration; this may be the reason for the lack of utilization of overtubes in this study. We believe that the combination of an endotracheal tube and an esophageal overtube creates difficulties because of a lack of space in the larynx and can induce trauma to the glottis and larynx.

In conclusion, our study suggests that if the push technique fails to remove an esophageal FB, the use of a cap device is superior to conventional devices in carrying out the pull technique. The use of a cap was associated with a higher success rate for FB removal, a higher rate of en bloc removal, a shorter procedural time, lower costs, and fewer endoscopy-related adverse events than the conventional methods.

CONFLICTS OF INTEREST

Guarantor of the article: Nam Q. Nguyen, MBBS, FRACP, PhD.

Specific author contributions: M.O.: data acquisition and interpretation, article drafting and revision, and statistical analysis. T.D.: data acquisition and interpretation, article drafting and revision, and statistical analysis. R.H.: data acquisition and interpretation, article drafting and revision, and statistical analysis. D.H.: data acquisition and interpretation, article drafting and revision, and statistical analysis. A.L.: data acquisition and interpretation, article drafting and revision, and statistical analysis. F.G.: data acquisition and interpretation, article drafting and revision, and statistical analysis. M.A.: data acquisition and interpretation, article drafting and revision, and statistical analysis. C.K.: critical article revision, data analysis and interpretation, and study supervision. N.Q.N.: study concept and design, data acquisition and interpretation, article drafting and revision, statistical analysis, obtained funding, and study supervision.

Financial support: The Departments of Gastroenterology at the Royal Adelaide Hospital and Queen Elizabeth Hospital provided in-kind support for this project, as patients who were included in the study did so as part of their treatment at these institutions.

Potential competing interests: None to report.

Registration details: Australian New Zealand Clinical Trials Registry (ACTRN12620000290998). https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=379292.

Study Highlights

WHAT IS KNOWN

- ✓ Food bolus (FB) impaction is a common endoscopic emergency seen in clinical practice worldwide.
- ✓ A food bolus can be removed by either conventional "push" or "pull" technique, with the aid of various endoscopic devices.
- ✓ A cap-assisted technique has been reported to be useful in removing foreign bodies in the esophagus.

WHAT IS NEW HERE

- ✓ Compared with conventional techniques, the cap-assisted technique is more effective in FB removal.
- ✓ The cap-assisted technique has shorter procedure time, higher en bloc removal rate, and lower rates of mucosal tear/bleeding.
- ✓ The cost of endoscopic consumables in the cap-assisted technique is approximately one-third of that in the conventional group.
- ✓ This randomized multicenter study provides strong support for the cap-assisted technique as first-line therapy for FB removal.

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