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Efficacy and safety of the SB Knife™ Jr. for the treatment of Zenker's diverticulum: a case series

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ABSTRACT

Background and aims: the stag-beetle knife is a new scissor-like endoscopic device that can be used for the treatment of Zenker's diverticulum, although experience is limited. The aim of this study was to evaluate the efficacy and safety of the SB Knife™ for the endoscopic treatment of Zenker's diverticulum.

Methods: a single-center prospective study of 16 patients was performed between May 2017 and April 2019. The rate of complications and symptom changes was evaluated.

Results: the median age was 78 years and 62.5% of the patients were male. All had dysphagia, 43.8% choking, 31.3% regurgitation and 6.3% respiratory symptoms. The median size of the diverticulum was 20 mm and the median follow-up was 281 days. There were no intra-procedure complications and only one major post-procedure complication was reported that was a microperforation. All patients had clinical improvement. Two patients had relapsing symptoms and were successfully treated with the same method.

Conclusions: the SB Knife™ seems to be a safe and effective technique for the treatment of Zenker's diverticulum.

Keywords: Zenker's diverticulum. Endoscopic septostomy. SB Knife™. Dysphagia.

INTRODUCTION

Zenker's diverticulum (ZD) is a "false" diverticulum that includes the mucosa and submucosa, which is located in the upper part of the cricopharyngeal muscle (1). It is a rare condition and the most common clinical manifestation is dysphagia (1). Historically, the treatment of choice was surgery, which is being replaced by endoscopy. The advantages of this approach are a lower rate of complications and a shorter intervention time and hospital stay (2-4). There are several endoscopic devices such as the needle-knife, LigaSure® and argon-plasma, as well as the most recently commercialized stag-beetle knife (SB Knife™) (5). The aim of this study was to evaluate the efficacy and safety of the SB Knife™ for the endoscopic treatment of ZD.

METHODS

This was a single-center prospective study of 16 patients with ZD (Table 1), selected between May 2017 and April 2019. Information about symptoms and their severity was collected, using the Dakkak-Bennet scale for dysphagia (0 = no dysphagia, 1 = solids, 2 = semi-solids, 3 = liquids, 4 = aphagia) (6).

All procedures were performed in a conventional endoscopy room by the same endoscopist, with previous experience in the treatment of ZD with LigaSure®. Patients were deeply sedated with propofol by an anesthesiologist but were not placed under orotracheal intubation. No patient received antibiotic prophylaxis due to the current tendency of clinical guidelines to eliminate this precaution for endoscopic procedures (7). A conventional Pentax CO_2 gastroscope, a SB Knife™ Junior device (Sumitomo Bakelite LTD, Tokyo, Japan) and a diverticuloscope were used in all procedures. The SB Knife™ was inserted through the working channel, acting as a scissor by initially grabbing the diverticulum septum and cutting the mucosa and submucosa using the endocut mode (60/40 W), and then dissecting the septum until the septostomy is

complete. No prophylactic hemoclips were placed due to the endoscopists' perception of a low risk of bleeding.

All patients were hospitalized with intravenous fluid therapy. If there were no complications, patients started a liquid diet and were discharged from hospital 24 hours after the procedure. The rates of complications and symptom changes were evaluated. This technique was approved by the Ethical Committee for this indication and the study met the principles of the Declaration of Helsinki. All patients signed the informed consent.

The IBM SPSS Statistics 19 software was used for statistical analysis.

RESULTS

Sixteen patients were included in the study with a median age of 78 years (interquartile range [IQR] 11, range 47-93) and 62.5% were male. None had a personal history of surgery or cervical trauma, or a family history of ZD. One patient had previously undergone endoscopic treatment with a needle-knife. All patients (100%) had dysphagia (average score 2.13 ± 0.34), 43.8% choking, 31.3% regurgitation and 6.3% respiratory symptoms. The median size of the diverticulum was 20 mm (IQR 13.7, range 10-40).

There were no intra-procedure complications and there was only one major post-procedure complication, which was a microperforation that was resolved after a fasting period, parenteral nutrition and antibiotic therapy. There were no hemorrhages. All patients were discharged from the hospital 24 hours after the procedure, except for three cases. One patient had pain and fever and stayed for 72 hours, another had pain and stayed for 48 hours and another patient who suffered a microperforation stayed for 13 days. The median follow-up was 281 days (IQR 123, range 25-706). All patients had clinical improvement, but two (12.5%) had a clinical relapse and were successfully treated with the same method.

DISCUSSION

Endoscopic treatment of ZD is evolving due to its lower rate of complications, shorter intervention time and hospital stay compared to surgical treatment (2-4). Therefore,

more and more devices are emerging, such as the SB Knife™. However, data on its efficacy and safety are still lacking and the published series are small. The study published by Battaglia et al. (8) included 31 patients with ZD that were treated with the SB Knife™. There were no peri-procedure complications and only one post-procedure complication (a hemorrhage) and five cases (19.3%) of clinical recurrence. The median follow-up time was seven months. The study by Goelder et al. (9) included 52 patients treated with this method and five (9.6%) had a clinical recurrence. There were five intra-procedure and three post-procedure complications and the median follow-up was 16 months.

In our study, all patients had clinical improvement after the procedure but two (12.5%) had a clinical relapse. Both were successfully treated with the same method. The rate of complications was low and all were mild, except for the microperforation, which was successfully treated in a conservative manner. We wish to highlight that in this case, the complication may have been related to a large septostomy for a small diverticulum (10 mm). However, we decided to treat it because the patient experienced many symptoms. We would also like to emphasize that, since there were three cases of fever (including the microperforation), it may be convenient to consider antibiotic prophylaxis from now on. Finally, we would also like to mention that there were no hemorrhages, either immediate or deferred. Thus, we believe that prophylactic hemoclips are not necessary. The median follow-up of the study was 281 days.

These results are comparable to other endoscopic devices (10-14) but this method has several advantages from our point of view. On the one hand, the SB Knife™ is inserted through the endoscope working channel, so it is easier to manage than the LigaSure® system, which is inserted parallel to the endoscope. On the other hand, it cuts but also coagulates and thus decreases the risk of bleeding, unlike the needle-knife. The main limitation of the study is the lack of a direct comparison with other endoscopic devices or surgery, as well as the small sample size.

In conclusion, we consider that endoscopic treatment of ZD with the SB Knife™ is a safe and effective option, as it is a minimally invasive technique with a low rate of complications and a high rate of technical success. However, larger sample sizes, a

longer follow-up and comparative studies with other endoscopic devices and surgery are needed.

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Table 1. Baseline characteristics of patients

Demographic characteristics	
Age, years, median (IQR, range)	78 (11, 47-93)
Previous treatments, n (%)	1 (6.2)
Clinical characteristics	
Dysphagia, n (%)	16 (100)
Choking, n (%)	7 (43.8)
Regurgitation, n (%)	5 (31.3)
Respiratory symptoms, n (%)	1 (6.3)
Malnutrition, n (%)	0 (0)
Dysphagia score, mean ± DT	2.13 ± 0.34
Endoscopy	
Diverticulum size, median (IQR, range), mm	20 (13.7, 10-40)
Food retention, n (%)	3 (18.7)
Complications	
Intra-procedure	0 (0)
Post-procedure	4 (25)
Pain, n (%)	2 (12.5)
Fever, n (%)	3 (18.7)
Hemorrhage, n (%)	0 (0)
Perforation, n (%)	1 (6.3)
Follow-up	
Follow-up, days, median (IQR, range)	281 (123, 25-706)
Relapse, n (%)	2 (12.5)
Total	16

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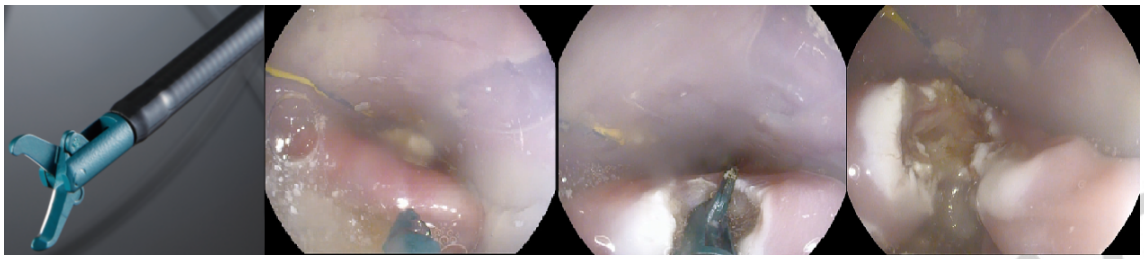

Fig. 1