LARYNGOLOGY



# Long-term results using LigaSure<sup>TM</sup> 5 mm instrument for treatment of Zenker's diverticulum

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Abstract The purpose of the present study was to evaluate the long-term results and patient's satisfaction of a new approach using the LigaSure<sup>™</sup> 5 mm instrument for treatment of Zenker's diverticulum (ZD) and to compare with other long-term results using traditional treatment modalities. Between December 2011 and August 2013, a total of 23 patients with ZD underwent endoscopic surgery using the LigaSure<sup>TM</sup> technique in our department. A retrospective evaluation of the surgery was based on medical records and additionally a long-term follow-up was performed using a standardized questionnaire that was send to all patients. The questions dealt with complaints according to a visual analog scale (VAS) and were sent a minimum of one year after the surgery (mean time 22 months, range 12-32 month). The overall response rate was 91%. The mean age of the patients was 69 years (range 37-89 years). The patients reported nine for overall satisfaction on the VAS (range 0-10: 10 being very content and 0 very uncontent, 25 and 75% quartiles: 7 and 10) regarding the final outcome of their surgery, although several of the patients had continuous symptoms within the first postoperative year. Eight patients (38%) reported no symptoms at all. Our results suggest that endoscopic management of ZD with the

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LigaSure<sup>TM</sup> 5 mm instrument is a minimally invasive, fast and safe method with solid long-term outcome with relief of symptoms and patient satisfaction. This new operative instrument was not found inferior to traditional endoscopic techniques and is now the standard treatment method for ZD in our departments.

**Keywords** Dysphagia · Zenker's diverticulum · LigaSure · Treatment · Outcome

### Introduction

Zenkers' diverticulum (ZD), synonyms hypopharyngeal diverticulum or pharyngeal pouch, was originally described in 1796 by Ludlow [1] and further explored in 1877 by the German physician Zenker [2]. This rare mucosal pouch permeates through the dorsal wall of the hypopharynx in a weak area between the oblique fibers of the inferior pharyngeal constrictor muscle and the horizontal fibers of the cricopharyngeal muscle, the triangle of Killian, resulting in interruption of mechanic passage of the food bolus through the hypopharynx into the narrow oesophageal inlet. Although the pathogenesis of the diverticulum is still unknown, van Overbeek et al. [3] have demonstrated structural changes in the cricopharyngeal muscle, which might be of importance. Age is, however, unquestionably a factor of significance, as the disease is rarely seen before the age of 40 and the classical patient is demonstrating symptoms during the seventh and eighth decade of life.

Predominating symptoms of ZD are progressive dysphagia and regurgitation of undigested food. However, patients may also present with more serious sequelae like repeated lung infections due to aspiration, mucus in the throat, chronic cough and weight loss, which affect their life quality significantly.

Treatment is recommended for symptomatic patients and surgery is the only effective approach since its successful introduction over a century ago [4]. During the last decades, the technique has shifted from traditional open transcervical approach towards less invasive endoscopic transoral approach using carbon dioxide (CO<sub>2</sub>) laser or stapler techniques to divide the hypopharyngeal septum [5–7]. Recently, a new endoscopic approach has been introduced, the LigaSure<sup>TM</sup> system, which is designed to reduce blood loss and operative time. The system is already widely used in, e.g. thyroid surgery but is new to ZD. The literature is therefore rife with endoscopic publications comparing the two main techniques [5, 8–10]. For the new LigaSure<sup>TM</sup> approach in ZD treatment, very little has been published [11, 12].

In 2014, our department at Rigshospitalet published the results after endoscopic surgery of 15 patients with ZD using LigaSure<sup>TM</sup> 5 mm technique [11]. However, the mean follow-up was limited to 9 months. The aim of the present study is to update our data from the 2014 survey by inclusion of more patients, with focus on long-term outcomes and patient satisfaction after surgical therapy of ZD using the LigaSure<sup>TM</sup> technique for endoscopic mucomyotomy.

### Materials and methods

We prospectively registered all procedures in patients who were treated for ZD using the LigaSure<sup>TM</sup> 5 mm–37 cm blunt tip instrument (Covidien, Mansfield, MA, USA) for endoscopic mucomyotomy at Rigshospitalet in the period between December 2011 and August 2013. The patient data were obtained by retrospective review of the medical records, including anaesthetic data, and the long-term results were acquired by sending the patients a questionnaire. A total of 23 consecutive cases were evaluated.

The diagnosis was in all patients confirmed by a barium radiography of the hypopharynx and the oesophagus. Each patient received complete medical evaluation and clearance for anaesthesia before surgery; general anesthesia with oral intubation was used in all of the patients. The therapeutic procedure was performed by placing the two branches of the Dohlmann rigid steel diverticuloscope in the diverticulum and oesophagus to expose the diverticular septum. The LigaSure<sup>™</sup> instrument was used to coagulate and seal laterally in both sides to achieve effective haemostasis and finally coagulate, seal and cut in the middle between the branches making a division of the septum. The operation was in all cases performed or supervised by either one of the two senior surgeons committed to the project. For more details, the procedure has been described previously and is available as video via YouTube [11].

After surgery, the patients were kept under observation in the hospital. If there was no development of fever, chest or back pain, oral intake of clear fluids was allowed 6 h after the procedure. Soft food diet was given on the first postoperative day and providing there were still no complications, the patient was discharged the day after surgery. A normal solid diet was recommended resumed after 1 week.

A standardized questionnaire was send by letter minimum one year after the primary surgery using a visual analog scale (VAS) varying from zero to ten (Fig. 1). We used a questionnaire in Danish consisting of seven complaints after Zenker divertulum surgery. The same questionnaire was used in a former study from our institution concerning long-term results after  $CO_2$ -laser treatment [13]. The answers are thus directly comparable between these two studies from the same institution. Results are reported as median score with interquartile range (25 and 75% quartiles) and ranges when appropriate. The data were analysed in Microsoft Excel ver. 14.0.0 2011.

Approvals from The Danish Data Protection Agency, as well as the local Regional Committee on Health Research Ethics, were applied before initiation of the study, though neither was found required after evaluation.

## Results

The mean size (depth) of ZD was 2.8 cm (range 1–6 cm) measured preoperatively and mean procedure duration was 34 min (range 14–72 min). The surgery lasting 72 min also included removal of a lymph node for another reason (with this surgery excluded, the mean procedure duration was 31 min).

Nineteen patients (83%) could resume oral intake the first day after surgery. One patient (4%) was diagnosed with perforation of the oesophagus but without fever and recovered completely on conservative treatment and antibiotics. This, however, prolonged the hospital stay to 11 days after the procedure.

Three patients (13%) had postoperatively fever but no detectable perforation and were treated with antibiotics. One patient (4%) experienced hoarse voice after surgery, but did not have any palsy of the vocal cords and the hoarseness was explained by reflux. The average length of stay was two days (range 1–11 days) in excess of the day of surgery. Three patients were previously operated for ZD, one by CO<sub>2</sub>-laser and two (8.7%) by the LigaSure<sup>TM</sup> technique. General questions to which the patients could answer 'yes' or 'no':

- 1) Do you need to take into account what you are eating due to your former diverticulum?
- 2) If yes, which food items are a problem?
- 3) Do you, in your opinion, cough due to your former diverticulum?
- 4) In your opinion, do you have regurgitation due to your former diverticulum?
- 5) Do you take any medications against reflux, ulcers or esophageal hernia?
- 6) In your opinion, do you loose weight due to your former diverticulum?
- 7) Do you have a problem eating with others due to your former diverticulum?

Questions evaluated on a visual analogue scale (VAS):

- 1) On a scale from zero to ten, zero being very dissatisfied and 10 very satisfied, how do you evaluate the result of the operation for your diverticulum?
- 2) On a scale from zero to ten, zero being no pain and ten being worst possible pain, how do you evaluate your pain at rest from your former diverticulum?
- 3) On a scale from zero to ten, zero being no pain and ten being worst possible pain, how do you evaluate your pain from your former diverticulum when eating?
- 4) On a scale from zero to ten, zero being no coughing and ten being worst possible cough, how do you evaluate your coughing from your former diverticulum when eating?
- 5) On a scale from zero to ten, zero being no regurgitation and ten being worst possible regurgitation, how do you evaluate your regurgitation from your former diverticulum when eating?
- 6) On a scale from zero to ten, zero being no nightly symptoms and ten being worst possible symptoms during night, how do you evaluate your night symptoms from your former diverticulum?

Fig. 1 Questionnaire sent to the patients translated from the original Danish language to English

Symptoms	Yes	No
Normal food intake without any limitations	12 (57%)	9 (43%)
Cough due to their former diverticulum	5 (24%)	16 (76%)
Regurgitation problems	7 (33%)	14 (67%)
Medication against reflux	16 (76%)	5 (24%)
Weight loss	3 (14%)	18 (86%)
Problems eating socially with others due to any symptoms	3 (14%)	18 (86%)
No symptoms at all	13 (62%)	8 (38%)

 Table 1
 Results of the questionnaire for long-term follow-up and patient satisfaction in 21 patients treated for Zenker's diverticulum

# Questionnaire long-term follow-up and patient satisfaction

The results of the questionnaire long-term follow-up and the questions evaluated on a visual analogue scale (VAS) are shown in Tables 1 and 2.

Out of the 23 patients treated, 2 patients had dementia and could not answer the questionnaire. Hereby, 21 (91%) consecutive patients were included in the evaluation of the symptoms and all answered the questionnaire. Eleven were males and ten were females, with a median age of 69 years (range 37–89 years). Mean time for evaluation after surgery was 22 months (range 12–32 months).

Twelve patients (57%) reported normal food intake without any limitations, whereas nine (43%) had to consider what they were eating. The most common food items causing problems were meat, bread and dry foods.

Sixteen patients (76%) did not cough due to their former diverticulum, whereas five (24%) thought they did. Fourteen (67%) had no regurgitation problems, whereas seven (33%) had. Sixteen (76%) took medication against reflux; five (24%) did not. The vast majority, 18 (86%) presented with no weight loss and 18 (86%) had no problems eating socially with others due to any symptoms. Overall, eight patients (38%) reported no symptoms at all.

When asked about how they would evaluate the overall outcome of their surgery on a VAS, the median score was nine (25 and 75% quartiles: 7 and 10) (ten being very content and zero very uncontent).

On the VAS (zero no symptoms and ten worst symptoms), the median score when asked about pain in rest was zero (25 and 75% quartiles: 0 and 0) and zero (25 and 75% quartiles: 0 and 1) when asked about pain when swallowing. Regarding coughing, the median VAS score

 Table 2
 Results of questions evaluated on a visual analogue scale

 (VAS) in 21 patients treated for Zenker's diverticulum

VAS	Median score	25 and 75% quar- tiles	
Overall outcome of surgery <sup>a</sup>	9	7 and 10	
Pain in rest <sup>b</sup>	0	0 and 0	
Pain when swallowing <sup>b</sup>	0	0 and 1	
Coughing <sup>b</sup>	0	0 and 3	
Regurgitation <sup>b</sup>	0	0 and 3	
Any nightly symptoms <sup>b</sup>	0	0 and 1	

<sup>a</sup>Ten being very content and zero very uncontent

<sup>b</sup>Zero = no symptoms and ten = worst symptoms

was zero (25 and 75% quartiles: 0 and 3). Median VAS score was also zero when asked about regurgitation (25 and 75% quartiles: 0 and 3). Finally, the median VAS score was zero (25 and 75% quartiles: 0 and 1) when asked about any nightly symptoms.

### Discussion

This study evaluates the long-term results of endoscopic surgery for ZD using the LigaSure<sup>TM</sup> and compares the results with other long-term results using traditional treatment modalities for ZD. Our study used the VAS questionnaire approach, that we previously used in a study of long-term results after endoscopic CO<sub>2</sub>-laser treatment for ZD [13]. To our knowledge, no others have used VAS for evaluation of long-term results after ZD surgery nor when comparing with other international studies (Table 3), and none of these have assessed the quality of life for their patients.

The present complication rate is relatively high when compared with other international studies using endoscopic laser or stapling technique (Table 3), although results are difficult to compare mainly due to different items included as a complication. In the present study, we include postoperative fever as the only postoperative symptom as a complication, while this is not included in several other studies. A table with and without fever as a complication has, therefore, been made (Table 3A, B). We had one patient (8.7%) who was diagnosed with a postoperative perforation, which was treated successfully. Our rate of serious complications

Table 3 Literature of treatment outcomes and complications for different types of treatment for Zenker's diverticulum

Treatment, references	Patients (n)	Complications (%)	Symptom relief/ satisfaction (%)	Evaluation time (months)	Days admitted (mean)	Recurrence (%)
(A) Studies also including fever	as complicati	on				
Endoscopic CO <sub>2</sub> -laser						
Velser et al. [13]	37	14	67.8	60 (12–96)	3	24
Anagiotos [14]	62	Unknown	91	100 (11–216)	Unknown	8
LigaSure						
Nielsen et al. [11]	15	13	80	9 (5–14)	Unknown	13
Noguera-Aguilar et al. [12]	5	0	100 (60 <sup>a</sup> )	21 (18-30)	1.2	0
Andersen et al.	21	19	80	22 (12-32)	2 (1–11)	8.7
(B) Studies without including fe	ever as compli	cation				
Endoscopic stapling						
Chang et al. [15]	159	9	88	32.2 (3-85)	0.76	11.8
Endoscopic CO <sub>2</sub> -laser						
Nyrop et al. [16]	61	10	92	37 (3–96)	3	10
Anagiotos [14]	62	Unknown	91	100 (11–216)	Unknown	8
Murer et al. [17]	29	17	1 <sup>b</sup>	20.4	4	4
Lippert et al. [18]	34	2.9	88 <sup>c</sup>	Unknown	Unknown	9
Van Overbeek [3]	278	7	Unknown	Unknown	Unknown	Unknown
Zbären et al. [19]	31	6.4	97	Unknown	8	3.2
LigaSure						
Andersen et al	21	4.8	80	22 (12-32)	2 (1–11)	4.7

<sup>a</sup>3/5 patients reported perfectly well. Two patients developed dysphagia after 12 and 24 months, respectively, but without evidence of relapse of the diverticulum

<sup>b</sup>Median satisfaction score was 1 (0=no symptom, 15=worst result)

°88% were without symptoms

is thus highly acceptable and comparable with others and shows that the endoscopic approach with the LigaSure<sup>TM</sup> instrument is a safe and gentle method. In this series, we used LigaSure<sup>TM</sup> only and did not convert to any other technique.

The long-term patient satisfaction was eight on the VAS with 10 being very satisfied corresponding to a mean satisfaction rate of 80%. After CO2-laser treatment of ZD in 37 patients, we have earlier reported a satisfaction rate using the same questionnaire and VAS of 67% [13]. The questionnaire survey reveals several long-term symptoms that either persist after surgery or may recur later after surgery implying some mechanical problems in swallowing. This is, however, not surprising, as the endoscopic surgical technique in its nature does not remove the diverticulum but only removes the septum between the pouch and the oesophagus. The pouch is thus still present after surgery in contrast to a transcervical approach, where the pouch is totally removed. The most frequently reported longterm symptom is that 43% still have dietary limitations compared to 65% in our former study using the CO<sub>2</sub>-laser treatment [13]. Also, 19% do have symptoms causing problems to eat in a social setting corresponding to 22% in our former study [13]. Weight loss related to ZD was reported by 14%. However, we have no information on the magnitude of the weight loss or whether this was a problem for the patients or not. Pain, cough and nightly symptoms was reported with low scores on the VAS and comparable with the results from the  $CO_2$ -laser study [13]. The patients should be informed of this and maybe suggested a followup after approximately one year. Nevertheless, the recurrence rate noted in this study approximate the same range of previously published rates after treatment with endoscopic laser or stapling technique (Table 3). This supports the argument that the LigaSure<sup>™</sup> technique is effective to similar degrees in terms of long-term relief for the patient.

A cost analysis was not the purpose of our study, though a traditional cost analysis comparing the costs of  $CO_2$ -laser treatment, stapler and LigaSure<sup>TM</sup> would be of interest. Such a comparison is, however, complicated and will probably differ from country to country and between departments due to differences in surgery time and other procedures at the departments with use of the different equipments and devices.

The LigaSure<sup>TM</sup> technique has some advantages to other endoscopical techniques. Besides the instrument is very easy to handle, it has the advantages that it is designed with a small tip, a blunt end that can be rotated. In addition, the cutting edge is 1 mm cranial to the end of the tip of the instrument.  $CO_2$ -laser treatment of ZD requires an expensive laser and a microscope although often available in most ORL-departments. The laser treatment is often rather time consuming and considering the advanced age of the patient population, reduced time under anaesthesia is important. The stapler technique requires a larger endoscope as the tip of the instrument is much larger than the tip of the LigaSure<sup>TM</sup> instrument. The endoscope used for the stapler technique is also shorter and this in combination may create problems to position the endoscope and reach the diverticulum for satisfactory visualization.

The LigaSure<sup>TM</sup> technique is now part of our department treatment modalities for ZD and has become so in several ORL departments in Denmark.

Our study has some limitations. First of all, the study is small in number of patients. Also, it is partly retrospective but with several outcome measures obtained prospectively as they are standard measures after ZD surgery. We have not performed a randomised controlled study involving the different available treatment modalities. However, we consider this as impossible, since the prevalence of ZD is approximately 1:100,000 adults in Denmark [20] and such a study will demand a very large material to be able to find any significant differences. Also, it seems reasonable to claim that the differences between the endoscopic treatment modalities are small if any.

The strengths of the study are that all procedures were performed or supervised by either one of the two senior surgeons, thus providing a main consistency in terms of surgical approach and postoperative patient management. Furthermore, the study has a long observation time with a high overall response rate of the questionnaire at 91% and the results are complete. Finally, we used the same questionnaire as in a former study making results directly comparable.

### Conclusion

The study results suggest that endoscopic mucomyotomy of ZD with the LigaSure<sup>™</sup> instrument is a minimally invasive, fast and safe method with solid long-term outcome, as well as high patient satisfaction and also not inferior to other endoscopic techniques. We find it important to inform the patients that there is a tendency after treatment to initial relief of symptoms, but with a later risk of relapse of some symptoms.

#### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest and the study has been carried out without any funding.

**Ethical approval** This article does not contain any studies with human participants or animals performed by any of the authors.

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