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Is Myotomy Plus Diverticulopexy Suitable for Symptomatic Zenker's Diverticula?

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Abstract
The aim of the study was to prospectively evaluate the outcome of myotomy plus diverticulopexy over short and long-terms. A prospectively collected consecutive series (2007–2017) of 37 patients undergoing myotomy plus diverticulopexy was analyzed for clinical condition, operative information, peri-operative events, and follow-up by means of interview and physical examination. Diverticulopexy was scheduled regardless of the diverticulum's features and patient condition, other than operability. There was no choice or selection between possible treatment options. Patients were evaluated pre-operatively, at post-operative day 30 and after 1 year. Follow-up aimed at assessing the subjective condition following treatment. During the interview, patients were asked to self-assess their ability to swallow before and after surgery. No patient had peri-operative events, complications associated with the procedure, wound infection or impaired swallowing. All patients could start drinking the day after operation, could return to solid diet on post-operative day 2 and be discharged on post-operative days 3–4. Barium swallowing was not necessary before discharge. Full solid diet was resumed according to patient's compliance from post-operative day 2 (some patients refused solid diet soon after the operation even if asymptomatic). Follow-up ranged between 1 and 8 years. No patient was lost at follow-up. No disease recurrence was observed. Finally, no patient needed or sought for a clinical examination between the follow-up calls. Patients reported at least 50% improvement of symptomatology after 1 year. Diverticulopexy appears to be clinically safe, methodologically reproducible, and an effective procedure; it avoids suturing and offers good outcome results along with high patient satisfaction.

Keywords Zenker's diverticular pouch · Myotomy · Diverticulopexy · Diverticulectomy · Esophagus · Deglutition · Deglutition disorder

Introduction

The treatment for Zenker's diverticulum is palliative but still remains a matter of discussion regarding the approach. In fact, there are several options to clinically restore adequate swallowing mainly endoscopic and surgical procedures. There is neither a consensus on the best treatment option and nor an effective etiological medical therapy [1].

Recent investigations into novel possibilities have led to enthusiasm for endoscopic procedures. However, trans-oral techniques are not totally favored by the scientific community because of the incomplete myotomy and blind distal suture [2]. Being so, surgery remains the only option that is widely performed. It is based upon cricopharyngeal myotomy and diverticulectomy or diverticulopexy is usually added to complete the procedure. Specifically, diverticulectomy has been preferred over diverticulopexy because is deemed to better restore the esophageal anatomy, but the risks associated with suturing/stapling and removing the diverticulum need to be carefully weighed

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when considering this procedure; both endoscopic and open diverticulectomy require leaving a suture line or staples, while diverticulopexy does not entail a mucosal resection [3].

In this regard, we performed an observational study on prospectively collected data concerning a consecutively enrolled series of patients undergoing myotomy plus diverticulopexy. The aim of this case series analysis was to evaluate the operative, peri-operative, short- and long-term outcomes after diverticulopexy, performed regardless of general and local conditions and without having hypothesized for other treatment options pre-operatively.

Patients and Methods

Thirty-seven patients complaining specific symptoms of Zenker's diverticulum were prospectively enrolled in this case series with their consent between 2007 and 2017. All patients, 8 females and 29 males, age ranging between 52 and 83 years (median 71), were recommended myotomy and diverticulopexy via left cervicotomy after general medical evaluation and barium swallow test. The patients were informed of other treatment options; the choice of diverticulopexy was not influenced by radiological findings, patient condition, habitus or past medical history. Moreover, whenever unexpected intra-operative findings had indicated a possible need to remove the pouch, diverticulectomy was not "a priori" excluded and patients were fully informed of this possible occurrence. No patient refused to undergo diverticulopexy. No other procedure in the treatment for Zenker's diverticulum was performed during the study period.

All intra-operative and peri-operative data were recorded and patients were followed up for at least 1 year through interview and physical examination. The pouch size was evaluated utilizing the most recent pre-operative barium swallow test and it was also measured intra-operatively.

The procedure was performed by a single surgeon through a short left longitudinal cervicotomy. Peri-diverticular tissue dissection was first carried out with the complete diverticular sac dissection. Myotomy was conducted with the use of $2.5 \times$ surgical magnifying glasses to include all the fibers of the cricopharyngeal muscle and the upper 2 cm of the esophageal muscular layers. The prevertebral fascia adjacent to the pharynx was then exposed and the bottom of the diverticulum was turned upsidedown and attached to the fascia, in an antigravity position, with 4-0 non-absorbable monofilament stitches. Any possible torsion of the suspended diverticulum was avoided. Despite the absence of a suture, the water seal test to rule out unexpected damage of the mucosa was routinely performed. A n.7 Jackson-Pratt drain was left in place.

Follow-up aimed at assessing the subjective condition following treatment. During the interview, patients were asked to self-assess their ability to swallow before and after surgery: 0% = the impossibility to swallow; 100% = problem-free swallowing. The limit to define patient satisfaction was 85% and patients were told to place themselves above 85% if satisfied or below 85% if not. This method is not a validated assessment scheme but already used in past publication [4]. We decided not to use the common dysphagia assessment tools, considering we were not trying to grade, to categorize, or to describe the kind of dysphagia. In fact, dysphagia assessment tools are aimed at going into deep of quality, timing, et cetera of the swallowing impairments, thus they are possibly unsound or even misleading for our study in which we just wanted to know the perceived condition of the patient. Moreover, patients were asked to report about their satisfaction according to a tree-tier spectrum of choice—low/medium/high—after 1 year. Barium swallowing test was performed long-term (between 12 or 18 months) to evaluate for recurrence even in the asymptomatic status.

Statistical Analysis

Microsoft Excel and R statistic version 3.3.3 (R Foundation for Statistical Computing, Vienna, Austria) were used for the statistical analyses. Homoscedasticity of the data was assessed using the Shapiro–Wilk's test for normality and Levene's test for equality of variance. Data are presented as median and range. The scores given by the patients at each considered times (pre-op, post-op 1, post-op 2 e post-op 3) expressed by subjective percentage of wellness were analyzed using a repeated-measures Friedman ANOVA followed by multiple comparison post hoc test to localize differences (packages "coin" and "multicomp").

The percentages of improvement in the score at 30 days, 1 year and more than 1 year were calculated using the percent variance formula. Differences between GERD groups (negative vs. positive) were assessed for patients' age, duration of symptoms, diverticulum size (radiographic finding and intra-operative record), dysphagia scores, and percent variances at each considered time using Student's t test or Mann–Whitney's U test, as appropriate; Chi squared test was used to assess differences in the sex between GERD groups. Statistical significance was set at $p < 0.05$.

Results

Patient characteristics are listed in Table 1. Dysphagia resulted being the most commonly reported symptom with onset on average 1 year before referral to the specialist. Other symptoms included: regurgitation, halitosis, sialorrhea, general discomfort, rumination, gurgling, cough, and odynophagia. The most commonly recorded systemic comorbidity was gastroesophageal reflux disease (46%) and its symptoms varied largely in terms of evolution and duration; other concomitant diseases including mild dementia, geriatric disorders, electrolyte imbalance, and chronic ischemic heart disease were found. Patients sought

Table 1 Patients characteristics

Sex	Age	GERD + PPI	Duration of symptoms (months)	Diverticulum size (mm)—radiograph	Diverticulum size (mm)—intra-operative
M	52	+	8	40	22
M	60	−	12	40	16
M	77	+	5	35	16
M	78	−	6	30	12
M	67	−	12	37	17
M	66	−	18	50	24
M	57	+	36	45	20
M	65	−	12	30	12
M	69	+	5	40	20
M	73	−	12	60	28
M	61	−	12	60	31
M	70	+	9	40	18
M	81	−	12	66	30
M	79	+	24	40	20
F	83	+	12	25	20
M	81	+	24	25	12
M	62	−	18	30	11
M	70	−	24	25	13
M	68	+	18	40	18
M	80	+	23	23	16
M	61	−	22	35	16
M	67	+	10	28	12
M	73	−	12	40	37
F	71	+	48	60	65
M	78	−	20	20	20
M	76	−	12	40	20
F	77	+	15	35	17
F	71	−	48	25	12
F	58	+	16	21	10
F	73	−	10	30	13
M	66	−	19	36	30
M	77	−	60	31	14
M	70	+	24	22	18
M	81	+	28	26	19
M	69	−	150	45	22
F	64	−	20	20	13
F	76	+	120	20	10

GERD + PPI gastroesophageal reflux disease under therapy with protonic pump inhibitors

clinical care for ongoing symptoms from 3 months to 5 years after initial onset.

The size of the diverticulum was calculated at imaging and intra-operatively. The diameter was reported to be from 20 to 66 mm at the most recent radiography, while it was found to be generally half of this value, when measured intra-operatively.

No patient had to undergo unscheduled diverticulectomy, so all scheduled diverticulopexies were performed, regardless the local condition and diverticulum's features. Diverticulopexy was never found to be inappropriate or unfeasible for the local conditions by the surgeon with the sole exception of a diverticulum too small to be suspended.

All patients returned to drinking on post-operative day 1 and were allowed to return to solid diet on post-operative day 2. Full solid diet was resumed according to patient preference (patients were free to choose on a spectrum of foods with a range of solidities). Patients were discharged between post-operative days 3 and 4. No wound complications were reported and no diverticulopexy related complications were described. Drainage was removed on post-operative day 1 in all patients. Barium swallow test was not performed before discharge, as no clinical elements supported it (no sutures, no complaints of dysphagia post-operatively, no difficulty at swallowing water or semi-solid/solid food). All patients had uneventful recoveries for surgical-related morbidity.

Follow-up results are reported in Table 2. Patients were evaluated at 30 days and 1 year after surgery. Overall 34/37 patients were contacted a third time to check on their condition after 1 year. The remaining ones have post-operative time shorter than 1 year. Follow-up ranged between 9 and 96 months (Me: 51). No patient was lost at follow-up and no admission to hospital for recurrence of dysphagia was reported. Several patients were affected by comorbidities that negatively impacted their general condition, but upper gastrointestinal tract problems were never recorded. Physical examination did not reveal surgery-related events at 30 day and 1 year follow-up. Cervicotomy resulted being well tolerated for all patients included in the series. When comparing data on pre-operative and post-operative patient condition at 30 days and 1 year, a slight mean improvement at 1 year was observed, probably due to the recent surgery after 30 days. When asked about treatment satisfaction, all patients responded "high" out of a possible: low/medium/high scale, after one year.

Despite the non-etiological nature of the treatment and the importance of patient symptomatology, 19/34 patients accepted to undergo the Barium swallow test as a long-term test (Gastromiro swallow test, Bracco SpA, Milan, Italy). No radiological findings supporting relapse or other loco-regional alterations were observed by the radiologist who was aware of the patient's surgical history.

Overall, the range of the self-assessed condition, reported by patients pre-operatively, was 10–50% (Median 30; average 31.62). Post-operative condition ranged from 80 to 100% (Median 95; average 94.59) at 30 days and, from 90 to 100% (Median 100; average 94.85) at 1 year. There was a significant increase in the score between the pre-operative and post-operative ($p < 0.001$); multiple comparison statistical analysis is reported in Fig. 1. A single decrease to 50% was reported after more-than 1 year by one patient; also in this patient, barium swallow test did not reveal any diverticulum recurrence.

There was no significant difference between GERD groups (positive or negative) regarding age of patients ($p = 0.44$), sex ($p = 0.28$), duration of symptoms ($p = 0.85$), diverticulum size at radiographs ($p = 0.29$), intra-operative diverticulum size ($p = 0.74$), pre-operative score ($p = 0.09$), post 30 days ($p = 0.92$), post 1 year ($p = 0.65$), post more than 1 year ($p = 0.81$), percent variance at 30 days ($p = 0.10$), at 1 year (0.19), and at more than 1 year ($p = 0.14$).

Discussion

Zenker and Von Ziemssen first reported on the clinical condition today known as Zenker's diverticulum in 1878 [5]. They described the acquired outpouching of the esophageal mucosa due to a high pressure in the pharyngeal tract after sequential incoordination between the pharyngo-esophageal muscles [6]. The etiology of this disease has been ignored, so the only currently available treatment options are palliative. We do know that this disease has a sneaky development, which is consistently correlated to the volume of the pouch increase with esophageal axis deviation and diverticulum lumen filling leading to further progression. Although several clinical aspects can be taken into account, symptomatology is generally based on progressive dysphagia [7]. In fact, it is usually indolent and patients tend to neglect it until they are almost unable to swallow or even until the onset of severe complications including ab-ingestis pneumonia. Diagnosis is reached by Barium swallow test [8, 9] and our results suggest that a positive result from this test is sufficient to submit the patient to surgery.

Several aspects regarding surgical treatment are still matter of debate. A great interest and optimism regarding the merits of trans-oral endoscopy have been expressed [2, 10–12] especially for the lack of skin incision, the need for peri-operative management and for a reduced hospital stay that is unavoidably longer after surgery being the traditional operation associated to specific events and requirements. Despite good results reported from several series, endoscopic procedures have several limitations,

Table 2 Follow-up results, subjective condition related to dysphagia in four different moments: pre-operatively, at 30 days post-operation, 1 year post-operation and later than 1 year

Sex	Age	Pre-operative (%)	Post 30-days (%)	Post 1-year (%)	Later than 1-year (%)
M	52	20	90	90	90
M	60	25	95	100	100
M	77	45	100	100	100
M	78	10	100	100	100
M	67	40	100	100	95
M	66	25	100	95	100
M	57	35	90	90	90
M	65	30	90	100	100
M	69	30	95	100	95
M	73	30	95	100	100
M	61	25	95	100	100
M	70	25	100	95	95
M	81	30	90	90	100
M	79	30	90	100	100
F	83	40	95	100	100
M	81	40	100	100	100
M	62	30	100	100	100
M	70	30	85	100	95
M	68	40	90	100	100
M	80	30	90	90	70
M	61	10	80	90	90
M	67	50	80	100	100
M	73	40	100	100	100
F	71	30	100	100	100
M	78	40	90	90	90
M	76	30	90	100	90
F	77	20	100	100	70
F	71	10	90	90	50
F	58	40	100	100	100
F	73	30	100	100	100
M	66	40	90	95	90
M	77	40	100	100	100
M	70	30	90	100	–
M	81	40	100	100	–
M	69	40	100	–	–
F	64	20	100	–	–
F	76	50	100	–	–

which have been recently recognized and contested, in view of the standard principles described for this disease treatment that remain convincing [13]. A recent meta-analysis has reported complication rates associated with endoscopic treatments a bit lower than those after open surgery; but outcome after endoscopic procedures remain unacceptably high considering the recurrence rate of 10.9% [3] and the reported lack of the diverticulum neck exposure in about 30% of patients with consequent failure of the procedure [1]. Moreover, endoscopic cricopharyngeal myotomy with laser technology (Carbon-dioxide or

Thulium laser) has been associated to good results; it seemed to be safe and feasible with reduced intra-operative time, reduced length of hospital stay and has shown an acceptable complication rate [14–16]. However, this technique requires an experienced team in view of the high failure rate reported [17] and shows all the limitations characterizing all the other endoscopic procedures described for Zenker's diverticulum. Furthermore, the endoscopic approach is not well suited for large and small sized diverticula. In fact, in the latter, the exposure of the diverticulum can be difficult, while in the former, multiple
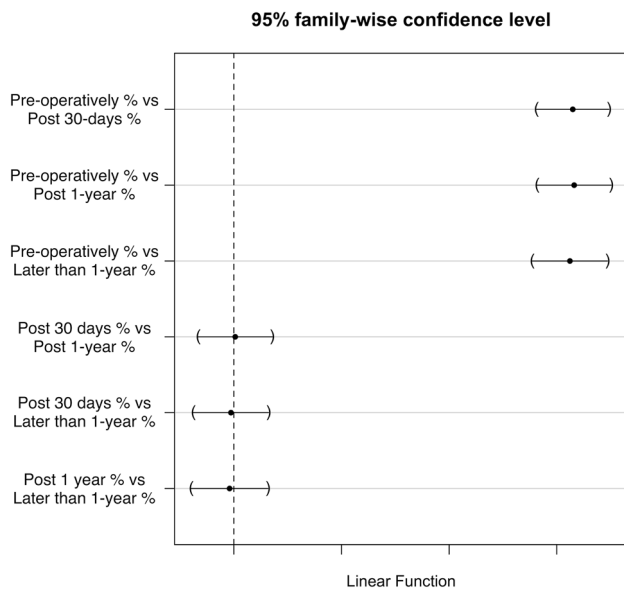
Fig. 1 Schematic representation of multiple comparisons showing the 95% family-wise confidence level of the different comparison. $p < 0.001$ between pre-operative condition and post-operative at 30 days, 1 year and later than 1 year; $p = 1$ between post-operative at 30 days and 1 year; $p = 0.997$ between post-operative at 30 days and later than 1 year; $p = 0.992$ between post-operative at 1 year and later than 1 year

stapler rows are required and entail a high risk of leakage. For all the proposed endoscopic techniques, the main concern is that the procedures entail a blind myotomy, with the risk of a partial crycopharyngeus muscle division. Indeed, an incomplete myotomy is possible after an endoscopic approach, as reported by past reported series, where repeated operative sessions were often required. On the other hand, re-operation has been reported to be less risky after a previous endoscopic approach than after open surgery. Another problem caused by the endoscopic treatment of large diverticula has been associated with the extent of a possible residual adynamic segment belonging to the upper esophagus; potentially compromising the esophageal motility [18]. We believe that endoscopic treatment, especially the flexible endoscopic method, is best suited for debilitated patients with middle-sized pouches, as general anesthesia is not usually required. Whereas, the precise cricopharyngeal myotomy through an open approach should be considered for all other patients, even in the absence of available evidence in Literature.

The central role of myotomy has been reported since the first description of this operation [19]. The myotomy relaxes the local environment and continuously decreases the intraluminal pressure guaranteeing the elimination of the disease-sustaining stimulus. The key concepts regarding the length of myotomy and the muscle fibers to peremptorily be included in the procedure have been

discussed and assessed [20]. Any other technique, surgical or endoscopic, that neglects this central issue is to be considered somehow suboptimal or at least an exception to the current gold standard.

Diverticulectomy and diverticulopexy are the most commonly performed accessory managements to myotomy for Zenker's diverticulum and few studies have compared them but no one study has been prospectively randomized [4, 21]. Furthermore, guidelines do not exist regarding treatment selection. In very small diverticula, surgeons preferring diverticulectomy over diverticulopexy may chose to leave the pouch in place to avoid the suture line. There is also a proposed indicative 4 cm pouch's diameter to set indication for diverticulectomy [22]. Both diverticulectomy and most of trans-oral treatments entail a suture line, which is not a simple suture because it needs to be placed on a motor disorder-related tissue in which the risk for solicitation is high. Recent studies reported a complication and failure rate much higher in endoscopic procedures (stapling or laser techniques) compared to those of open surgery [1]. For this reason, we sought to evaluate operative, peri-operative, short- and long-term outcomes after diverticulopexy, performed regardless of general and local conditions and without having hypothesized for other treatment options pre-operatively. In this case series review, we found that diverticulopexy was successfully performed in terms of overall outcome in all local conditions regardless of the diverticulum size. Likewise, the results above support the hypothesis that the diverticular sac becomes remarkably reduced in volume once it has been emptied and pulled upside-down, so it does not create mass effects or fill space. To this regard, a recent study comparing diverticulectomy versus pexis, reported that an experienced radiologist was unable to recognize any radiographic differences between the two procedures when followed up with the barium swallow test at least 1 year after surgery [4].

The main advantage of diverticulopexis over diverticulectomy is that it does not require any suturing, thereby avoiding any risk of suture-related leakage. Additionally, the risk of suture leakage is even increased in cases of incomplete myotomy because of a possible tension, due to the same intraluminal pulsion that is responsible for the pathophysiology of the disease. Another important advantage of diverticulopexy is its lower risk of stenosis, compared to diverticulectomy. This fact has been rarely described though theoretically present and sufficiently important to have led to the widespread use of bougie in order to avoid excessively stressed narrowing of the lumen during suturing.

In this case series analysis, we found that myotomy and diverticulopexy had no associated morbidity or mortality and an excellent palliation of symptoms along with high

patient satisfaction. These results suggest that diverticulopexy may be suitable for the treatment of most Zenker's diverticula.

Another finding of potential practical value is the huge disparity between the measurements of diverticula diameter, obtained at the moment of Barium swallow test and at the moment of cervicotomy respectively. This result can be an important information for the endoscopic treatment planning if confirmed. For this scope, dedicated investigation focusing on this variable is needed.

The study limitations included the following: it was of an observational nature even though prospectively carried out study; information was an induced subjective response to the physician's interview with potential bias in the quality of data. Moreover, the lack of a comparison group does not allow to highlight real differences among different techniques.

Conclusions

Treatment selection for crycopharingeal diverticula needs to be based upon the following aspects: surgical incision versus endoscopy, hospital stay, precise versus blind myotomy, and pouch removal versus suspension. However, when considering all principles of the procedure methodology, the risks for complications and enduring effectiveness, our study suggests that diverticulopexy seems to be a suitable option for reducing symptoms, avoiding risks and preventing recurrence. Diverticulum suspension also seems to be feasible for large diverticula as this series showed that it was associated with relief of symptoms accompanied by a significant decrease in operative risks. Although the promising results, larger sample size, comparison groups, and randomized clinical trials are needed.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed Consent All involved subjects, or their legally authorized representative, provided informed written consent prior to study inclusion.

Human Rights The study was approved by the University of Perugia Medical School Institutional Review Board. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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