Flexible diverticulotomy for Zenker's diverticulum – a bicentric study

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Flexible diverticulotomy for Zenker's diverticulum – a bicentric study

Flexible Divertikulotomie bei Zenker-Divertikel – Eine bizentrische Studie

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ABSTRACT

Introduction Flexible diverticulotomy is an established procedure for the treatment of Zenker's diverticulum. In a bicentric study, we investigated the development of the procedure since its introduction at the Ordensklinikum Linz Barmherzige Schwestern and Elisabethinen in 2010.

Methods All flexible diverticulotomies performed between January 2010 and December 2019 at the above-mentioned clinics were evaluated retrospectively. Patients were divided into two 5-year periods (2010–2014 and 2015–2019) and statistical tests were performed for comparison of data.

Results In all, 69 flexible diverticulotomies were performed. The procedure was technically successful in 93.5 % of cases. No lethal outcome was encountered. Only 2 (2.9 %) interventions led to serious complications which had to be treated in the intensive care unit. Mild complications occurred in 14.5 % of cases. 54 patients were evaluated in the follow-up period; 11 (20.3 %) patients experienced relapses of dysphagia. The primary intervention resulted in a significant improvement over the observation period. Patients in the second intervention group had shorter average hospital stays and longer recurrence-free intervals.

Conclusion Flexible diverticulotomy is a safe and effective procedure for the treatment of Zenker's diverticulum. However, as the success rate appears to depend on the expertise and experience of the department, flexible diverticulotomy should be performed at centers with high caseloads.

ZUSAMMENFASSUNG

Hintergrund Die flexible Divertikulotomie gilt inzwischen als etablierte Behandlungsoption in der Therapie des Zenker-Divertikels. In unserer bizentrischen Studie des Ordensklinikums Linz Barmherzige Schwestern und Elisabethinen untersuchten wir, inwiefern sich dieses Verfahren seit dessen Einführung im Jahr 2010 entwickelt hat.

Methoden Diese retrospektive Studie umfasst alle endoskopisch-flexiblen Divertikulotomien, die im Zeitraum vom 01.01.2010 bis zum 31.12.2019 in den genannten Kliniken durchgeführt wurden. Die Patienten wurden in 2 sequenzielle 5-Jahres-Intervalle (2010–2014 und 2015–2019) aufgeteilt und statistisch verglichen.

Ergebnisse Insgesamt wurden 69 konsekutive flexible Divertikulotomien ausgewertet. Ein primärer Eingriffserfolg konnte bei 93,5 % erzielt werden. Es kam zu keinem letalen Outcome und bei 2 (2,9 %) Eingriffen zu schweren intensivpflichtigen Komplikationen. Leichte Komplikationen traten in 14,5 % der Fälle auf. Im Follow-Up konnten 54 Patienten evaluiert werden. Hiervon entwickelten 11 (20,3 %) ein Rezidiv. Der primäre Eingriffserfolg zeigte eine signifikante Verbesserung über den Beobachtungszeitraum. Außerdem profitierten Patienten der zweiten Interventionsgruppe im Durchschnitt von einer kürzeren Hospitalisationszeit und einem längeren Rezidiv-freien Intervall.

Schlussfolgerung Die flexible Divertikulotomie ist eine sichere und effektive Methode für die Behandlung des Zenker-

Divertikels. Die Erfolgsrate scheint aber von der Expertise und Erfahrung der Abteilung abzuhängen, weshalb die flexible Divertikulotomie primär in Zentren mit hohen Fallzahlen durchgeführt werden sollte.

Introduction

Zenker's diverticulum is a pseudodiverticulum of the hypopharynx that may lead to dysphagia, regurgitation and aspiration [1, 2].

Anatomical weakness of the Killian's triangle, functional disorders of the upper esophageal sphincter and gastroesophageal reflux have been discussed as potential causes. Age has been clearly confirmed as a risk factor. The peak incidence is between the ages of 70 and 80 years [3, 4, 5]. Since we lack any satisfactory conservative treatment for Zenker's diverticulum, it usually requires surgical or interventional treatment [6]. However, this exposes the elderly patient population to a high risk of surgery as well as anesthesia. Therefore, a gentle treatment method such as flexible diverticulotomy is desirable [7, 8].

Flexible diverticulotomy was first performed and published by Mulder et al. in 1995 [8], and a number of subsequent studies proved its safety and effectiveness. A meta-analysis conducted by Ishaq et al. in 2016 reported a success rate of 91 %, a complication rate of 11.6 %, and a recurrence rate of 11 % for the procedure [9].

Since 2010 we have been using flexible diverticulotomy in addition to rigid diverticulotomy for the treatment of Zenker's diverticulum at the Ordensklinikum Linz Barmherzige Schwestern and Elisabethinen.

In the present study, we investigated the association between the outcome of this challenging procedure and the increasing know-how of our department.

Methods

A bicentric study included all patients with Zenker's diverticulum treated with flexible diverticulotomy at the Ordensklinikum Linz Barmherzige Schwestern and Elisabethinen between 1 January 2010 and 31 December 2019. In addition, rigid diverticulotomy was used as a comparison group for the same time period.

Flexible diverticulotomy is intended to transect the diverticular septum to reestablish a common lumen of the diverticulum and esophagus. The placement of a gastric tube or guidewire into the esophagus is recommended initially in order to mark it. To visualize the diverticular septum and to fix it during the procedure, the flexible diverticuloscope and/or the distance cap is used. Once the septum is well set and visible, the actual diverticulotomy can be performed. Depending on the endoscopist's preference, the diverticular septum can be cut with a triangle tip knife, hook knife, needle-knife, argon plasma-coagulation or endoscopic scissors. Subsequently, the success of the procedure can be verified by easily intubating the esophagus with the gastroscope.

Medical documentation, intraoperative protocols, imaging studies, and nursing documentation from the hospital information system SAP Logon Pad 740 were evaluated. A total of 69 patients were included.

The aim was to determine the potential effect of our department's experience on success, complication, and recurrence rates. Patients were divided into two groups (group 1 = 2010–2014, group 2 = 2015–2019) and the data were compared. The tools used (hook knife, triangle tip knife, argon-plasma-coagulator, SB knife, needle-knife, biopsy forceps, diverticuloscope, distance cap), as well as the size of the diverticulum were analyzed as possible co-factors.

For the statistical analysis, the size of the diverticulum was checked for normal distribution (test of normality: Kolmogorov-Smirnov with Lilliefors significance correction, type I error = 10 %). Since the data were not normally distributed, univariate comparison was performed by the Mann-Whitney U test. Data of dichotomous variables were compared by Fisher's exact test.

The log-rank test was used to compare the time to recurrence, depicted by Kaplan-Meier plots.

Multivariate comparisons of endpoints (identification of covariates through the univariate comparisons of time periods) were performed with the generalized Cochran-Mantel-Haenszel test (technical success, complications) and with an adjusted log-rank-test (time to recurrence).

The influence of the endoscopist's increasing experience in performing the procedure on technical success, complications, and recurrence rates was investigated by logistic regression analysis and by Cox regression analysis (adjusted with further independent variables, selected as mentioned above) (**see Appendix, Tables 3–5**).

The type I error was not adjusted for multiple testing. Therefore, the results of inferential statistics are only descriptive. Statistical analysis was performed using the open-source R statistical software package, version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria). Due to the retrospective nature of the study, some datasets were not complete. Therefore, not all patients could be assessed for each characteristic. The numbers of patients which were actually analyzed for each characteristic are listed in the respective figure.

Results

Patients' characteristics (▶ Table 1)

Intervention

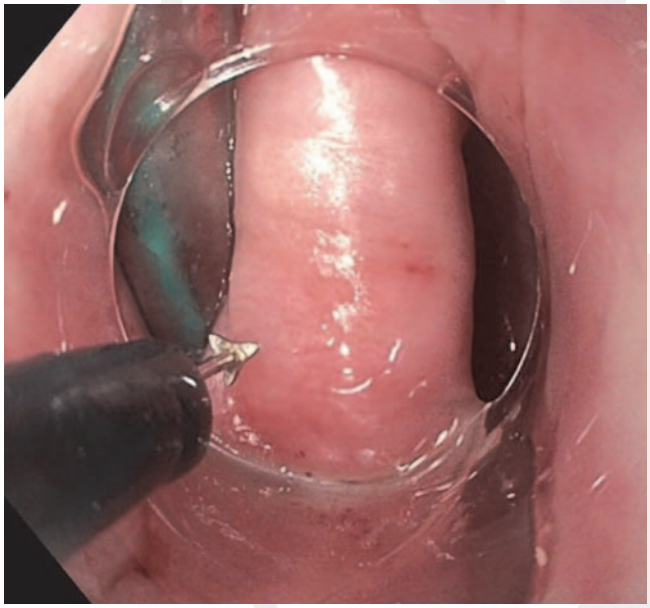
In group 1 (n = 11), the hook knife (54.5 %) was used most frequently for diverticulotomy. Occasionally, a needle-knife, argon plasma-coagulation and endoscopic scissors were used.

In group 2 (n = 58), diverticulotomy was largely performed with the hook knife (43.1 %) and the triangle tip knife (37.9 %).

The site of entry and the course of the proximal esophagus were marked in group 1 and group 2 with a gastric tube (n = 2

▶ **Table 1** Patients' characteristics.

Patients' characteristics	Intervention group 1 (2010–2014; n = 11)	Intervention group 2 (2015–2019; n = 58)	Rigid diverticulotomy (n = 40)
Sex			
▪ male	6 (54.5 %)	41 (70.7 %)	28 (70.0 %)
▪ female	5 (45.5 %)	17 (29.3 %)	12 (30.0 %)
Average age in years (SD)	78.18 (± 13.37)	71.00 (± 12.30)	70.68 (± 9.83)
Symptoms			
▪ dysphagia	10 (90.9 %)	44 (75.9 %)	31 (77.5 %)
▪ regurgitation	6 (54.5 %)	33 (56.9 %)	20 (50.0 %)
▪ aspiration	7 (63.6 %)	10 (17.2 %)	5 (12.5 %)
Other conditions causing dysphagia	7 (63.6 %)	26 (44.8 %)	16 (40.0 %)
Size of Zenker's diverticulum in cm (SD)	3.3 (± 1.5)	3.2 (± 1.4)	3.1 (± 1.5)
Pretreatment			
▪ rigid diverticulotomy in the same hospital	0	2 (3.4 %)	0
▪ previous treatment elsewhere	0	10 (17.2 %)	5 (12.5 %)
Median hospital stay in days	8.5	4.0	5.0



▶ **Fig. 1** Zenker's diverticulum peri-interventional with a distance cap and a triangle tip knife.

and n = 32), a guidewire (n = 8 and n = 15) or a diverticuloscope (n = 7 and n = 12).

The distance cap was predominantly used in both groups (86.2 %) to visualize the diverticulum. Clips were employed in 6 cases in group 1, and in 37 cases in group 2 (▶ **Fig. 1**).

Case numbers over time

The rising number of cases at the mentioned institutions above over the last 10 years indicate that flexible diverticulotomy is increasingly used for the treatment of Zenker's diverticulum (▶ **Fig. 2**).

Primary technical success of the intervention

Primary technical success of the intervention was defined as a complete transection of the diverticular septum or smooth intubation of the esophagus with an endoscope. Technical success was achieved in 75 % of cases in group 1 (n = 8), and in 96.3 % of cases in group 2 (n = 54). The effect of time by itself was statistically significant (p = 0.025 (**see Appendix, Table 2**)). The effect was weaker when the co-factors were taken into account, but remained identifiable as a trend. With 81.6 %, rigid diverticulotomy also shows a high success rate (▶ **Fig. 3**).

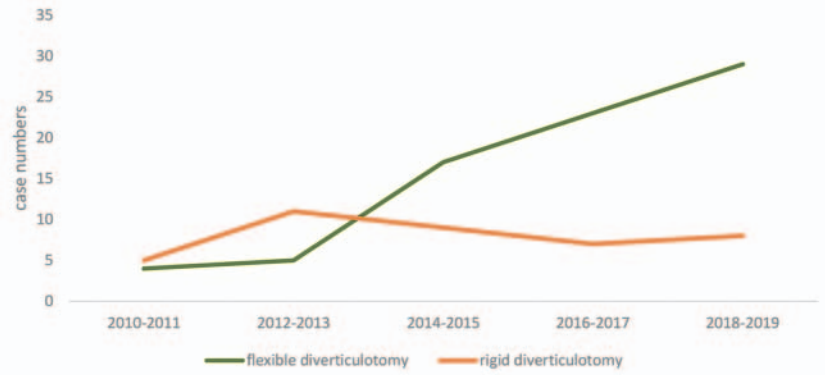
Primary clinical success

Clinical success rates for flexible diverticulotomy were higher than technical success rates in both groups taken together (95.7 %). However, this value should be viewed with caution because the median hospital stay was only 4 days and the patients were still on a soft diet at the time. Interestingly, however, the technical success of the intervention was not related to its clinical success. All four patients in whom we failed to achieve complete technical success were clinically symptom-free and remained so throughout the course of the study.

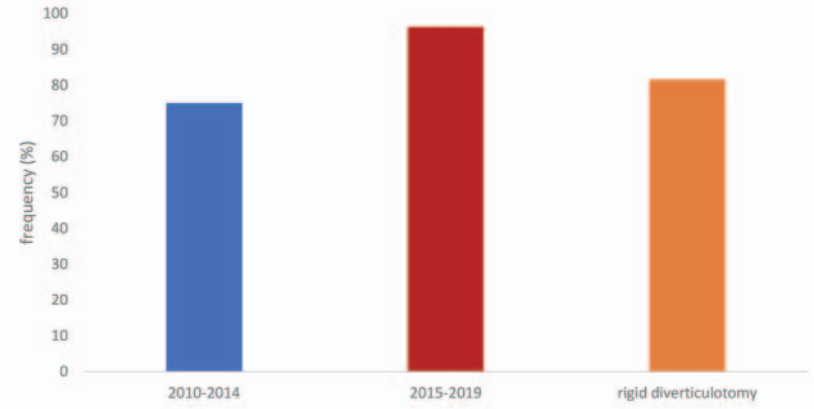
Safety of the intervention

Complications were classified as lethal, severe (requiring ICU treatment) or mild.

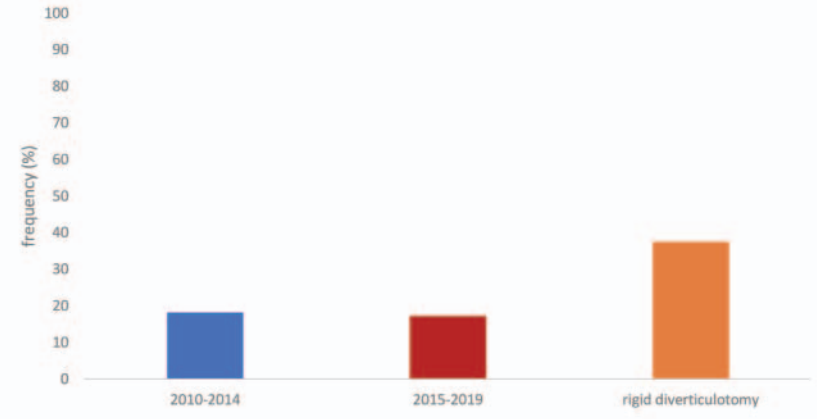
No lethal outcome was encountered. Only 2 (2.9 %) interventions required a stay in the intensive care unit due to perforation and wound dehiscence. Mild, well-controlled bleeding occurred in



▶ **Fig. 2** Case numbers for flexible diverticulotomy (n = 69) and rigid diverticulotomy (n = 40).

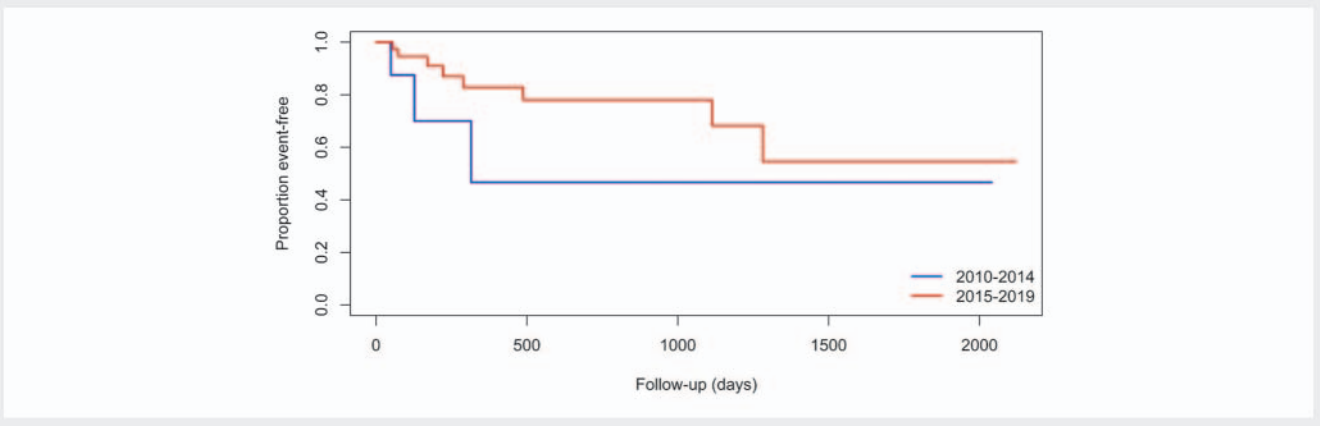


▶ **Fig. 3** Success rates (2010–2014 n = 8; 2015–2019 n = 54; rigid diverticulotomy n = 40).



▶ **Fig. 4** Complication rates (2010–2014 n = 11; 2015–2019 n = 58, rigid diverticulotomy n = 40).

10 (14.5 %) interventions. All in all, 12 (17.4 %) interventions resulted in complications. Complications were evenly distributed between the two intervention groups and no improvement was observed over time during the study period. Mild complications (37.5 %) were more common with rigid diverticulotomy, but no patient required ICU care (▶ **Fig. 4**).



▶ **Fig. 5** Time to recurrence (2010–2014 n = 8; 2015–2019 n = 46).

Long-term success

54 patients were able to be evaluated during follow-up (group 1 n = 8; group 2 n = 46).

Disease recurrence was registered in 3 (37.5 %) patients in the first group and 8 (17.4 %) patients in the second group. Notably, recurrences in group 1 occurred after a median of 127 days, and in group 2 after 255 days. Patients in group 2 generally benefited from the intervention for a longer period of time, as demonstrated by the flatter course of the graph for group 2 in ▶ **Fig. 5**.

Eight patients underwent a second intervention, of which 6 were successful. One additional patient became symptom-free after a third intervention. Despite using all options of intervention, 4 (5.8 %) patients could not be helped satisfactorily.

All in all, the overall recurrence rate of interventions conducted with the flexible diverticulotomy was 20.4 %, in contrast to the recurrence rate after interventions with the rigid diverticulotomy, which amounted to 37.5 %.

Discussion

Based on a comparison of flexible diverticulotomy in two time-dependent subgroups, we identified various trends and learning effects. The validity of the results is limited by the small size of group 1 (11 patients) compared to group 2. Nevertheless, the overall case numbers in the study (69 patients) were rather high. In contrast, the 20 studies analyzed in the meta-analysis by Ishaq et al. had a median of 32 patients [9].

Flexible diverticulotomy has been given preference over rigid diverticulotomy for the treatment of Zenker's diverticulum in the last 10 years.

We also noted differences in the composition of the two groups. Patients in group 1 (78.18 years) were older than those in group 2 (71.00 years). Group 1 also had a much higher level of distress and a clearly higher rate of dysphagia and aspiration. Taken together, these data indicate the widespread use of flexible diverticulotomy. The procedure is no longer reserved for the most vulnerable group, but is also increasingly used as first-line therapy for Zenker's diverticulum in younger patients. The observation is also consistent with the most recent recommendations of the European Society of Gastrointestinal Endoscopy [10].

The duration of the hospital stay was clearly shorter in group 2. This may be due to the younger age of the patients or the significantly higher technical success rate. The endoscopist's confidence in the method grew with increasing experience, resulting in a shorter post-interventional observation period.

The technical success of the intervention in our study is consistent with the success rates reported in the meta-analysis from Ishaq et al. We found that an imperfect technical outcome was not related to clinical success of the procedure or recurrence rate. Therefore, any future analysis should be focused on an objective clinical evaluation of patients. The dysphagia score may be used for this purpose. Other scores, such as the Eckardt score for achalasia, could be utilized for future evaluations. Xuan Li et al. employed the Eckardt score to evaluate per-oral endoscopic myotomy for Zenker's diverticulum [11].

Our recurrence rate of 20.4 % was substantially higher than that reported in the above mentioned meta-analysis (11 %) [9]. However, two facts are worthy of note. First, the loss of patients to follow-up may be due to a self-selection process. Patients with no symptoms are unlikely to report at the hospital again. Second, the recurrence rate in the second intervention group (17.5 %) was close to that reported in the meta-analysis, which indicates a learning process. Another five-year analysis would probably yield interesting data.

The complication rate registered in our study was slightly higher than the rate reported in the meta-analysis. However, as complications were not graded and compared by severity in the above mentioned meta-analysis, we looked for an appropriate severity-based analysis. In a large review, Jain D et al. classified complications according to their severity and reported a much higher rate of severe complications (5.3 %) than that registered in our study (2.9 %) [12].

Conclusion

In summary, our data clearly show that the effectiveness of the procedure increases as the know-how of our department increas-

es. Patients benefit from shorter hospital stays and longer recurrence-free intervals. Flexible diverticulotomy should be performed primarily at specialized centers with high case numbers.

Conflict of Interest

The authors declare that they have no conflict of interest.

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