Chapter 3

A randomized comparison of electrocautery incision with Savary bougienage for relief of anastomotic gastroesophageal strictures

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Abstract

Background: Benign gastroesophageal anastomotic strictures are common and often refractory to treatment. Various endoscopic dilation techniques have been reported, but none of these methods has been proven to be superior.

Objective: Comparison of efficacy and safety of dilation of previously untreated anastomotic strictures by using electrocautery incision (EI) and Savary bougienage (SB).

Design: Randomized, prospective study.

Setting: Multicenter study.

Patients: Sixty-two patients with an anastomotic stricture after esophagogastrostomy and dysphagia Atkinson grade II to IV were included.

Interventions: Patients were treated with EI or SB.

Main Outcome Measurements: Objective and subjective results were compared with baseline and 1, 3, and 6 months after the first treatment. Complications of both treatments were noted. Primary endpoints after 6 months were the mean number of dilation sessions and success rate (percentage of patients with ≤5 dilations in 6 months). Study participation ended after 6 months or if dysphagia grade II to IV recurred despite 5 treatment sessions.

Results: No complications occurred with both treatments. There was no significant difference between the EI and SB group in the mean number of dilations (2.9; 95% CI, 2.7-4.1 vs 3.3; 95% CI, 2.3-3.6; *P*=0.46) or the success rate (80.6% vs 67.7%, *P* = .26, and 96.2% vs 80.8%, *P* = .19).

Limitations: In a small study with negative primary endpoints, secondary endpoints and subgroup analyses are hypothesis generating only.

Conclusions: This prospective trial demonstrated that EI of gastroesophageal anastomotic strictures is a safe therapy and equivalent to SB as a primary therapy. EI can be used as an alternative or additional therapy for SB.

Introduction

Benign gastroesophageal anastomotic strictures occur in 5% to 46% of patients after resection of the esophagus for esophageal cancer.[1-4] Dysphagia caused by stricture formation is a major source of morbidity and can drastically impair quality of life.[5] Postoperative complications, such as anastomotic leakage, fistula formation, and ischemia of the proximal gastric tube, contribute to anastomotic stricture formation.[2] Various endoscopic dilation techniques have been reported for the treatment of these strictures, but no method has been proven to be superior.[1-4;6-8] The success rate of dilation therapy with Savary bougies (SB), balloons, or Eder-Puestow olives ranges from 70% to 90%.[1-4;6-9] Dilation therapy often has to be repeated to achieve a sustained ability to pass solid foods. The median number of dilation sessions can vary from 2 to 9 per patient, and as many as 39% of patients with postoperative anastomotic stricture require more than 3 dilation sessions to achieve adequate results.[1-6] In refractory strictures, self-bougienage with Maloney dilators may be a safe and effective alternative.[10] Other therapies that have been described for postoperative anastomotic stricture dilation are intralesional steroid injection combined with dilation therapy and self-expandable stents. Success rates with these therapies have been variable.[5;7;11-16] Electrocautery incision (EI) therapy of GI strictures has been reported in a small series of patients with a Schatzki ring and has also been used for the management of circular anastomotic strictures after GI surgery.[17-31] In our series of 20 patients with gastroesophageal anastomotic strictures refractory to SB, EI with a needle-knife proved to be safe and effective.[21] Based on these results, we designed a prospective, randomized, controlled study. The aim of this study was to compare the efficacy and safety of EI therapy with standard dilation therapy with SB and to assess quality of life after both treatments.

Patients and methods

This multicenter, randomized, controlled clinical trial was designed and executed following the principles outlined in the CONSORT (Consolidated Standards of Reporting Trials) statement.[32;33] The study was conducted at the Departments of Gastroenterology and Hepatology of the Erasmus MC (University Medical Center), Rotterdam, and the Academic Medical Center of the University of Amsterdam in The Netherlands. The protocol was approved by the Medical Ethics Committees of both participating centers, and the study was then registered with Current Controlled Trials Ltd (registration number ISRCTN81239664), London.[34] After written informed consent was obtained, patients were randomized to either dilation with EI or SB.

Patients

Between June 2004 and February 2007, all patients with an esophageal anastomotic stricture after an esophagogastrostomy who had dysphagia Atkinson grades II to IV were considered for inclusion in this trial. Exclusion criteria were previous dilation, suspicion of recurrent malignancy, bleeding diathesis, respiratory failure, severe or unstable cardiac disease, thoracic aortic aneurysm, and anastomotic leakage or infection.

Clinical care and assessment

On inclusion, patient characteristics, medical history, use of medication, indication for surgical resection, and body weight were carefully documented. All perioperative complications and details of the administration of any neoadjuvant therapy were obtained from the hospital charts. Dysphagia was graded as Atkinson grades I to IV (I, normal passage of solids and liquids; II, for solids; III, for semisolids; and IV, for liquids). Symptoms were scored by using questionnaires designed for benign esophageal stenosis (EORTC Health-Related Quality of Life Questionnaires SF-36 C-30 version 3 and OES 18).[35,36] Follow-up data were obtained at 1, 3, and 6 months after the first procedure. Body weight was recorded, dysphagia was graded, and the symptoms were scored by using a questionnaire on each of these occasions. In addition, two 5-point Likert scales were used, the first immediately after the first procedure to assess how patients had tolerated it, and the second at 1, 3, and 6 months follow-up to assess their satisfaction with the results of the therapy.

The treating physician performed the endoscopic evaluation of the stricture at baseline and, if repeat endoscopy was necessary, describing the location of the stricture in centimetres from the incisors, the length of the stricture, and the ability to pass the videogastroscope through the stricture before and after the procedure. Endoscopy was repeated during follow-up if a patient had more than 3 kg of weight loss or recurrent dysphagia grades II to IV. If there was a recurrent stricture, repeat dilation was performed in exactly the same manner as at baseline. Recurrent stricture was defined as either no passage of the standard videogastroscope or only with pressure. Retreatment and time interval between dilation sessions were noted. The incidence, character, and severity of complications of treatment with EI or SB were recorded.

The primary endpoints of this study were the number of dilation sessions at 6 months and the proportion of patients requiring 5 or fewer dilation procedures in 6 months (the success rate). Secondary endpoints were the time interval between the treatment sessions, weight change, quality of life scores from questionnaires, the patients' ability to tolerate the first dilation procedure, and satisfaction after therapy at 1, 3 and 6 months follow-up. Recurrence of dysphagia grades II to IV despite 5 treatment sessions, was considered a treatment failure.

Endoscopic interventions

Upper GI endoscopy was performed by an experienced endoscopist with the patient under conscious sedation by using midazolam (Dormicum; Roche Nederland BV, Mijdrecht, The Netherlands) in a dose of 2.5 to 7.5 mg, administered intravenously. The diameter of the stricture was estimated by passing the tip of the endoscope (GIF Q160, diameter 9.5 mm; Olympus Optical Co, Hamburg, Germany) or the outer sheath of the needle-knife catheter (1.7-mm needle diameter, 4-mm needle length) (Wilson-Cook Medical Inc, Winston-Salem, NC) through the stricture. The diameter of the stricture was graded as 9.5 mm or more when the endoscope passed effortlessly, between 2 and 9.5 mm when the endoscope passed with pressure or not at all, and as 2 mm or less (pinpoint) when the outer sheath of the needle knife could just pass the stricture or not pass through at all. If indicated biopsy specimens of the stricture were obtained to rule out tumor recurrence. If histology showed tumor recurrence, an alternative therapy was offered.

SB dilation was performed with Savary Gilliard bougies (Wilson-Cook Medical Inc). Stepwise dilation to 16 mm was generally achieved in 1 session, although multiple sessions within a week were sometimes required when there was a pinpoint stricture or when a lot of pressure was needed to pass even a small bougie.[1-3] EI therapy was performed as described in our earlier study, with the tip of the endoscope positioned just proximal to the stricture, and the needle-knife catheter advanced through the working channel.[21] A bimodal blended electrocautery current was used (ERBE ICC 200; ERBE Electromedizin GmbH, Tübingen, Germany) with software-controlled fractionated cuts (Endocut). The effective cutting power was maximized at 120 W for 50 ms. The maximum coagulation power during the forced coagulation mode was 45 W for 750 ms. With the needle-knife catheter under direct vision, multiple longitudinal incisions were made around the circumference of the stenotic ring. The number and radial position of the incisions were chosen to completely open the rim of the stricture. The required length of the cut was chosen according to the length of the fibrotic stricture determined at endoscopy. The depth of the incision, estimated by comparison with the length of the needle-knife, was not more than 4 mm. The procedure was terminated when the endoscope could easily pass the stricture (Figure 2-5). After EI or SB therapy, patients remained in day care observation for 2 hours in accordance with our standard procedures. Patients were allowed to drink water when awake and were discharged only when the endoscopist was satisfied that there were no symptoms suggestive of a complication. After the procedure, the patients remained on a liquid diet for the first day and resumed solid foods thereafter.

Statistical analysis

For sample size calculation, the distribution of the number of dilation sessions was assumed to be normal. However, this assumption may not be valid and therefore, to take

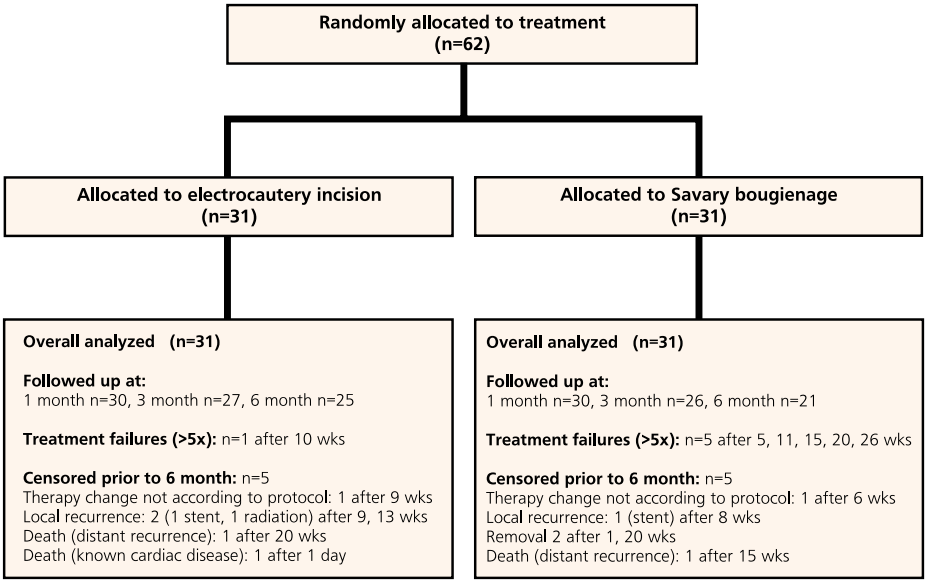

Figure 1. Study flow diagram. The diagram includes the number of patients with active follow-up at different times during the trial.

this into account, an extra 10% (approximate extra numbers needed for a nonparametric test) of the calculated sample size was added. The mean number of dilations over the 6-months timeframe was set for EI at 1.5 and for SB at 3. The estimated common standard deviation was 2.00. We thus calculated that a sample of 31 patients per treatment group would be required to provide a statistical power of 0.80 with a 2-tailed significance level of .05. An interim analysis was planned when 14 patients from each treatment arm had completed the study. The trial coordinator and participating physicians were unaware of the results of the interim analysis. For randomization, an independent research nurse used a permuted-block scheme. The opaque envelopes containing the assigned treatment were stratified per center. The patients were not blinded to the treatment received. SPSS software, version 15.0.0 (SPSS Inc, Chicago, Ill), was used for all statistical analyses. Analysis of the different endpoints was performed by applying the *t* test for analysis of paired continuous data with a normal distribution, the Mann-Whitney *U* test for nonparametric data, and the χ^2 test or Fisher's exact test to analyze categorical variables. The Poisson regression was used to estimate the mean number of dilations needed in 26 weeks, expressed as dilation incidence rate per 26 weeks, for both treatment arms. With the Poisson regression, censoring is taken into account and the Poisson regression allows for adjustment of baseline variables such as stricture length. The difference between the 2 study arms was expressed, by using the Poisson regression, as the relative rate (RR). The analysis of the difference in the number of weeks between dilations in the 2 treatment groups was analyzed by using the Kaplan-Meier survival analysis and Cox

regression, adjusting for the fact that 1 patient may have multiple dilations and can be censored before week 26. The symptom scores in the EI and SB groups were compared with those at baseline and at 1, 3, and 6 months after the first treatment. The overall subjective criteria scores for both treatments were also compared.

Results

Between June 2004 and February 2007, 62 patients (50 men, 12 women; age 41-76 years; mean 61.7) were included (Figure 1). All patients had undergone a trans-hiatal esophagectomy and intrathoracic gastric tube reconstruction with cervical anastomosis because of esophageal cancer. The end-to-side anastomoses were located at 17 to 20 cm from the incisors, were hand sewn, and no flap was brought up to the anastomosis. At baseline, the EI and SB treatment groups showed no significant differences with respect to sex, age, weight, estimated diameter of the stricture, time between surgery

Table 1. Baseline Characteristics.

Characteristics	Electrocautery incision (n = 31)	Savary bougienage (n = 31)
Men, n (%)	24 (77.4)	26 (83.9)
Age, y, mean (SD)	61.7 (7.5)	61.8 (9.1)
Weight, kg, mean (SD)	70.0 (12.4)	73.6 (10.9)
Stricture length,* (cm)		
Mean (SD)	1.35 (1.2)	0.55 (0.4)
Range	0.2 - 5.0	0.2 - 2.0
Dysphagia score,† n (%)		
Grade I	0 (0)	0 (0)
Grade II	11 (35.5)	12 (38.7)
Grade III	18 (58.1)	17 (54.8)
Grade IV	2 (6.4)	2 (6.5)
Estimated diameter stricture, mm, n (%)		
≥9.5	15 (48.4)	18 (58.1)
2.0-9.5	6 (19.3)	7 (22.6)
≤ 2	10 (32.3)	6 (19.3)
Peri-operative complications, n (%)	9 (29.0)	8 (25.8)

* P = .002 (n-Whitney <.001). † Grade I, normal passage of solids and liquids; grade II, for solids; grade III, for semisolids; grade IV, for liquids.

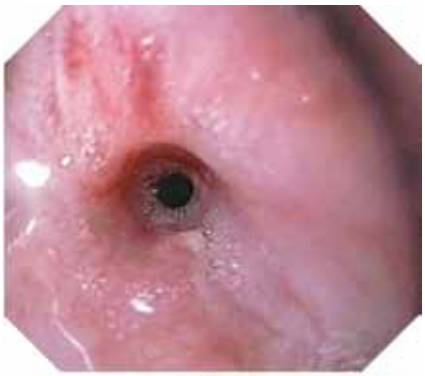

Figure 2. Esophageal anastomosis with a complex long stricture before EI therapy.

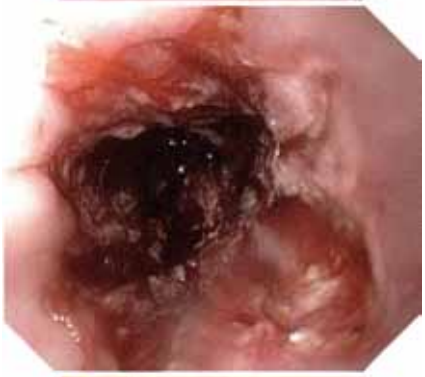

Figure 3. Esophageal anastomosis with a complex long stricture during EI therapy. Incisions are made in the upper part of the stricture.

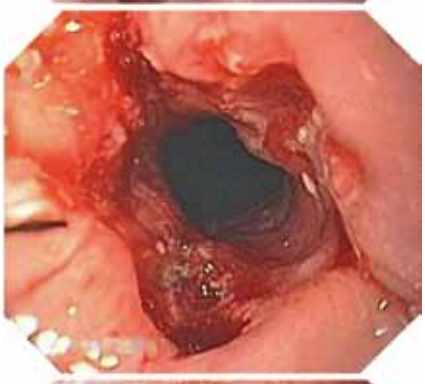

Figure 4. Esophageal anastomosis with a complex long stricture after EI therapy. Working downward, incisions are made in the lower part of the stricture.

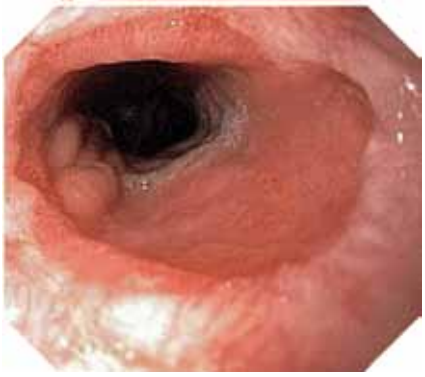

Figure 5. Esophageal anastomosis with a complex long stricture several weeks after EI therapy.

Table 2. Primary and secondary endpoints after 6-month follow-up.

	Electrocautery incision (n = 31)	Savary bougienage (n = 31)	P value
Primary endpoints			
Total no. of dilations/total follow-up, wk	80/712	85/673	
Dilation incidence rate per 26 wk (95% CI)	2.9 (2.7-4.1)	3.3 (2.3-3.6)	.46
Success rate, intention to treat, n (%)	25/31 (80.6)	21/31 (67.7)	.26
Success rate, completed 26 wk (%)	25/26 (96.2)	21/26 (80.8)	.19
Secondary endpoints			
Weight change at end follow-up, kg, mean (SE)	+ 0.8 (0.9)	– 2.0 (1.0)	.05
Weeks between dilations, median (95% CI)	6.0 (3.1-8.9)	6.0 (4.4-7.6)	.84

and first dilation, dysphagia score, perioperative complications, neoadjuvant therapy, and grading of quality of life by using the clinical questionnaires. The overall stricture length was significantly longer in the EI group (P = .002) (Table 1). Seventy-six percent of all dilation procedures (both EI and SB) were performed within 4 months after surgery. Perioperative complications had been present in 9 patients in the EI therapy group and in 8 patients in the SB group. Six patients were considered treatment failures because of persistent dysphagia grades II to IV despite 5 treatment sessions; 1 in the EI group and 5 in the SB group (Figure 1). In both study groups, 5 patients were censored before 6 months (Figure 1). After 6 months of follow-up, no complications from EI therapy or SB were seen. The primary endpoints showed no significant difference between the 2 groups of patients. The mean number of dilation sessions, expressed as dilation incidence rate per 26 weeks, showed no significant difference (P = .46; RR 1.1; 95% CI, 0.8-1.5; P = .46 of SB versus EI corrected for stricture length, RR 1.3; 95% CI, 0.9-1.8, P = .14), and the success rate did not reach significance (P = .26 and P = .19 respectively) (Table 2). Regarding the secondary endpoints after 6 months, the overall weight change was more favorable in the EI group (P = .05), and there was no significant difference between EI and SB with respect to the time interval between dilations (P = .84) (Table 2). During follow-up, significant improvements were noted in both treatment groups for the majority of the criteria scored with the clinical questionnaires when comparing the scores at 1, 3, and 6 months after treatment with baseline data (P values varying between .01 and .001). There was no significant difference between IE and SB with regard to the criteria scored with the clinical questionnaires. Patients' tolerability of the procedure, scored with the Likert scale, was significantly better with EI than with SB (P < .001). Patient satisfaction after therapy at 6-months follow-up was also significantly better with EI than with SB (P = .002).

Discussion

Dysphagia caused by stricture formation after an esophagogastrostomy is a common complication and can be refractory to treatment.[1-4;6-9;11-16] These strictures often lead to dysphagia and food regurgitation, which severely impair quality of life and adequate food intake. Most patients in whom stricture develops after a cervical esophagogastrostomy present within the first few months after surgery, as is shown in our current study.[37] The anastomotic strictures are generally short and straight, but they can be longer and tortuous and extremely narrow.[1-4;6] The endpoint in the bougie arm in this study was 16 mm because the fibrotic tissue of the stricture can resist SB with high bougie diameters, especially in pinpoint strictures. In these cases, the risk of perforation might be higher.[1;2;21;37] Irrespective of the character of the stricture, esophageal dilation with EI or bougienage is rarely contraindicated.[38] The complication rate of EI therapy, reported in small series of patients, seems to be low. Perforation has never been reported.[17-31] After esophageal dilation with bougies or balloons, perforation and/or hemorrhage is reported to occur in 0.1% to 0.4% of patients.[1;2;7-9;39] This may be a true difference; however, SB is judged by many to be a more straightforward procedure than EI and may therefore be performed by less experienced endoscopists. The authors also admit that there were far fewer EI cases than SB cases. For this reason, the confidence interval around the 0% complication rate with EI remains large. If EI was performed as much as SB, the complication rate could equal or even be higher than the rate observed with SB. This is, to our knowledge, the first randomized, controlled study comparing the efficacy and safety of primary EI therapy with SB in patients with an anastomotic esophageal stricture.[35,36] In the present series of 62 patients, no complications occurred with either technique. This study shows that EI is equivalent to, but not superior to, SB as a primary therapy for esophageal anastomotic strictures. After a follow-up of 6 months, there was no significant difference between EI and SB with respect to mean number of treatment procedures or success rate. Despite randomization, there were significantly more long strictures in the EI group. One could hypothesize that this may have made it more difficult to demonstrate any superiority of EI over SB. As we know from our previous study, EI seems to be a good single treatment modality for refractory short-segment anastomotic strictures, whereas longer segment strictures appear to require repeated treatment sessions before similar results are obtained.[21] This was a small study whose primary endpoints are negative. This means that the secondary endpoints and subgroup analyses after 6 months are hypothesis generating only and not positive or significant. Time interval between dilations seemed, from this study, to be the same in both EI and SB groups. Overall weight change seemed to favor EI. Weight change can be related to factors other than the endoscopic intervention, for example, the amount of elemental feeding consumed by the patients. There seemed to be an improvement in the majority of symptoms over time in both treatment groups. Patient satisfaction after treatment and

tolerance of the procedure seemed to be better with EI. However, subjective assessment by patients must be interpreted with great caution in this study; in the absence of blinding, there may be bias in favor of EI.

In conclusion, our prospective study demonstrated that EI of gastroesophageal anastomotic strictures is a safe therapy and equivalent to SB as a primary therapy. An expert endoscopist can easily use this quick and elegant method as an alternative or additional dilation therapy. In less experienced hands, EI should be used only as an alternative or additional therapy in cases in which dilation fails. EI should be available for therapeutic intervention for gastroesophageal anastomotic strictures. Subgroup analysis of patients with perioperative complications and more complex strictures and study of the impact of stricture length on treatment results with EI are areas for further attention.

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