Systematic Review and Meta-analysis

Efficacy and safety of triamcinolone acetonide in the prevention of esophageal stricture after endoscopic submucosal dissection: a meta-analysis

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SUMMARY. Aim: The role of triamcinolone acetonide (TA) in the prevention of esophageal stricture is not well established. This meta-analysis aimed to evaluate its safety and efficacy for the prevention of esophageal stricture after endoscopic submucosal dissection (ESD). Methods: A comprehensive search was performed in electronic databases including PubMed, the Cochrane Library, Embase for possible controlled studies. The primary outcomes were stenosis rate and endoscopic balloon dilation (EBD) sessions required, and secondary outcome included complications. Random effects were used to calculate the pooled outcome. Sensitivity analysis and publication bias were conducted to verify the robustness and reliability of the results. Results: Ten studies containing 499 patients were obtained. In the pooled analysis, statistical significance was found in triamcinolone acetonide injection reduced the incidence of stenosis (OR = 0.29, 95% CI [0.11, 0.80], P < 0.05) and the number of endoscopic balloon dilation (MD = −3.33, 95% CI [−4.15, −2.50], P < 0.0001) compared with control. Triamcinolone acetonide injection therapy did not increase the risk of complications (OR = −0.77%, CI [−1.62, 0.09], P = 0.08). Subgroup analysis indicated that the single injection of triamcinolone acetonide after endoscopic submucosal dissection significantly reduced the incidence of stenosis compared with without any prophylaxis. Different concentrations and single session volume of triamcinolone acetonide reduced the incidence of stenosis. It also showed that the dose according to the size of the lesion was more effective than the fixed dose in preventing esophageal stricture. Conclusion: Triamcinolone acetonide injection can reduce the incidence of stricture formation as well as the need for EBD sessions without increasing complications.

KEY WORDS: endoscopic balloon dilatation, endoscopic submucosal dissection, meta-analysis, stricture, triamcinolone acetonide.

INTRODUCTION

As we know, esophageal cancer is one of the cancers with high mortality rate worldwide. The geographic distribution of esophageal cancer varies greatly with the highest incidence rates in East Asia. The prognosis of patients with esophageal cancer was poor, mainly because most patients have advanced metastatic disease at the time of initial diagnosis. However, the 5-year survival rate for esophageal cancer patients with endoscopic resection at early stages was over 90%. Therefore, early diagnosis and treatment of esophageal cancer can significantly reduce morbidity and mortality of esophageal cancer.

With the development of techniques for endoscopic diagnosis, esophagus carcinoma is detected more frequently at early stages. Endoscopic resection (ER) with minimal invasiveness, which has been widely accepted as an effective method for early esophageal cancer. Among the ER methods, so far, ESD has considered as a prominent method for resection. However, widespread mucosal resection may lead to postoperative stricture of esophagus. About 90% of patients with mucosal defects of circumference >3/4 and 40% of patients who had undergone esphagectomy will experience postoperative stenosis, which commonly require treatment with repeated endoscopic balloon dilatation (EBD). As we known, EBD can lead to a medical economic load, a decrease in patients’ quality of life, and a risk of adverse events such as esophageal perforation.

Up to now, many approaches have been applied to prevent esophageal stenosis after extensive ESD, including tissue engineering, endoscopic dilation, steroid, and endoscopic stents implantation, etc., and each method has its own advantages and
disadvantages. Among these strategies, steroid prophylaxis, particularly local triamcinolone acetonide (TA) injection, is currently the relatively effective and safe method to prevent esophageal stricture. Several studies have investigated the efficacy of additional steroid administration versus EBD alone to prevent post-ESD strictures with limited sample sizes. So far, several meta-analyses on safety and efficacy of steroid for the prevention of esophageal stricture have been published. Yang J et al. and Siddique S reported steroid injection appears to be an effective prevention method for postoperative stricture formation. Wang W et al. showed local injected steroid was effective in prevention of esophageal stricture, whereas due to varied methods and doses of steroid administration, the finding needs to be clarified in the future. Subsequently, Shen Z et al. showed TA injection therapy is safe in the management of stenosis, at the same time, they also reported that there is a certain relationship between the dose of TA and incidence of stenosis. However, the present meta-analysis investigating the efficacy about the different concentrations and single session volumes of TA in the prevention of esophageal stricture are lacking. What is more, new literatures have been published since the last meta-analysis of this topic.

Hence, the purpose of our study was to provide an updated meta-analysis evaluating the efficacy and safety of TA for esophageal lesions. In addition, we examined the effect of different concentrations and single session volume of TA on the incidence of stenosis rate.

**MATERIAL AND METHODS**

**Search strategy**

This meta-analysis and systematic review was written in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations for reporting on systematic reviews. Literature search was conducted by retrieving electronic databases including the Cochrane Library, PubMed, and Embase. The full search strategy is as follows:

1. esophageal carcinoma[MESH].
2. (carcin* or cancer* or neoplas* or tumor* or tumor* or cyst* or growth* or adenocarcin* or malign*)[Title/Abstract].
3. (esophagus or esophageal or esophageal) [Title/Abstract].
4. #2and#3.
5. #1or#4.
6. Endoscopic Mucosal Resection [MESH] or Endoscopic Submucosal Dissection [Title/Abstract] or ESD [Title/Abstract].
7. #5and#4

**Study selection**

1. Types of studies—retrospective or prospective, case-control or cohort studies, and clinical trials (including randomized controlled trials and quasi randomized controlled trials).
2. Types of participants—1) adult patients (age ≥ 18 years old); 2) participants were patients diagnosed as early esophageal cancer and underwent circumferential ESD; 3) study intervention: all patients accepted TA injection after ESD without limiting the dose, concentration, frequency and single injection volume; 4) control methods including: without any prophylaxis or oral hydrocortisone sodium succinate and aluminum phosphate gel (OHA).
3. Types of outcome measures—The main outcomes were stenosis rate and the number of endoscopic balloon dilatation (EBD). Secondary outcome was treatment-related complications. Stenosis was defined after finding evidence of impossibility of passing by a normal endoscope. Treatment-related complications included perforation, bleeding, hypokalemia and bone fracture, and infection.
4. Exclusion criteria: 1) patients with esophageal stenosis due to non-ESD causes, such as ulceration or corrosion, etc. 2) patients who submitted to open surgery involving transection and anastomosis for esophageal cancer rather than ESD. 3) articles which data cannot be obtained. Two reviewers independently reviewed the search results according to the inclusion criteria. Disagreements were solved by consensus with the intervention of a third reviewer if necessary. The full text of all selected studies was screened according to the predefined inclusion and exclusion criteria.

**Data extraction**

Two reviewers independently extracted the data including basic information, outcome measures, and methodological quality items by using a standardized data extraction sheet. The data extraction form included: (1) author name, (2) publication year, (3) Country, (4) sample in each group, (5) the interventions of each group, (6) information of TA dose, concentrations of TA and single session volumes of TA, (7) outcomes. Any disagreements between the reviewers were resolved by discussion.

**Risk of bias**

To verify methodological quality of eligible studies, two reviewers were working independently to assess the risk of bias in randomized controlled trials on randomization, and assess quality using Cochrane Collaboration’s tool. Simultaneously, the same reviewers used Newcastle-Ottawa Scale for risk of bias assessment, which used a ‘star scoring system’ to judge three aspects of the study groups: (1) selection,
(2) comparability, and (3) ascertainment of either exposure or outcome of interest for case–control or cohort studies, respectively, with a total of 8 items and 9 stars. A study achieving 5 stars was considered high quality, with 9 being the maximum.

**Statistical analysis**

Dichotomous variables were reported as frequency and proportion, odds ratio (OR), and corresponding 95% confidence intervals (CI) were summarized to evaluate the outcome effects. As regard to continuous variables, mean difference (MD) with its 95% CI was used for assessing the effect sizes. The Cochran Q test and $I^2$ were used to evaluate for heterogeneity.$^{13}$ $I^2 > 50\%$ and $P < 0.1$ were deemed as significant heterogeneity. Random-effect model was applied in all analysis. We would conduct a series of subgroups to explore the source of heterogeneity. Subgroups were performed based on different concentrations, single session volume, and dose of TA. In addition, Sensitivity analysis was performed only in randomized controlled trials. Publication bias was also evaluated by using the Egger’s test. A two-tailed $P < 0.05$ was considered statistically significant. Forest plots were used to graphically present the results of the pooled analysis. All statistical analyses were performed using the Stata 16 and Review Manager 5.3 software.

**RESULTS**

**Study selection**

In total, 5238 studies were identified through our database query; of which 1077 were duplicates. Out of the remaining 4161 studies, an additional 4124 irrelevant articles were excluded based on the titles and abstracts. Full text review was then performed on 37 studies using the predefined inclusion and exclusion criteria; after which 10 studies were retained$^{14–23}$ (Figure 1). Among the studies, 6 out of the 10 studies were cohort studies, 2 studies were case–control studies and 2 studies were randomized controlled trial. Among the 10 studies, 5 studies were from Japan, 3 from China, and 2 studies from the Korea (Table 1).
The studies were published from 2011 to 2021 and the total number of participants was 499. All patients were clearly diagnosed as early esophageal cancer and received ESD treatment. All articles reported the outcome of incidence of esophageal stenosis, and 6 articles recorded the outcome of the number of balloon dilations. Six articles reported the outcome of complications. Among them, the intervention of the study group in 7 articles was single injection of TA. In 3 articles, the intervention of the study group was TA combined with oral prednisolone. The TA dose was varied in 2 studies and fixed in 6 studies ranging from 0.2 to 1.0 mL. The concentrations of TA were varied from 0.2 mL/10 mg/mL to 1.0 mL/5 mg/mL in 5 studies. The scores of methodological quality of observational studies were all >5 scores. According to Cochrane Collaboration’s tool, the risk of bias in the 2 randomized studies was low. Thus, overall risk of bias was moderate to good (Table 2).

### Table 1 Basic information of included studies and evaluation of endoscopic injection therapy for esophageal stenosis

| Study                  | Design       | Country   | Sample | Intervention | Control | TA dose/single session volume/concentration | Outcome                        |
|------------------------|--------------|-----------|--------|--------------|---------|---------------------------------------------|---------------------------------|
| Hashimoto et al.14     | Cohort study | Japan     | 41     | ETI          | ESD     | 18–62/0.2 mL/10 mg/mL                       | Stenosis rate/number of EBD/complications |
| Hanaoka1 et al.15      | Cohort study | Japan     | 59     | ETI          | ESD     | 100/0.5–1.0 mL/5 mg/mL                      | Stenosis rate/number of EBD/complications |
| Takahashi et al.16     | RCT          | Japan     | 32     | ETI          | ESD     | −0.5 mL/10 mg/mL                            | Stenosis rate/number of EBD/complications |
| Nagami et al.17        | Case–control | Japan     | 56     | ETI          | ESD     | 80/0.5 mL/−                                  | Stenosis rate/number of EBD     |
| Nagami et al.18        | Case–control | Japan     | 74     | ETI          | ESD     | 80/0.5 mL/−                                  | Stenosis rate/number of EBD     |
| Yuan Chu et al.19      | Cohort study | China     | 70     | ETI + oral prednisolone | ESD     | 80–120/0.5–1.0 mL/8 mg/mL                   | Stenosis rate/number of EBD/complications |
| Pih GY et al.23        | Cohort study | Korea     | 31     | ETI          | ESD     | 40–160/0.5–1.0 mL/−                         | Stenosis rate/number of EBD/complications |
| Dan Nie et al.2019     | Cohort study | China     | 27     | ETI + oral prednisolone | OHA     | 80/−/−                                       | Stenosis rate/number of EBD/complications |
| Zhang et al.22         | RCT          | China     | 63     | ETI + oral prednisolone | OHA     | 80/−/−                                       | Stenosis rate/number of EBD/complications |
| Ruan et al.20          | Cohort study | China     | 49     | ETI          | ESD     | 800/0.2–0.4 mL/10 mg/mL                     | Stenosis rate/number of EBD/complications |

Abbreviations: EBD, endoscopic balloon dilatation; ESD, endoscopic submucosal dissection; ETI, endoscopic triamcinolone injection; OHA, oral hydrocortisone sodium succinate and aluminum phosphate gel; RCT, randomized controlled trial; TA, triamcinolone acetonide.

### Table 2 Risk of bias evaluation based on Cochrane Collaboration’s tool for randomized studies and Newcastle-Ottawa quality assessment scale for nonrandomized studies

| Randomized studies | Cochrane Collaboration’s tool | Nonrandomized studies | Newcastle score |
|--------------------|-------------------------------|-----------------------|-----------------|
| Hiroaki Takahashi1 et al.15 | Low bias                     | Satoru Hashimoto et al.14 | 7              |
| Yiyang Zhang et al.22    | Low bias                      | N. Hanaoka et al.16    | 6              |
| Dan Nie et al.2019       | Low bias                      | Yasuaki Nagami et al.17| 6              |
| Yuan Chu et al.19        | Low bias                      | Yasuaki Nagami et al.18| 6              |
| Gyu Young Pih et al.23   | Low bias                      | Yuan Chu et al.19      | 6              |
| Dan Nie et al.2019       | Low bias                      | Gyu Young Pih et al.23  | 6              |
| Ruan, R W et al.20       | Low bias                      | Dan Nie et al.2019     | 6              |

**Stenosis rate**

The data of stenosis rate was available for 10 studies (n=499 patients). Among them, 238 were included in the study group and 261 were included in the control group. In the pooled analysis, statistical significance was found in TA injection reduced the incidence of stenosis compared with control (OR = 0.29, 95% CI [0.11, 0.80], I² = 80%, P < 0.05; Figure 2). However, significant heterogeneity was detected (I² = 80%; Figure 2).

Considering the clinical heterogeneity, subgroup analysis according to different study methods was first conducted. In the new pooled subgroup analysis, the single injection of TA after ESD significantly reduced the incidence of stenosis compared with without any prophylaxis of control group (OR = 0.13, 95% CI [0.08, 0.24], P < 0.0001, I² = 14%, Figure 2). In 3 articles, the intervention of the study group was TA combined with oral prednisolone, and the results suggested that TA combined with oral prednisolone...
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| Study or Subgroup | ETI | Control | Odds Ratio M-H. Random, 95% CI | Odds Ratio M-H. Random, 95% CI |
|------------------|-----|---------|-------------------------------|-------------------------------|
| Gyu Young Pih 2019 | 2   | 6       | 0.50 [0.08, 3.32]             | -                             |
| Hiroaki Takahashi 2015 | 10  | 16      | 0.24 [0.04, 1.43]             | -                             |
| N. Hanaoka et 2012 | 3   | 30      | 0.06 [0.01, 0.24]             | -                             |
| Ruan, R. W. 2019  | 5   | 22      | 0.10 [0.03, 0.38]             | -                             |
| Satoru Hashimoto 2011 | 4   | 21      | 0.08 [0.02, 0.35]             | -                             |
| Yasuaki Nagami 2016 | 3   | 28      | 0.07 [0.02, 0.28]             | -                             |
| Yasuaki Nagami, 2017 | 7   | 37      | 0.27 [0.10, 0.78]             | -                             |
| Subtotal (95% CI) | 160 | 179     | 0.13 [0.08, 0.24]             | -                             |

Total events 34  114

Heterogeneity: Tau² = 0.08; Chi² = 6.95, df = 6 (P = 0.33); I² = 14%
Test for overall effect: Z = 6.78 (P < 0.00001)

**Fig. 2** Stenosis incidence of triamcinolone acetonide injection compared with control group.

Simultaneously, we also conducted a sensitivity analysis, which was restricted to randomized trials. In the new pooled analysis, 2 randomized trials investigated efficacy of TA injection after ESD; TA injection did not significantly reduce the risk of incidence of stenosis (OR = 1.19, 95% CI [0.06, 24.87], P = 0.91, I² = 86%; Figure 3).

We performed a subgroup analysis of the relationship between TA concentration and the incidence of stenosis, separating TA by different concentrations. The results showed that different concentrations of TA injection significantly reduced the incidence of stenosis, and the odds ratio was 0.10 (95% CI [0.04, 0.25], P < 0.0001, I² = 8%) in <10 mg/mL subgroup and 0.12 (95% CI [0.05, 0.27], P < 0.0001, I² = 0%) in 10 mg/mL subgroup (Figure 4).

The subgroup analysis by separating different TA single session volumes was conducted. For different TA single session volumes of intralesional triamcinolone acetonide, the odds ratio was 0.09 (95% CI [0.03, 0.24], P < 0.0001, I² = 0%) with less than 5 mL, 0.25 (95% CI [0.12, 0.54], P < 0.0001, I² = 0%) with 5 mL, and 0.15 (95% CI [0.05, 0.42], P < 0.0001, I² = 38%) with 0.5–1.0 mL (Figure 5).

To further investigate the relationship between TA dosage and incidence of stenosis, a subgroup analysis was performed. The results showed that TA injection obviously reduced the incidence of stenosis in ≥80 mg subgroup (OR = 0.10, 95% CI [0.04, 0.26], P < 0.0001), without significant heterogeneity (I² = 8%). However, the incidence of stenosis did not significantly reduced in the 80 mg subgroup (OR = 0.76, 95% CI [0.14, 4.04], P = 0.74, I² = 86%) (Figure 6).

**EBD sessions**

Six studies reported the number of EBD sessions required was for resolution of stenosis. Among them, there are 106 people in the TA group and 165 in the control group. TA injection significantly reduced...
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the number of EBD sessions (MD = −3.33, 95% CI [−4.15, −2.50], P < 0.0001, I² = 12%; Figure 7). Among the remaining 4 studies, 2 of them had inappropriate data formats, and the other 2 studies did not present the data as mean and standard difference. Thus, they were not combined and analyzed.

Complications

Seven studies reported complications related to steroid injection, which included deep submucosal tear (without perforation) (2/0), perforation (2/0), hemorrhage (2/1), infection (3/10), cardiac arrhythmia (0/2), and hypokalemia (6/10). In the pooled
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Fig. 6 Stenosis incidence of triamcinolone acetonide injection for different doses.

Fig. 7 The number of EBD sessions required after triamcinolone acetonide injection.

Fig. 8 Complications after triamcinolone acetonide injection compared with control group.
analysis, there were no significant differences in TA injection and control group (OR = −0.77%, CI [−1.62, 0.09], P = 0.08, I² = 0%; Figure 8).

Publication bias

About the publication bias, Egger’s tests to screen for the association between TA injection and the incidence of stenosis, and no clear publication bias was observed (P = 0.08).

DISCUSSION

This meta-analysis showed that local injected TA is effective to reduce the stricture rate and required EBD sessions without increasing complications. Subgroup analysis showed all concentrations and single session volumes of TA appear to be efficacious. Subgroup analysis 7 studies found that dose of TA was mainly according to the defect size, which may be more efficacy compared with fix dose. Moreover, sensitivity analysis did not materially alter the results. In terms of the association between TA injection and the incidence of stenosis, no clear publication bias was observed. In our analysis, only 2 randomized controlled studies were included, and the small sample size would lead to certain deviations in the results. At the same time, there is no uniform standard for the dose, concentration and single injection volume of triamcinolone acetonide injection, which also affects the research results.

Post-procedure stricture is a common complication of ESD surgery for patients with early esophageal cancer, which markedly decrease the patient’s quality of life. Therefore, it is crucial to develop the strategies to prevent esophageal strictures. Although there are many methods for preventing esophageal stenosis after ESD, none of them has been widely accepted as effective in clinical practice.

The Kochhar et al. initial reports about steroid therapy demonstrated that intralesional injections of triamcinolone acetonide reduced the frequency of esophageal strictures in the endoscopic field. Subsequently, triamcinolone acetonide has been used to prevent esophageal strictures after ESD. A course of studies had suggested that endoscopic triamcinolone injection is effective in prevention of esophageal stricture after ESD with lower incidence of stenosis and fewer number of EBD. However, Taka-hashi et al. showed that endoscopic triamcinolone injection did not reduce the frequency of stricture formation but significantly reduced the number of EBD. Insufficient statistics caused by small sample size and unquantified TA dose may affect the study results. Our meta-analysis indicated that TA injection reduced both the incidence of stenosis and the required EBD sessions after endoscopic submucosal dissection. The advantages of TA injection are its easy endoscopic procedure and lower risk of systemic complications. The occurrence of esophageal stenosis is mainly caused by the destruction of the muscularis propria and fibrosis. Reducing mucosal inflammation will reduce the destruction of the muscularis propria and delay the process of fibrosis, thereby preventing stenosis. The exact mechanisms of TA injections reduce the esophageal strictures is unknown. Ashcraft et al. suggested that TA prevents esophageal stenosis by inhibiting not merely collagen synthesis, but also fibrosis and inflammation.

Hanaoka et al. found that using TA injection alone had limited effectiveness for larger esophageal mucosal defects. Some studies have investigated the efficacy of TA plus oral prednisolone in preventing stricture following esophageal ESD with larger mucosal defect. Among the included studies, Chu et al. showed that TA plus oral prednisolone significantly reduced incidence of stenosis and number of EBD sessions compared with without any prophylaxis. Nie et al. and Zhang et al. compared TA plus oral prednisolone with OHA, which is a mixture of aluminum phosphate gel and hydrocortisone sodium succinate, and demonstrated OHA is superior to ETI plus oral prednisone in preventing esophageal stricture, but with more severe complications such as hypokalemia and bone fractures, which were related to long-term oral steroid. Hence, larger sample sizes studies across multiple centers are needed to further evaluate safety and efficacy between them.

So far, there are no standard guidelines about the timing, concentration, single session volume and dose of triamcinolone acetonide in preventing strictures, and there is no standardized implementation process. Our meta-analysis suggested that all concentrations and single session volumes of TA appear to be efficacious. Given the risk of adverse effects, additional randomized studies may be necessary to determine the lowest effective concentration for the prevention of esophageal stricture after endoscopic submucosal dissection. Consistent with Wang’s results, dose of TA was mainly according to the defect size, which may be more efficacy compared with fix dose. Due to the limited relevant studies at present, large sample size is still needed for further verification in the future.

With advances in endoscopic techniques, endoscopic balloon dilatation (EBD) has recently become the first line of therapy for esophageal stricture. TA significantly reduced required EBD sessions compared with without any prophylaxis after ESD. This may be related to the reduction in the incidence of esophageal stenosis after local injection of TA, which reduced the number of balloon dilations.

The complications related to TA injection mainly including bleeding, perforation, and infection. Among them, perforation was a serious treatment-related complication. A previous related research showed perforation during EBD was reported in 9.2% of
patients.\textsuperscript{28} The complication rate is likely to increase with repeated EBD sessions and might also be related to steroid injection. Among the included studies, a series of studies\textsuperscript{15,19,22,29} have been reported delayed perforation was associated with triamcinolone injection. The onset of delayed perforation was probably due to tissue damage caused by the injection into the muscularis propria, which would be risk factors for incidence of delayed perforation. However, Takahashi et al.\textsuperscript{16} reported the perforation complication, which was not related to steroid injection, but were caused by dilatation procedures. Therefore, patients are at a lower risk of esophageal perforation if they undergo fewer dilatation treatments. In the study of Zhang et al., infection was the most common complications. The author suggested that the lower injection incidence of the TA injection could attribute to the anti-inflammatory effect of local–regional injection of TA. In general, based on our analysis results, TA injection was safe without increased incidence of complications. The lower steroid-related complication is related to low dose of local injection.

LIMITATIONS

First of all, the major limitation of this review was that the included studies involve both randomized trials and observational studies in pooled analysis, which result in heterogeneity. However, we conduct sensitivity analysis, in some extent, which made up for the limitations caused by inconsistent study types. Secondly, the dose, concentration and single injection volume were varied in different studies; while we have performed a subgroup analysis, it may still bring heterogeneity, thereby affecting the results of the analysis. Thirdly, the sample size included in the study was small, thus large-sample, high-quality multi-center studies still need to be further verified the results.

CONCLUSION

TA injection is a promising efficacy method for stricture prevention after ESD, as it reduced the stricture rate and the required EBD sessions without increasing complications.

AUTHOR CONTRIBUTIONS

Yuting Jia: Designing the study. Bin Guo, Wenbin Zhang, and Erfeng Li: Collecting, analyzing, and interpreting the data. Quanmao Zhang and Yuting Jia: Writing the report. All authors agree to submit for publication.

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None.

ABBREVIATIONS

ESD, endoscopic submucosal dissection; TA, triamcinolone acetonide; EBD, endoscopic balloon dilatation

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CONFLICT OF INTEREST

The authors report no conflict of interest.

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