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Retrospective Study

Oral higher-dose prednisolone to prevent stenosis after endoscopic submucosal dissection for early esophageal cancer

Zhan SG *et al*. Prevention of esophageal stenosis

Abstract

BACKGROUND

Esophageal stenosis is one of the main complications of endoscopic submucosal dissection (ESD) for the remedy of large-area superficial esophageal squamous cell carcinoma and precancerous lesions (≥3/4 of the lumen). Oral prednisone is useful to prevent esophageal stenosis, but the curative effect remians controversial.

AIM

In present study, we will share our experience of the precautions against esophageal stenosis after ESD removing large superficial esophageal lesions.

METHODS

Between June 2019 to March 2022, we enrolled patients with large superficial esophageal squamous cell carcinoma and high-grade intraepithelial neoplasia experienced ESD. Prednisone (50 mg/day) was administrated orally on the second morning after ESD for 1 month, tapered gradually (5 mg/week) for 13 weeks.

RESULTS

In total, there were 14 patients measure up to the criteria. All of them received ESD without operation-related bleeding and perforation. There were 11 patients with ≥3/4 and < 7/8 of lumen mucosal defects and 1 patient with ≥7/8 of lumen mucosal defect and 2 patients with the entire circumferential mucosal defects owing to ESD. The longitudinal extension of the esophageal mucosal defect were less than 50 mm in 3 patients and greater than or equal to 50 mm in 11 patients. The esophageal stenosis rate after ESD was 0% (0/14). One patient was got esophageal candida infection on the 30th day after ESD, and completely recovered after 7 days of the administration of oral fluconazole 100 mg/day. No other adverse events of oral steroids were found.

CONCLUSION

Oral prednisone (50 mg/day) and prolonged prednisone usage time may effectively prevent esophageal stricture after ESD without increasing the incidence of glucocorticoid-related adverse events. However, further investigation of larger samples was required to warrant feasibility and safety.

Key Words: Early esophageal cancer; Stenosis; Prednisone; Endoscopic submucosal dissection

Zhan SG, Wu BH, Li DF, Yao J, Xu ZL, Zhang D, Shi RY, Tian YH, Wang LS. **Oral higher-dose prednisolone to prevent stenosis after endoscopic submucosal dissection for early esophageal cancer.**

Core Tip: Esophageal stenosis is one of the main complications of endoscopic submucosal dissection (ESD) for the remedy of large-area superficial esophageal squamous cell carcinoma and precancerous lesions (≥3/4 of the lumen). Oral prednisone (30 mg/day) is one of the most commonly used treatment measure to prevent postoperative stenosis after esophageal ESD, however, several studies have drawn inconsistent conclusions. For the first time, we took a higher dose of prednisone (50 mg/day) orally to prevent esophageal stenosis after esophageal ESD and no stenosis occurred in 14 patients, meanwhile, no significant glucocorticoid related adverse events occurred.

INTRODUCTION

Endoscopic submucosal dissection (ESD) was one of main treatment measures for early esophageal cancer and esophageal high-grade intraepithelial neoplasia[1]. It was minimally invasive and permitted *en* bloc resection of large esophageal lesions without Esophagectomy. However, esophageal stenosis generally occured after ESD resection of esophageal lesions, especially for the lesions ≥3/4 of the lumen. Multivariate analysis showed that esophageal mucosal membrane defect over 3/4 lumen was an important predictor of stenosis formation. Without prophylactic treatment, the occurrence rate of

esophageal strictures can reach 83.3-94.1%, especially when the lesion affects the whole circumference of the esophagus, the rate of esophageal strictures was even higher[2,3]. This often required repeated endoscopic balloon dilatation (EBD) to alleviate symptoms, however, the benefit was limited[4].

Recently, it had been reported that hormone, as a preventive treatment, can reduce the occurrence of stricture after esophageal ESD[5,6]. Yamaguchi firstly reported that oral prednisone 30 mg/d can effectively prevent esophageal stenosis after ESD, and the postoperative stenosis rate can be reduced to 5.3% (1/19)[5]. Study had also shown that oral prednisone 30 mg /d was not effective in preventing esophageal stenosis in patients with entire circumference or ≥ 7/8 circumferential mucosal defects[7]. Meanwhile, one case reported that a patient with superficial esophageal squamous cell carcinoma received high-dose dexamethasone therapy (40 mg for 4 days) for multiple myeloma on the 9th day after ESD. After three courses of treatment, no esophageal stenosis was found in the follow-up gastroscopy, the histopathological evaluation showed that the submucosa became thinner, and the fibrosis degree of wound scar after ESD was the lowest[8]. In a prospective study of Nakamura, 11 patients with superficial esophageal squamous cell carcinoma with lesions ≥ 3/4 of the circumference were treated with steroid pulse therapy from the next day after ESD (intravenous infusion of sodium methylprednisolone succinate 500 mg/day for 3 consecutive days from the next day after ESD)[9]. It was found that although steroid pulse therapy was safe, however, steroid pulse therapy has no preventive effect on esophageal stenosis after ESD. Therefore, oral hormone is an effective method to prevent esophageal stenosis after esophageal ESD, but the dose, use time, effectiveness and safety of hormone need to be further studied.

MATERIALS AND METHODS

Patients

Between June 2019 to March 2022, 74 patients with superficial esophageal squamous cell carcinoma or precancerous lesions of esophagus were *en* bloc resected with ESD at

the Digestive Endoscopy Center of Shenzhen People's Hospital. Of these, 18 patients accepted mucosal resection via ESD, and the mucosal defects involving 3/4 or larger circumference of esophageal lumen. However, 1 patient who had received additional chemoradiotherapy (CRT) and 3 patients who had underwent additional surgery were removed from our study. Ultimately, there were 14 patients included in this study. The indication criteria were as follows: 1) Before esophageal ESD, the intraepillary capillary （IPCL） of lesion mucosa observed by Narrow band imaging (NBI) magnifying endoscopy (NBI-ME) was type B1. 2) The preoperative lesions of ESD were histologically confirmed as superficial esophageal squamous cell carcinoma or esophageal high-grade intraepithelial neoplasia. 3) Thoracoabdominal enhanced CT showed no lymph node or distant metastasis. 4) Provision of written informed consent. 5) No achalasia. 6) No corrosive injury of esophagus. The exclusion criteria were as follows: 1) The patients could not be followed up for 6 mouth or longer. 2) patients whose stenosis has formed before esophageal ESD. 3) Patients who had prior esophageal cancer with CRT. 4) Patients with additional CRT or additional esophagectomy after non-curative ESD.

ESD procedure

The ESD was operated in an operating room. The patients were endotracheal intubated and kept in the left lying position. An endoscope (GIF-Q260J; Olympus Co, Tokyo, Japan) was attached with forward water delivery function and was used with carbon dioxide insufflation. The head end of the endoscope was connected with a pellucid cap (D-201-11804; diameter 12.4 mm, length 4 mm, Olympus Co, Tokyo, Japan). 0.75% iodine staining was used for identifying the range of the lesion, and a dual knife (KD-650Q; Olympus Co, Tokyo, Japan) marking dots 3mm away from the edge of the lesion. An electronic surgical workstation (VIO 200D, ERBE, Germany) was used with an operating mode (FORCED COAG model, effect 2, Maximum power 20W). The 0.9% saline solution containing 0.3% indigo carmine was used for adequate submucosal injection along the marked dots. After circumferential mucosal incision, submucosal dissection was operated by the dual knife (KD-650Q) from the oral side to

the anal side of the lesion under an operating mode (Endocut I mode, FORCED COAG model, effect 2, maximum power 50W, VIO 200D, ERBE, Germany). Bleeding during the operation and visible blood vessels were handled with hemostatic forceps (FD-410LR; Olympus Co, Tokyo, Japan) under a soft coagulating mode (SOFT COAG mode, effect 4, maximum power 80W, VIO 200D, ERBE, Germany).

Postoperative related bleeding was defined as bleeding requiring blood transfusion or surgical intervention, or bleeding that resulted in a 2 g/dL decline in hemoglobin levels. Postoperative related perforation was diagnosed by endoscopy or chest CT[7]. All of the patients treated with proton pump inhibitor, esmeprazole, with a dose of 20 mg, twice a day after ESD for 28 days[5,9]. After ESD, each patient received 2 pieces of Calcium Carbonate and Vitamin D3 chewable tablets (each tablet contains 300 mg calcium and 60IU vitamin D3) per day until the prednisone was stopped to prevent glucocorticoid-Induced osteoporosis[10].

Management for esophageal stenosis prevention

Prednisolone was taken orally at a dose of 50 mg/day from the next morning after ESD for one month, then decreased gradually (45, 40, 35, 30, 25, 20, 15, 10, and 5 mg for 7 days each) until 13 weeks later.

Follow up

Regular endoscopy was examined at 1, 3, 6 months after ESD operation, and then annually thereafter. In addition, endoscopic examination should be performed whenever the patient has dysphagia to check up whether there was esophageal stenosis or not. EBD would performed subsequently if esophageal stricture was identified. Any abnormal mucosa required biopsy for pathological evaluation of whether there was local tumor recurrence. Meanwhile, regular physical and blood examinations were carried on to evaluate the side effects of the steroid. Bone mineral density (BMD) testing were performed before ESD treatment and 6 months after ESD treatment respectively.

Outcomes

Main outcome measures: incidence of esophageal stenosis. Esophageal stenosis was defined as the inability of 9.9 mm diameter gastroscope (Olympus GIF-Q260J) to pass

through the esophageal stenosis. Secondary observation indicators: glucocorticoid related adverse events were observed at 1, 3, and 6 months after ESD, such as newly diagnosed diabetes or aggravation of diabetes, pepticulcer, adrenocortical insufficiency, aggravation of osteoporosis or fracture, corticosteroid related mental disorders.

End point: The follow-up was terminated if tumor recurrence and serious adverse events of glucocorticoid and procedure-related complications (procedure-related bleeding and procedure-related perforation) occurred.

Statistical analysis

Continuous variables were represented by mean ± standard deviation (SD) or median (inter-quartile range, IQR, 25% - 75%). Categorical variables were expressed by proportion. Date analysis were completed through SPSS 23.0 software (version 23.0 for Mac).

RESULTS

Background characteristics of patients

After ESD surgery, there were 18 patients with mucosal defects more than 3/4 of the esophageal circumference. One patient received additional CRT treatment, and three patients received additional surgery and were removed from this study. Eventually, a total of 14 patients met the criterion. Patients and characteristics of lesions were shown in Table 1 and Table 2. Male patients accounted for 64%, with a mean age of 62.1 years (ranging from 45 to 75 years). According to the Paris endoscopic classification, 13 cases of endoscopic tumor morphology were classified type 0-IIa and 1case was type 0-IIc. The lesions were mainly located in the middle and lower esophagus, and 1 case was located in the upper esophagus. Each patient successfully received esophageal ESD treatment, and postoperative pathology confirmed that the lesion was completely removed. All patients had no procedure-related bleeding and procedure-related perforation after esophageal ESD. The mean resection size was 55.5mm in diameter (ranging 47.5 mm to 65.0 mm). According to the range of esophageal mucosal defect, 11 cases involved ≥ 3/4 and <7/8 circumference,1 case

involved ≥ 7/8 circumference and 2 cases involved the entire circumference. The longitudinal extension of mucosal defect was <50 mm in 3 patients and ≥50 mm in 11 patients. In 12 cases, the depth of invasion of pathological tissues were limited within the epithelium and lamina propria mucosa, while 2 Lesions were limited within muscularis mucosa without lymphovascular infiltration.

The shortest follow-up time of all cases was 6 months, the longest follow-up time was 28 mo, and the median follow-up time was 13 mo. During this period, all of the patients were followed up by endoscopy regularly without dysphagia. The incidence of esophageal stenosis was 0% (0/14) (Table 3). Representative cases are shown in Figure 1 and Figure 2.

Only one patient was found esophageal Candida infection on the 30th day after ESD and recovered completely after 7days of treatment with oral fluconazole 100 mg/day. Glucocorticoid-related adverse events were dis-observed, such as newly diagnosed diabetes or aggravation of diabetes, pepticulcer, adrenocortical insufficiency, aggravation of osteoporosis or fracture, corticosteroid related mental disorders.

DISCUSSION

In current study, increasing the dose of oral hormone (prednisone acetate 50 mg/day) and prolonging the treatment time (13 wk) were effective to prevent esophageal **stenosis** in patients with mucosal defects ≥ 3/4 circumference after ESD. Studies have shown that the occurrence of esophageal stricture after ESD was related to the infiltration of postoperative inflammatory cells and vascular proliferation[11,12]. At the same time, epithelial cells proliferated and migrated from the edge of wound after ESD, then fibroblasts proliferate continuously, and finally fibrous scar was formed. This process is divided into three stages: acute inflammation stage, proliferation stage and remodeling stage, however the duration of this process was unknown. Through the dog model study, Honda found that within about 1 mo after esophageal EMR, the mucosal defect healed and was covered by squamous cells. Although the proper muscle layer was not damaged, muscle fiber atrophy still occurred in the first week after operation,

and finally fibrosis was formed[13]. Some clinical studies also observed that esophageal stenosis mostly was occurred within 2 to 4 wk after operation[3, 14], but this was confined to endoscopic observation. Glucocorticoid has a strong anti-inflammatory effect, which can not only inhibit the synthesis of collagen, but also promote the decomposition of collagen, so as to inhibit the formation of stenosis. In our study, all cases did not have esophageal stenosis after ESD. We believe that increasing the dose of prednisolone can enhance the anti-inflammatory effect in the acute inflammatory period, especially in the critical period of the first month after ESD. Meanwhile, we speculate that the process of esophageal stenosis may last longer than expected, and prolonging the usage of prednisolone may inhibit the proliferation of fibroblasts steadily, so as to prevent esophageal remodeling and the formation of esophageal stenosis.

There are several reports on the application of steroids to prevent stenosis after ESD operation for large-area superficial esophageal squamous cell carcinoma and precancerous lesions. Yamaguchi *et al* reported the therapeutic effect of oral prednisolone after esophageal ESD for the first time. In their report, Prednisone was taken on the third day after ESD, with an initial dose of 30mg/day, and then decreased gradually (30, 30, 25, 25, 20, 15, 10, and 5 mg for 1 week each). The incidence of stenosis after semi circumferential ESD resection and entire circumferential ESD resection were 6.3% (1/16) and 0% (0/3), respectively [5]. However, for the cases of circumferential esophageal mucosal defect after ESD, Sato found that oral prednisone 30 mg/day could not reduce the incidence of postoperative esophageal stenosis, but could decrease the total number of EBD expansions required [15]. In Kadota' study, the stenosis rate of patients with less than entire circumferential ESD resection and with oral prednisone 30 mg/day administration was similar to Yamaguchi' results, while patients with entire circumferential ESD resection showed higher stenosis rate (10/14) even with additional local submucosal steroid injections [7]. Meanwhile, two studies of submucosal injection of triamcinolone acetonide within the mucosal defects combined with oral prednisone in the prevention of esophageal stenosis post-ESD for lesions more than 3/4 circumference have obtained completely opposite results. Chu Y reported that after

treated with submucosal injection of triamcinolone acetonide within the mucosal defects combined with oral prednisone 30 mg/d, the incidence of esophageal stenosis was only 18.2% (2/11), including lesions with total circumferential resection [16]. Surprisingly, in Hanaoka N' study of 12 cases with whole circumferential defect, the same steroid submucosal injection combined with oral prednisone 5 mg/d were used for post-ESD treatment, nevertheless, 11 patients failed to avoid postoperative stenosis [17]. This discrepancy may be caused by different doses of orally-taken prednisolone in these studies. A study about short-term usage of oral prednisolone (30, 20, and 10 mg/day for 1 week each) for mucosal defects ≥ 3/4 circumference, including 3 patients with total circumferential resection that showed a stenosis rate of 18% (3/17). And one of the three patients with total circumferential resection withstood stenosis [18]. Accordingly, we speculate that the prevention of esophageal stenosis after esophageal ESD by oral prednisone was correlated to the dose and the use time. In our study, we increased the dose of prednisone to 50 mg/day and prolonged the treatment time to 13 wk. During our follow-up, 14 patients had no feedback of dysphagia symptoms, and no esophageal stenosis observed by endoscopic examination. Especially the two patients with entire circumference mucosal defects, although the esophageal wounds were fibrotic, the 9.9mm diameter gastroscope (Olympus GIF-Q260J) could pass, and we did not add EBD treatment. In addition, studies have shown that the injury of the intrinsic muscle layer was one of the risk factors for esophageal stenosis after ESD for early esophageal cancer and precancerous lesions[19,20]. Therefore, we paid more attention to avoid the injury of the intrinsic muscle layer as much as possible during ESD operation, which we think was also helpful for the prevention of postoperative esophageal stenosis.

Furthermore, systemic steroids were associated with adverse events, including newly diagnosed diabetes or aggravation of diabetes, pepticulcer, adrenocortical insufficiency, aggravation of osteoporosis or fracture, corticosteroid related mental disorders. Stuck *et al* Showed that when the cumulative dose of oral prednisone exceeded 700 mg, the risk of infectious complications in patients taking prednisone

increased with the increase of prednisone dosage[21]. One study also found that even short-term steroid use was related to increased risks of adverse events [22]. However, in our protocol, the accumulated dose of oral steroids was 3075 mg, which was higher than that of other studies, and PPI, oral calcium and vitamin D3 were taken simultaneously. One patient was found to have esophageal Candida infection on the 30th day after operation, and completely recovered after 7 days of oral fluconazole 100 mg/d therapy, and no patients gave the feedback of other adverse incidents related to orally-taken prednisolone. Therefore, we believed that the treatment scheme of increasing the dose of prednisone (50 mg/day) was safe, but it still needs long-term follow-up and observation.

Finally, there were several limitations in our study. First of all, this study was a retrospective analysis in single-centered and possible bias could not be avoided. Secondly, the follow-up time was insufficient and could not comprehensively evaluate the feasibility and safety of hormone. Thirdly, the number of subjects were relatively small, and the control group was lacking, so statistical difference analysis cannot be conducted. Due to these limitations, prospective randomized controlled studies should be established to validate the efficacy and safety of prophylactic steroid therapy.

CONCLUSION

In conclusion, increasing the dose of oral prednisone (50 mg/day) and prolonging the usage time (total 13 wk) may effectively prevent esophageal stenosis after ESD removing large-area superficial esophageal squamous cell carcinoma or precancerous lesions of esophagus, and does not increase the incidence of glucocorticoid-related adverse events.

ARTICLE HIGHLIGHTS

Research background

Esophageal stenosis is one of the main complications of endoscopic submucosal dissection (ESD) for the treatment of large-area superficial esophageal squamous cell

carcinoma and precancerous lesions (≥3/4 of the lumen). Oral prednisone is useful to prevent esophageal stenosis, but the curative effect remians controversial.

Research motivation

Explore more effective methods to prevent esophageal stenosis after ESD for early esophageal cancer and precancerous lesions

Research objectives

we will share our experience of the precautions against esophageal stenosis after ESD removing large superficial esophageal lesions.

Research methods

Patients with large superficial esophageal squamous cell carcinoma and high-grade intraepithelial neoplasia experienced ESD were enrolled. Prednisone (50mg/day) was administrated orally on the second day after ESD for 1 mo, tapered gradually (5mg/week) for 13 wk.

Research results

According to the range of esophageal mucosal defect, 11 cases involved ≥ 3/4 and <7/8 circumference,1 case involved ≥ 7/8 circumference and 2 cases involved the entire circumference. The incidence of esophageal stenosis was 0% (0/14), and only one patient was found esophageal Candida infection on the 30th day after ESD and recovered completely after 7days of treatment with oral fluconazole 100mg/day.

Research conclusions

Further investigation of larger samples was required to warrant feasibility and safety.

Research perspectives

In conclusion, increasing the dose of oral prednisone (50mg/day) and prolonging the usage time (total 13 wk) may effectively prevent esophageal stenosis after ESD

removing large-area superficial esophageal squamous cell carcinoma or precancerous lesions of esophagus, and does not increase the incidence of glucocorticoid-related adverse events.

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