

# BOUGIE DILATATION IN BENIGN ESOPHAGEAL STRICTURES: EVALUATION OF ADJUVANT METHYLPREDNISOLONE INJECTION

## BENİGN ÖZOFAGEAL STRİKTÜRLERDE BUJİ DİLASYONU: ADJUVAN METİLPREDNİZOLON İNJEKSİYONUNUN DEĞERLENDİRİLMESİ

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**Cite this article as:** Koker IH, Senturk H. Bougie dilatation in benign esophageal strictures: Evaluation of adjuvant methylprednisolone injection. J Ist Faculty Med. Published online June 2, 2022. doi: 10.26650/IUITFD.1011641

### ABSTRACT

**Objective:** Mechanical dilatation and adjuvant injection of triamcinolone acetate (TA) effectively preserve the opening provided and reduce the number of bougie dilation (BD) in benign esophageal strictures. In this study, we aimed to evaluate the role of Methylprednisolone (MP) injection after BD in providing permanent/long-term lumen opening.

**Materials and Methods:** Among 22 patients diagnosed with benign esophageal strictures (BES) between January 2017 and October 2020, we evaluated the results of 8 patients who continued the endoscopic follow-up program and underwent BD and MP injection, then compared with the literature.

**Results:** We treated 8 patients [6 (75%) women, mean age 61±16.9 years (range 22-77)] with strictures of different etiologies (3 anastomotic, 2 iatrogenic esophageal rupture repairs, 2 recurrent webs, and 1 scleroderma) with BD followed by intralesional MP injection. We performed median BD sessions 3.5 times (range 1-8). We gave a median 3 intralesional MP injection (range 1-7). The median time to resolve stricture was 2.5 months (range 1-4). The median endoscopic follow-up time was 4.5 months (range 1-17).

**Conclusions:** Adjuvant MP injection is successful in preserving the lumen patency provided after mechanical dilatation. Randomized controlled studies are needed to determine the steroid type and dose to provide the most optimal permanent lumen opening with lesser dilatation sessions in BES.

**Keywords:** Benign esophageal stricture, bougie dilation, endoscopic therapy, methylprednisolone

### ÖZET

**Amaç:** Benign özofageal striktürlerde mekanik dilatasyon sonrası adjuvan triamsinolon asetat (TA) injeksiyonu bujilerle sağlanan açıklığın korunmasında ve buji dilatasyon (BD) seans sayısını azaltmada etkilidirler. Bu çalışmada, buji dilatasyonu sonrasında Metilprednizolon (MP) injeksiyonunun kalıcı/uzun dönem lümen açıklığını sağlamadaki etkinliğini araştırmayı planladık.

**Gereç ve Yöntem:** Ocak 2017- Ekim 2020 tarihleri arasında benign özofageal darlık (BES) tanısı alan 22 hasta arasından BD ve MP injeksiyon seanslarına alınan ve endoskopik takip programına devam eden 8 hastanın sonuçlarını değerlendirerek literatürle karşılaştırdık.

**Bulgular:** Farklı etyolojik nedenlere (3 anastomotik, 2 iatrojenik özofageal rüptür onarımı, 2 rekürren web ve 1 skleroderma) bağlı striktürleri olan 8 hastayı [6 (75%) kadın, yaş ortalaması 61±16,9 yıl, (22-77)] buji dilatasyonu ve takiben intralezyonel MP injeksiyonu ile tedavi ettik. Kalıcı açıklığın sağlanması için median BD seans sayısını 3,5 (1-8) saptadık. İntralezyonel olarak uyguladığımız median MP injeksiyonu sayısı 3 (1-7) oldu. Striktürlerin median düzelleme zamanı 2,5 aydı (1-4). Hastaların median endoskopik takip sürelerini ise 4,5 ay (1-17) olarak belirledik.

**Sonuçlar:** Mekanik dilatasyon sonrasında sağlanan lümen açıklığının korunmasında adjuvan MP injeksiyonu başarılıdır. Benign özofageal striktürlerde en az dilatasyon sayısı ile optimal kalıcı lümen açıklığını sağlamada kullanılacak steroid tipi ve dozunu belirlemede randomize kontrollü çalışmalara ihtiyaç vardır.

**Anahtar Kelimeler:** Benign özofageal striktür, buji dilatasyonu, endoskopik tedavi, metilprednizolon

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**Submitted/Başvuru:** 18.10.2021 • **Revision Requested/Revizyon Talebi:** 11.11.2021 •

**Last Revision Received/Son Revizyon:** 12.04.2022 • **Accepted/Kabul:** 18.04.2022 • **Published Online/Online Yayın:** 02.06.2022



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## INTRODUCTION

In gastrointestinal tract injury, the normal process of wound healing causes scar tissue formation. During the remodeling phase of tissue healing, fibroblasts promote wound contraction, which leads to stenosis in the tubular structure of the gastrointestinal tract (1).

Mechanical dilatation of strictures with bougie or balloon is the splitting of the scar tissue within the stricture. It can be helpful temporarily in the opening of the stenosis. Therefore, the opening provided by mechanical dilatation in the stricture area can recur in a short time. For this reason, after the bougie dilatation, steroid injection was started to be applied into the stenotic area to maintain the passage.

Intralesional steroid injection in benign esophageal strictures (BES) was first applied experimentally in animal models by Ashcraft et al. (2). The proposed mechanism in intralesional steroid injection reduces collagen formation by local inhibition of the inflammatory response by intralesional steroids (3). Intralesional triamcinolone acetate (TA) injection to the stricture areas, which has high anti-inflammatory and topical efficacy, is a successful method widely used in the last two decades, especially in anastomotic line strictures that develop after esophageal atresia operations, as well as peptic and corrosive strictures (4-8). Dexamethasone (DM), used less frequently, takes second place among the steroids injected intralesionally (9).

Methylprednisolone (MP) is also a glucocorticoid with an anti-inflammatory and topical activity that can be injected similarly to TA and DM. However, to the best of our knowledge, there is no study in the English literature on intramucosal MP injection in BES. In this study, we aimed to evaluate the results of intralesional MP injection after mechanical BD in BES.

## PATIENTS AND METHODS

### Study design and participants

We evaluated the results of 8 patients who could continue the endoscopic treatment program out of 22 patients with BES between January 2017 and October 2020 according to their clinical, radiological, and endoscopic features. The same endoscopist did all the endoscopic procedures. We used MP since TA was not available at that time. Demographic data, medical history, GI endoscopic findings, BD, and adjuvant MP injection results of these patients were retrieved from the electronic medical records. This study was approved by the local ethics committee of Bezmialem Vakif University (Date: 29.12.2020, Number: 22/420).

### Endoscopes used

Fujinon endoscope K017, Pentax gastroscope G123459 with 9.4 mm outer diameter.

### Mechanical (Bougie) dilation and methylprednisolone injection into mucosal tears created by bougies

For mechanical dilatation of benign strictures, guide-wire-based, varying lengths of tapering at the tip and also have radiopaque markers to allow for fluoroscopic guidance, Savary-Gilliard dilators (Wilson-Cook Medical Inc., Winston, Salem, USA) were used. Patients were progressively dilated (rule of 3 bougies of increasing size per session) at 7 or 14-day intervals until the 15 or 17 mm dilator was introduced.

We performed BD sessions with the method of advancement without fluoroscopic follow-up over the guidewire placed under endoscopic vision. We used the fluoroscopy device in only 1 patient, as it was considered that BD would increase the risk of perforation of the residual esophageal lumen during the advancement of bougies.

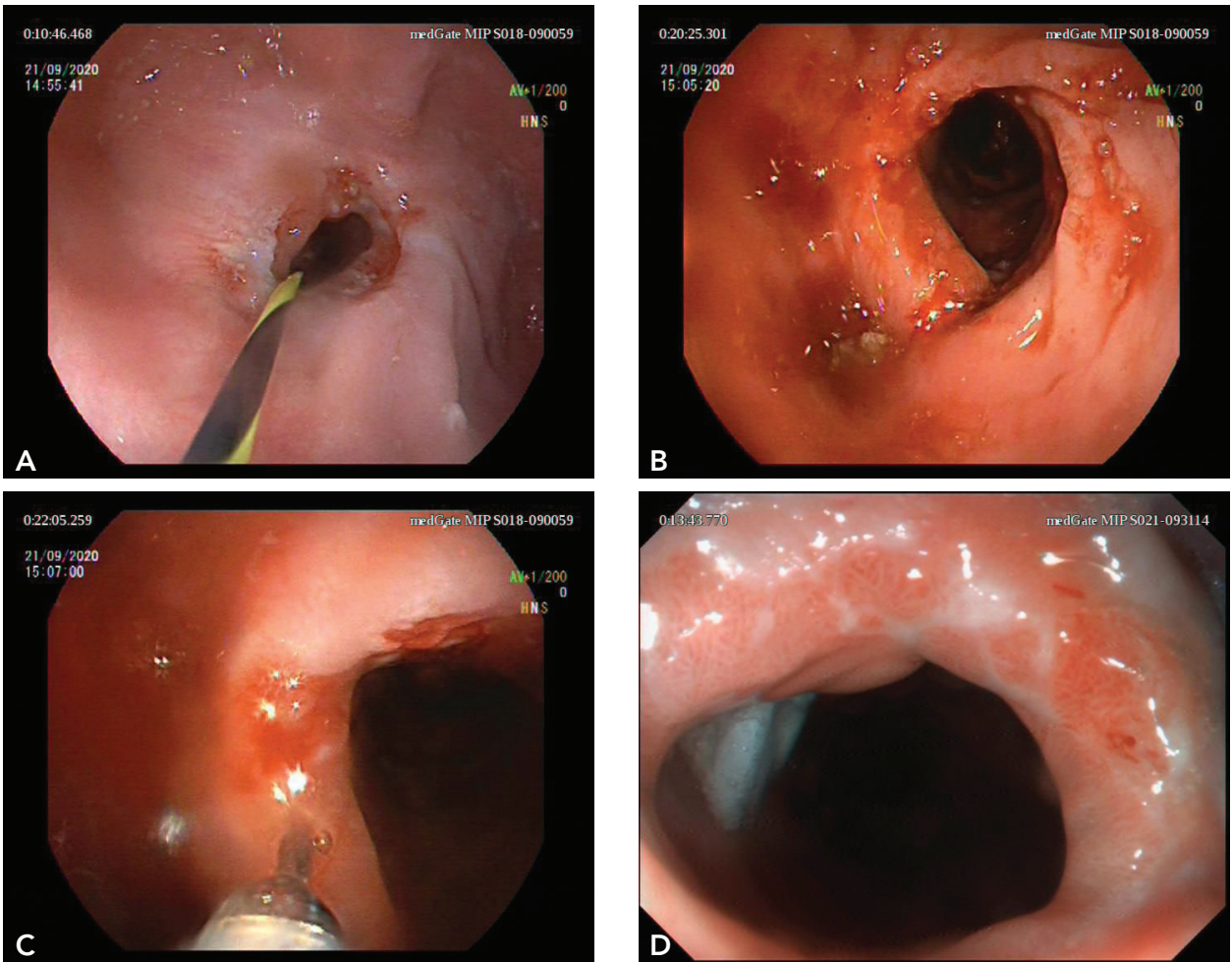
We gradually enlarged the surface area by making mucosal tears in the stricture with bougies. In the first three patients, we applied BD 3 times in the first patient and once in the other 2 patients without steroid injection (SI). However, in the endoscopic control, 1 or 2 weeks later, the opening provided in the area of the stenosis had disappeared, and it was necessary to return to the initial bougie number applied before. For this reason, we performed intralesional MP injection in addition to bougie dilatation in these patients and the following 5 patients with BES.

After the BD disruption, as evidenced by a notable tear of the stricture on post-dilation endoscopy, we added adjuvant intralesional MP injection immediately into the mucosal tears created by BD same session. We injected a total of 20 mg methylprednisolone (PREDNOL-L 20 mg, MN, Istanbul, Turkey) into the areas of mucosal tears using a 22-gauge, 0.7 mm sclerotherapy needle (Micro-Tech (Nanjing) Co., Jiangsu, China). Methylprednisolone was injected in a 1:5 dilution of 2 mg/ml/3-4 mL for each area. Figure 1 shows the anastomotic stricture and the dilatation stages of the stenosis.

Bougie dilatation and adjuvant MPI were continued with 1 or 2-week intervals until we observed the reshaped lumen opening was preserved in the following control. Afterward, we gradually extended the control periods to 4, 8, and 12 weeks.

### Ensuring the continuity of the opening provided in the stenotic lumen with methylprednisolone injections - Providing permanent/long-term opening

The follow-up periods from the first to the last session of the patients who underwent BD and subsequent MP injection were recorded. For the necessity of dilatation and sequential SI, the endoscopic evaluation was based on the easy passage of the 9.4 mm endoscope through the stenosis. If it passed easily, no further dilatation and injection was performed, and the patients were switched



**Figure 1:** A. Anastomotic line stenosis, B. Mucosal tears surrounding the enlarged lumen after bougie dilatation, C. MP injection into mucosal tears with sclerotherapy needle, D. The stenosis is reshaped by providing an optimal opening

from the endoscopic treatment sessions to endoscopic follow-up. The follow-up was terminated after it was found that the lumen opening did not change.

### Statistical analysis

All statistical analyses were performed using SPSS Statistics software version 25 (IBM Corp., Armonk, NY, USA). The Kolmogorov–Smirnov test and Shapiro–Wilk tests showed the distribution of the data. Descriptive statistics were presented using medians and range values for non-normally distributed and ordinal variables. Correlations of the postoperative stricture development time and bougie dilatation number were analyzed using the Pearson’s rank test since both data had a normal distribution. A two-tailed p-value of <0.05 was accepted as statistically significant.

### RESULTS

The characteristics of the patients who underwent BD and adjuvant MP injection are shown in Table 1. The me-

dian age of the patients was 65.5 years (range 22-77). The median duration of symptomatic stricture development in postoperative BES was 5.5 months (range 1-15).

**Table 1:** Patient characteristics who underwent BD and adjuvant MP injection (n=8)

<b>Age, years median (range)</b>	65.5 (22-77)
<b>Gender, female (%)</b>	6 (75)
<b>Stricture etiology*</b>	
1. Anastomotic	3 (37.5)
2. Web	2 (25)
3. IERR	2 (25)
4. Scleroderma	1 (12.5)
<b>PSDT n, mo median (range)</b>	5, 5 (1-15)

\*Values are presented as n (%), IERR: iatrogenic esophageal rupture repair, mo: month, n: number, PSDT: Postoperative stricture development time

In this patient group, we evaluated the primary stricture etiology, the postoperative growth period of the stricture in anastomotic strictures, the number of BD sessions, the number of adjuvant MP injections, and the time to resolve the stricture (Table 2).

We applied adjuvant MP injection to a 66-year-old male patient during the 4<sup>th</sup> and 5<sup>th</sup> BD sessions whose anastomotic stenosis recurred despite three BD at 1-week intervals. The patient's follow-up was terminated after two successful adjuvant MP injection sessions due to sufficient lumen opening in the endoscopic control. However, 9 months after the second MP injection, the patient underwent BD due to the recurrence of the stenosis, but he was removed from the BD program upon the development of a perforation. We attribute the recurrence of stenosis to the low number of MP injection sessions compared to the other anastomotic stricture cases. In 3 of the other 4 patients with anastomotic stricture, MP injection sessions were performed 4, 5, and 7 times, respectively (Table 2).

In the female group, apart from operative strictures, 2 patients had stenosis due to web and 1 patient due to scleroderma. Therefore, the median BD and MP injection numbers were lower in women.

### Methylprednisolone injection into and around mucosal tears, response to treatment and time to resolve stricture

The number of BD sessions, intralesional MP injection sessions, follow-up time, and time to resolve stricture are shown in Table 3. We defined time to resolve stricture from the beginning of BD and subsequent MP injection until a permanent/long-term lumen opening is achieved.

We did not find a significant correlation between the duration of postoperative stenosis and the number of BD sessions in 5 patients with anastomotic stenosis ( $r=-0.269$ ,  $p=0.662$ ).

We observed that the opening provided was maintained in the following BD sessions; we continued MP injection by increasing the bougie numbers gradually. Later, when we observed that the patency provided by MP injection was preserved and it was a safe procedure with no significant side effects, we started BD and adjuvant MP injection together in the following 5 patients.

### Complications

No complications developed as a result of intralesional injections such as perforation, bleeding, or esophageal candidiasis.

**Table 2:** Bougie dilation and adjuvant MP injection in BES

Patient	Age, gender	Stricture etiology	POSD time (mo)	BD session no	MPI session no	Follow-up time (mo)	Time to resolve stricture (mo)
1.	65, F	A	15	4	4	5	2
2.	77, F	A	5	2	2	4	1
3.	22, F	I	5	8	7	17	3
4.	66, M	A	8	5	2	9	2
5.	58, M	I	1	6	5	4	4
6.	74, F	W	NA	3	3	3	1
7.	60, F	W	NA	1	2	14	1
8.	66, F	S	NA	1	2	1	1

A: anastomotic, BD: bougie dilation, F: female, I: iatrogenic esophageal rupture repair, M: male, mo: month, MPI: methylprednisolone injection, NA: not available, POSD: postoperative stricture development, S: scleroderma, W: web, y: year

**Table 3:** The patient outcomes undergoing BD and intralesional MPI

<b>BD session n, median (range)</b>	8, 3.5 (1-8)
<b>MPI total sessions</b>	27
<b>MPI n, median (range)</b>	8, 3.0 (1-7)
<b>Time to resolve stricture n, mo median (range)</b>	8, 2.5 (1-4)
<b>Total endoscopic follow-up time n, mo median (range)</b>	8, 4.5 (1-17)

BD: bougie dilatation, mo: month, MPI: intralesional methylprednisolone injection, n: number

## DISCUSSION

Endoscopic mechanical dilatation is still the first-line treatment in BES. Also, an intralesional steroid injection is recommended as first-line therapy in refractory strictures (10). However, there is no guideline regarding the steroid type, dosage, frequency, and effectiveness of adjuvant intralesional steroid injection administered simultaneously with mechanical dilatation.

In previous studies, adjuvant intralesional TA or DM injection was used in esophageal strictures unresponsive to BD (Table 4). In this study, we used MP, which can be injected like TA and DM. We performed a retrospective analysis of 8 patients with various stricture types who underwent BD and intralesional adjuvant MP injection in our endoscopy unit. The median number of BD was 3.5 (range 1-8), while the median BD and adjuvant MP in-

**Table 4:** Studies with mechanical dilatation and adjuvant SI in benign esophageal strictures

Author	No of patients (SG/CG)	Stricture type	Dilatation n, (mean±SD/median+(range) / (IQR))	Steroid type, injection modality	Conclusion
Zein et al., (4)	7/0	3P, 1RT, 1A, 1C, 1TR	2 (range 2-7)	TA. 10 mg Before BD. Repeated 2 times,	May decrease the esophageal dilations and surgical repairs
Lee et al., (5)	31/0	Esoph 12P, 8A, 6RT, 1S, 1 PI Pyl: 2 P, 1 Py	NA	TA. 28 mg After dilation. With each dilation.	Safe. Reduce the overall cost and complications of BD.
Miyashita et al., (9)	11/22	A	1.1±0.3	DM. 8 mg After balloon dilation. Repeating schedule unclear	Prevents the recurrence of anastomotic stricture.
Kochhar et al., (6)	17/0	C	3.57±2.9	TA. 10 mg After BD Repeated up to 3 times	Augment the effect of BD
Kochhar et al., (19)	71/0	29 C, 14 P, 19 A, 9 RT	3.73	TA 40 mg After BD Repeated up to 4 times	Augment the effect of BD in all forms of BES.
Altıntaş et al., (7)	10/11	6 P, 2 C, 1 A, 1 RT/ 4P, 1C, 3A, 3RT	2-12	TA 8 mg After BD Only first time	Decrease the requirements for dilations.
Ramage et al., (8)	15/15	15P/15P	NA	TA 20 mg Before dilation With each dilation	Decrease the requirement for dilations
Orive-Calzada et al., (21)	9/14	2A, 3P, 4C/ 2A, 9P, 2C, 1 RT	3.33±1.8	TA 40 mg Before BD. Only first time	Improves dysphagia
Hirdes et al., (11)	29/31	A/A	2 (range 1-7)	TA 40 mg Before BD Repeated up to 3 times	Do not reduce dysphagia
Pereira-Lima et al., (13)	10/9	A/A	3±2	TA 40 mg After BD With each dilation	Significant improvement or resolution of dysphagia.
Nijihawan et al., (20)	11/0	C	5	TA 40 mg After BD Weekly during 5 weeks	Reduce the frequency of BD, improving dysphagia
Hanaoka et al., (12)	33/32	A/A	2.0 (IQR 1.0-2.5)	TA 50 mg. After balloon dilation With each dilation	SI shows promising results for the prevention of stricture recurrence.

A: anastomosis, BES: benign esophageal stricture, C: corrosive, CG: control group, DM: dexamethasone, Esoph: esophageal, IQR: interquartile range, MP: Methylprednisolone, n: number, P: peptic, PI: pill-induced, Py: pyloroplasty, Pyl: pyloric, RT: radiotherapy, S: sclerotherapy, SI: steroid injection, SG: study group, TA: Triamcinolone acetonide, TR: tracheobronchial remnant

jection number to resolve the stricture was 3 (range 1-7). The median time taken to recover the stenosis with this treatment was 2.5 months, range (1-4) months. The median endoscopic follow-up period of 8 patients included in the study was 4.5 months (range 1-17). No recurrence was observed in 7 patients; however, in a male patient with anastomotic stenosis, although we provided an optimal opening in the stenotic area with 2 BD and MP injection sessions, the anastomotic stenosis recurred after 9 months.

The methods and conclusions of some of the previous studies, mainly with TA, are shown in Table 4.

As seen in Table 4, the number of BD sessions in our study and the number of BD sessions in previous studies performed with most TA is similar. We also evaluated the correlation between the postoperative stricture development time and BD session number. However, we found no relation with each other.

Steroid injection was applied in a limited number in some studies, while it was performed in every BD session in others, as in our study (Table 4). According to these studies, adjuvant SI is beneficial, except for Hirdes et al (11).

Another result of our study is that the median time required to resolve the stricture was 2.5 months (range 1-4) with BD and adjuvant MPI. Recently, Hanaoka et al. reported the median required time to resolve the stricture as 22 days (range 0-70) (12). Also, their median number of dilatation was 2.0 (Interquartile range 1.0-2.5) which was lower than ours 3.5 (range 1-8). However, after 6 months of follow-up, 39% of their patients remained recurrence-free. In our patient group, we observed no recurrence at the end of the 6th month. Accordingly, we think having SI at least 3-4 times for each patient after BD is essential in remodeling, especially in refractory BES. Also, it may be essential to apply the SI before or after BD. Also, where it is applied might be important as the number of SI.

In previous studies, steroid use was done with two different methods, as before and after dilation. Among these studies, the only study finding intralesional SI unsuccessful was Hirdes et al. in a multicenter RCT (11). They applied SI before BD to prevent the risk of perforation of the lacerated esophageal wall. Accordingly, they concluded that SI did not reduce dysphagia (Table 4). However, according to the results of our study and in most of the previous studies, some of which are summarized in Table 4, SI before or after BD is successful in reducing the number of BD sessions and providing permanent lumen patency. Hence, we agree with Kiil J, et al, that the SI into the mucosal tears created with BD inhibits the contraction of collagen with a topical effect and prevents the re-narrowing of the acquired opening (3). Like our

study, Pereira-Lima et al. also performed TA injection to the next or at the borders of the lacerations developing after BD in 19 patients and concluded that dysphagia was significantly improved (13).

There are also studies examining the prophylactic preventive effect of intralesional TA in forming the post-ESD stricture with a large surface area. While intralesional TA injection was successful in some of these, some stated that it was unsuccessful (14, 15).

A case report stated that high dose systemic MP and subsequent oral prednisolone administration prolonged the BD-free period in two pediatric patients with caustic burns who did not respond to intralesional DM injection (16). In our 8 case series, we arranged the MP injection sessions according to the improvement of the patients' complaints and the easy passage of the endoscope through the stenosis area, regardless of a pre-established protocol. We observed that the need for MP injection sessions was higher in operative strictures (Table 2). In this case, the current question that needs to be answered is which steroid type, dose, and frequency should be administered into the mucosal tears created by dilation.

Henskens et al. also recommended intralesional SI in peptic strictures and stated that it could be considered in radiation-induced, corrosive strictures, and anastomotic strictures (17). However, they recommended limiting steroid use to a maximum of 3 times, depending on the risk of candida esophagitis. Considering the infrequent side effects such as candida esophagitis reported in several studies, limiting the SI to a maximum of 3 times does not seem reasonable (4, 11). However, in the case of candida esophagitis and similar adverse events during SI, esophagitis frequency and dose adjustment may guide the injection frequency. Therefore, the lack of other significant serious side effects of SI suggests that it is suitable for more frequent use due to its benefit.

The first limitation of our study is that the number of patients we have applied MP injection is relatively small, but the results of this case series are almost compatible with the previous studies in the literature (Table 4). Therefore, we do not think that more patients' evaluation is needed regarding adjuvant MP injection in providing lumen patency in BES. Besides, most of the intralesional SI study reports in the English literature are about TA. To the best of our knowledge, our study is the first study performed with MP. The second limitation of the study is that, instead of the Ogilvie score (18) used in clinical trials, we used more subjective criteria based on the failure of the standard upper endoscope to pass through the stenosis patient is symptomatic. However, the usefulness of these criteria is evident in the other studies (7, 19-21).

## CONCLUSION

Intralesional methylprednisolone injection into the mucosal tears created by mechanical dilatation effectively maintains the permanent/long-term lumen opening. However, we believe that randomized controlled studies are needed regarding the type of steroid injected and the optimal dose to minimize the number of mechanical dilatation sessions in benign esophageal strictures.

**Ethics Committee Approval:** This study was approved by the local ethics committee of Bezmialem Vakif University. (Date: 29.12.2020, Number: 22/420).

**Peer Review:** Externally peer-reviewed.

**Author Contributions:** Conception/Design of Study- İ.H.K., H.Ş.; Data Acquisition- İ.H.K.; Data Analysis/Interpretation- İ.H.K.; Drafting Manuscript- İ.H.K.; Critical Revision of Manuscript- H.Ş.; Approval and Accountability- H.Ş.; Supervision- H.Ş.

**Conflict of Interest:** There is no conflict of interest among the authors.

**Financial Disclosure:** The authors declared that this study has received no financial support.

**Acknowledgments:** We would like to thank nurses Ayşe Tezel, Deniz Akıncı and Nebahat Bal for their devoted work.

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