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The use of Triamcinolone Injection in treatment of refractory benign Esophageal Stricture in children

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ABSTRACT

Objectives: To evaluate the efficacy of Intra-lesional triamcinolone injection in the management of refractory benign esophageal Stricture in children.

Methods: Before endoscopic dilatation, triamcinolone acetate (40 mg/ml) was be applied in the first 5 dilations with an interval of one week between the first and second dilation and then every 2 weeks.

Results: A total of 67 children with refractory benign esophageal stricture out of 183 children (36.6%) who presented with esophageal stricture were enrolled in the study, Cause of esophageal stricture was post-corrosive injury (n=59, 88.1%), with a smaller proportion attributed to post-TEF repair (n=8, 11.9%), There was a significant reduction in the number of dilatations required before and after the triamcinolone injections. The mean maximum dilation improved from 10.66 mm SG(Savary-Gilliard) before injections to 13.13 mm SG after injections, periodic dilatation index (PDI) showed significant reduction post-treatment. The mean PDI decreased from 1.07 to 0.27, There was a significant improvement in the grades of dysphagia, there was no significant changes in cortisone levels, ACTH (Adrenocorticotropic hormone) levels showed no significant change, there were no major complications of the procedure.

Conclusion: findings suggest that intralesional triamcinolone injection is an effective and safe treatment option for refractory benign esophageal strictures in children.

Keywords: *Savary-Gilliard dilator, periodic dilatation index, dysphagia*

1. INTRODUCTION

A refractory or recurrent stricture is defined as an anatomic restriction resulting from cicatricial luminal compromise or due to fibrosis leading to clinical symptoms of dysphagia in the absence of any endoscopic evidence of inflammation. This may occur either as a result of an inability to successfully resolve the anatomic problem up to a diameter of 14 mm over five sessions at 2-weeks intervals (refractory stricture) or due to an inability to maintain a satisfactory luminal diameter for 4 weeks once the target diameter of 14 mm has been achieved (recurrent stricture)[1]

More than 80–90 % of esophageal strictures can be treated successfully with endoscopic dilation using bougies or balloons. Esophageal dilation is a procedure with a very low rate of serious complications, mainly bleeding and perforation[2], the incidence of the different etiologies varies between countries, In developing countries, caustic injuries are more frequent [3].

Ingestion of highly alkali or acidic substances is a major cause of morbidity and mortality worldwide, especially in developing regions. Victims are largely unsupervised preschool children, Most taste or drink household cleaning agents due to curiosity or while searching for food or drink. Toddlers are most at risk, averaging 3 years of age at ingestion[4], Esophageal anastomotic stricture remains one of the main complications occurring after repair of esophageal atresia: this event occurs in 18–60 % of children who undergo surgery[5, 6].

Intralesional corticosteroid injection as an adjunct to dilatation has been proposed to prevent stricture recurrence approximately 50 years ago ,However, in the last two decades, there has been a growing interest in the use of this therapy for refractory benign esophageal strictures of various etiologies[7].

Triamcinolone acetonide is a synthetic corticosteroid with a preventive effect on collagen synthesis, fibrosis, and chronic cicatrization that has been used for many years, applied in intralesional injection [8].

2. METHODS

Patients selection

This is a prospective study conducted at gastrointestinal endoscopic unit of Assiut University Children's Hospital from 1st of October 2020 to the end of September 2022.

Inclusion criteria

Any child present with refractory benign esophageal stricture during the study period was eligible for the study[9].

Exclusion criteria

Any child with one or more of the following criteria was excluded from the study;

- **Pharyngeal stenosis precluding endoscopic examination and dilatation.**
- **Gastric cicatrisation that precluded safe placement of a guidewire**
- **Any patient who was unfit for general anesthesia**

All children included in this study were subjected to through history taking (age, sex, residence, cause of stricture, age at start of endoscopic dilatation, number of endoscopic dilatation, degree of dysphagia) and detailed examination including measurements of height , weight, blood pressure were recorded, Laboratory investigation (Adrenocorticotropic hormone (ACTH) and cortisone (am, pm) level before and after completing course of steroid injection), complete blood count (CBC), prothrombin time (PT), prothrombin concentration (PC), Sessions of dilatation and postprocedural complications were recorded. In addition to, weight and grade of dysphagia were reported at baseline and after last session of dilatation.

Patient preparation:

Laboratory investigations (CBC, PT , PC,serum Na,K,Ca,kidney functions)

A gastrografin swallow and gastrografin meal were administered to assess site and length of stricture before first session of dilatation with injection of steroid and after last session of dilatation with injection of steroid in patient still had symptoms of dysphagia.

Pre-procedure fitness

Informative written consent of the procedure

The objective of the study:

To evaluate the efficacy of Intra-lesional triamcinolone injection in the management of refractory benign esophageal Stricture in children

Endoscopic dilatation and steroid injection

Before endoscopic dilatation, triamcinolone acetate (40 mg/ml) was diluted upto 4 mL of normal saline and one milliliter of this solution was injected into each quadrant in proximal margin of the stricture in four quadrants with a sclerotherapy needle,(a 21,23-gauge and 5 mm in length) was used , the mucosa elevation around the stricture confirms that the solution was injected in and not outside the esophagus, then, endoscopic dilatation was done using Savary-Gilliard dilators of different diameters (5mm,7mm,9mm,…)., The steroid was be applied in the first 5 dilations with an interval of one week between the first and second dilation and then every 2 weeks [10, 11],Observation of all patients after the procedure for any symptoms and signs of complications (fever, chest pain, dyspnea). All patients were discharged home on the second day of the procedure on proton pump inhibitors (esomeprazole, dose: weight up to 20 kg: 10mg once daily, weight >20kg: 20 mg

once daily) treatment for one week, there was no other adjuvant therapy been used, after the five sessions of steroid injection and dilation, follow-up dilatation was standardized according to the standard rules of dilatation.

Outcomes

- **Successful dilatation** that defined as absence of dysphagia for 6 months after the last dilation [12].
- **Periodic dilatation index (PDI)** that defined as total number of dilations divided by the duration of time in months [13], that was calculated at the end of follow up period that was one year.
- **Dysphagia score (DS)** based on clinical dysphagia scoring system [14]:

✓ Score: 0 - No dysphagia: able to eat a normal diet.

✓ Score:1 - Moderate passage: able to eat some solid foods.

✓ Score: 2 - Poor passage: able to eat only semi-solid foods.

✓ Score: 3 - Very poor passage: able to swallow only liquids only.

✓ Score: 4 - No passage: unable to swallow anything.

- **Number of sessions** till the end point of the study (the endpoint for dilatation in children more than 5 years of age was 14 mm and in children ≤ 5 years of age up to 12 mm Savary-Gilliard (SG) bougie dilator) [10, 11]
- **Maximum dilatation** in mm after end of triamcinolone injection.
- Adrenocorticotropic hormone (ACTH) and cortisone (am, pm) level before and after completing course of steroid injection.

Ethical considerations

The study was approved by the Ethical Committee of faculty of Medicine Assiut university with IRB no: 17200528 and registered on clinicaltrials.gov with NCT04524897. All methods and protocols of our work were performed in accordance with the relevant guidelines and regulations of the Declaration of Helsinki and Assiut University. All caregivers of all participants have given their informed written consent. Every patient was free to refuse participation in the study without affecting the service or the clinical management. They were, also, free to ask any question about the study. Privacy and confidentiality of all data were assured.

Statistical analysis

The Statistical Package for the Social Sciences – SPSS software version 25.0 was used. All variables are expressed as mean plus or minus standard deviation. Paired t tests were performed to compare the continuous variables before and after the procedure. Nominal data were expressed as frequency (percentage) and compared by Chi2 test. Level of confidence was kept at 95% and hence, p value was significant if < 0.05.

3. RESULTS

During the study period a total of 67 children, diagnosed with refractory benign esophageal stricture were enrolled in this study (36.6%) among 183 children presented with esophageal stricture, Demographic data and clinical characteristics of children with refractory esophageal stricture and non-refractory shown in (Table1).

The total number of dilatation sessions of these 67 children underwent before the study was 770, and the total sessions of steroid injection was 335, The data shows a significant reduction in the number of dilatations required before and after the complete five session of triamcinolone injections among the study patients on follow up of our patient, Before the injections, the mean number of dilatations was 11.28 with a standard deviation of 3.39, after the injections, the mean number of dilatations decreased to 3.24 with a standard deviation of 0.94 with significant p value ($p<0.001$), The total number successful dilatations after injection of steroid were 335, from our patients 47(70.1%) reached grade 0 dysphagia and 20(29.9%) patients needed re-dilatation after the follow up period.

The analysis of maximum dilatations before and after injections demonstrates a significant increase in the dilation size. The mean maximum dilation improved from 10.66 mm SG with a standard deviation of 1.05 before injections to 13.13 mm SG with a standard deviation of 1.21after injections with significant p value $p<0.001$.

The assessment of the periodic dilatation index (PDI) before and after injections in study patients showed a significant reduction after injection, The mean PDI decreased from 1.07 with a standard deviation of 0.38 to 0.27 with a standard deviation of 0.05 with significant p value $p<0.001$.

A significant increase in the body weight of the study patients following the administration of triamcinolone injections, as shown in (Table 2), Results showed no significant changes in cortisone levels at both time points, also, the ACTH levels showed no significant change, as shown in (Table 2), no significant change in the height of the study patients before and

after the administration of triamcinolone injections, before the injections, the height Z score was -4.26±1.34, after the treatment, the height Z score was -4.37±1.44.

The data indicates a significant improvement in the grades of dysphagia after the administration of triamcinolone injections among the study patients, as shown in Figure (1).

The follow-up study of patients revealed that a significant portion, 23 subjects (34.3%), experienced chest pain. However, there were no cases of major bleeding, mediastinitis, esophageal perforation, or esophageal candidiasis reported. Additionally, no subjects exhibited Cushing symptoms due to steroid use. Anesthesia-related complications were noted, with 11 subjects (16.4%) experiencing bronchospasm.

4. DISCUSSION

In the present study, the steroid was be applied in the first 5 dilations with an interval of one week between the first and second dilation and then every 2 weeks, in other studies, Abdelhay, Mousa et al. 2020, needed one or more sessions of corticosteroid injection without dilatation[15], Another study limited the total number of injections of steroids to three (Kochhar et al., 1999) [16], This difference might be due to there is no standard protocol of steroid injections in refractory stricture and number of session of injection of steroid might be different from one patient to another according to (the cause, length, number, complexity of stricture) and response of stricture to previous steroid injection.

The mean number of dilatations required decreased significantly from 11.28 ± 3.39 before injections to 3.24 ± 0.94 after injections ($p<0.001$). This reduction is comparable to that reported in other studies, as, Ismail et al. 2021**,** they found that intralesional injection of steroids decreased the number of dilatations [17], A metanalysis conducted by Zhang et al., 2018 , showed that intralesional triamcinolone injection combined with endoscopic dilation was safe and effective and reduced the stricture rate and further endoscopic sessions[18], This finding coincides with the study of Takahashi et al., 2015, who reported that endoscopic triamcinolone injection reduced the mean number of dilatation sessions per patient from 12.5 to 6.1.[19], A meta-analysis by Szapáry et al., 2018 reported that, endoscopic intralesional steroid injections may be useful and may reduce the number of necessary dilations[20], this reduction in number of dilatations supports the efficacy of triamcinolone in management of refractory esophageal stricture, On the other hand, Altintas et al., 2004 reported that there was no significant difference between controls and the studied cases regarding the total number of dilatations [21].

The maximum dilatation diameter increased from 10.66 ± 1.05 mm to 13.13 ± 1.21 mm ($p<0.001$), indicating improved esophageal patency, This improvement is consistent with findings from other studies using intralesional steroid injections ,as, Takahashi et al., 2015[19], Narayanan et al., 2022 reported that post injection the number of patients in whom Savary-Gilliard dilation could be done up to 15 mm increased from 3 to 9[22],this improvement in maximum dilatation diameter supports the efficacy of triamcinolone in management of refractory esophageal stricture.

The PDI decreased significantly from 1.07 ± 0.38 to 0.27 ± 0.05 ($p<0.001$), suggesting a reduced need for frequent dilatations. This agrees with Narayanan et al., 2022 [22],These results are similar to those seen in the study by Kochhar et al., 2002 [23],In accordance, Szapáry et al., 2018 reported that, the PDI values were calculated with the mean difference method due to the similar measures and showed a significant improvement of the PDI in the steroid group[20],This was true across all etiologies and irrespective of length or location of the stricture[11, 24],Nijhawan et al., 2016 showed a statistically significant, strong improvement in the PDI with the combined therapy in patients with corrosive strictures only[11].

There was a significant improvement in dysphagia grades after treatment ($p<0.001$). Before treatment, 80.6% of patients had grade III dysphagia, while after treatment, 70.1% had no dysphagia (grade 0). This dramatic improvement is more pronounced than in some other studies (Kochhar et al., 1999, Camargo et al., 2003)[16, 25], possibly due to our comprehensive treatment protocol, In agreement with the findings in this study, Narang et al., 2017 [26], the same results were obtained by Kochhar and Makharia 2002 who reported a decrease in dysphagia score from 2,34 to 0,656[23], Pereira-Lima et al .2015, proved a significant improvement in the dysphagia score (DS) in the combined therapy group in a randomized controlled trial[27].

Contrary to the current findings, Camargo, Lopes et al. 2003,another randomized, double-blind triamcinolone (10mg/mL) and saline, triamcinolone injections did not reduce the dilatation frequency and dysphagia score compared to placebo, but increased the diameter of the dilators passed in the following sessions[25], also, Szapáry et al. 2018, reported that, the dysphagia score (DS) did not improve after intralesional steroid injection, but intralesional steroid significantly increased the time between endoscopic dilations, from 1.3 to 0.3dilations/month[20].

There were no significant changes in ACTH or cortisol levels, suggesting minimal systemic absorption of the steroid, this reflect the safety profile of intralesional triamcinolone injections in studied patients, also, This is consistent with other studies reporting the safety of local steroid injections, Ramage Jr et al., 2005 [28],also, Helal and Daboos 2019 [29], Contrary to the current findings, van Hal et al., 2022 [30], Divarci et al.,2016 [31], the absence of Systemic side effects (no significant changes in ACTH or cortisol levels, no Cushing syndrome) in the present study show safety profile of intralesional triamcinolone injections.

There was a small but significant increase in weight Z score -3.25±1.51 to -2.26±1.31, p=0.020, these findings align with other study Gandhi et al., 1989 [32], likely due to improved swallowing function.

On follow up of patients after the procedure, The common observed complaint was chest pain (34.3%), which is just observed in the studied patients and managed conservative without any complications were reported and we observed no severe complications such as perforation, mediastinitis, or major bleeding, Other studies have been reported complications albeit rarely ,as, Ahn et al., 2015 [33], Altintas et al., 2004 who had reported 2 perforations ,one in the dilation only and one in the combined treatment group, both in caustic strictures[21], Hirdes et al., 2013 who recorded one gastrointestinal bleeding in the monotherapy group and five adverse events, such as one laceration and four candida esophagitis in the patients treated with intralesional steroid[34], the absence of major complications (perforation, mediastinitis, or bleeding) in the present study show the safety of the procedure and steroid injection.

The limitation of our study is the lack of a placebo control arm, the follow-up period was limited to one year, and longer-term outcomes should be assessed, In conclusion, this study demonstrates that intralesional triamcinolone injection is an effective and safe line of treatment for refractory benign esophageal strictures in children. It significantly reduces the need for repeated dilatations and improves dysphagia symptoms, with a favorable safety profile.

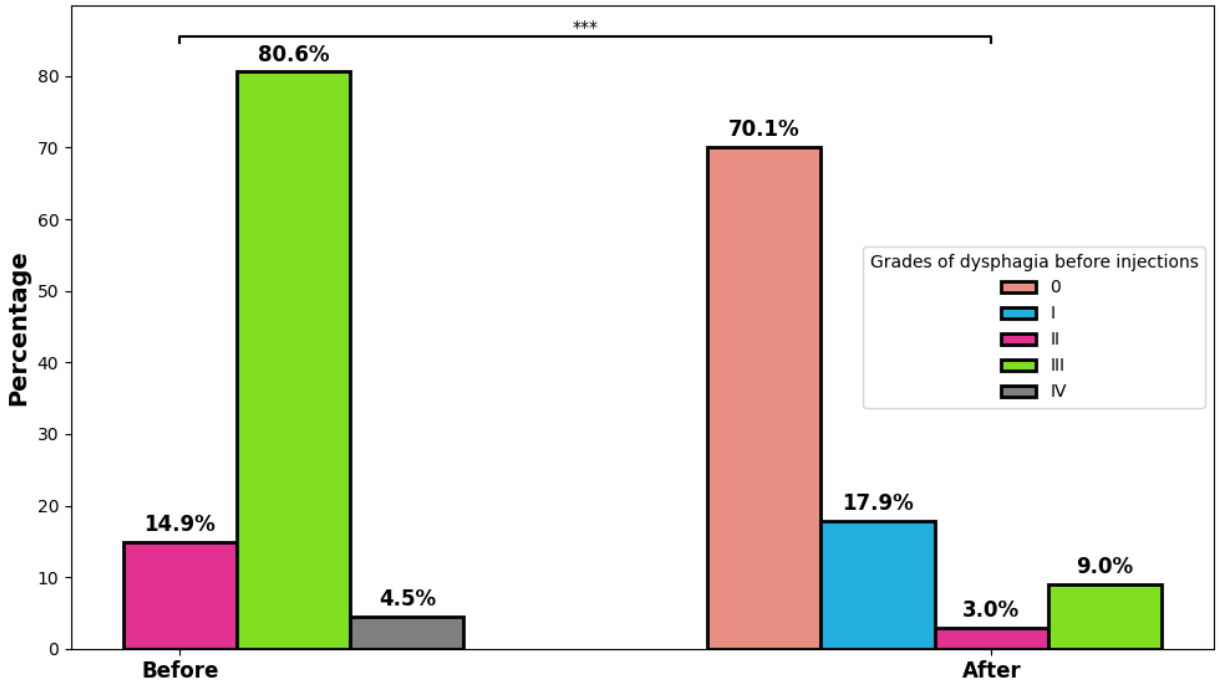

Figure (1): Grades of dysphagia before and after Triamcinolone injections.

TABLES

Table 1: Demographic data and clinical characteristics of children with refractory esophageal stricture and non-refractory.

		Refractory	***Non Refractory***	***Test Result***
		n=67	*n=116*	
Age (Years)	*Median (Min-Max)*	*3.80 (2.40-14.00)*	*3.50 (1.20-16.00)*	*p=0.131*
Sex	*Female*	*27(40.3%)*	*45(38.8%)*	*p=0.965*
	Male	*40(59.7%)*	*71(61.2%)*	
Residence	*Rural*	*39(58.2%)*	*64(55.2%)*	*p=0.807*
	Urban	*28(41.8%)*	*52(44.8%)*	
Weight (kg)	Median (Range)	11.00 (8.20-47.00)	10.00 (9.1-52.00)	*p=0.603*

	Z score	-3.25±1.51	-2.25±1.51	
Post corrosive		*59(88.1%)*	*87(75.0%)*	*p=0.054*
Post TEF		*8(11.9%)*	*29(25%)*	*p=0.244*
Site of stricture	*Lower Esophageal*	*19 (28.4%)*	*44 (37.9%)*	*p=0.006**
	Mid-Esophageal	*13 (19.4%)*	*35 (30.2%)*	
	Upper Esophageal	*26 (38.8%)*	*32 (27.6%)*	
	Upper/Mid-Esophageal	*7 (10.5%)*	*0 (0%)*	
	Mid/Lower Esophageal	*2 (3.0%)*	*5 (4.3%)*	
Length Of Stricture	*Long>5Cm*	*13(19.4%)*	*0(0.0%)*	*p<0.001**
	Short<5Cm	*54(80.6%)*	*116(100.0%)*	
Number Of Stricture	*Multiple*	*9(13.4%)*	*8(6.9%)*	*p<0.001**
	Single	*58(86.6%)*	*108(93.1%)*	
Type Of Corrosive	*Acidic*	*21(35.6%)*	*32(36.8%)*	*p=0.865*
	Alkali	*38(64.4%)*	*55(63.2%)*	

* for significant p value (<0.05)

Table 2: Cortisone and ACTH levels before and after Triamcinolone injections, Body weight before and after Triamcinolone injections.

		Before	***After***	***P***
		n=67	*n=67*	
Weight (kg)	*Median (Range)*	*11.00 (8.20-47.00)*	*12.00 (9.20-47.50)*	*p=0.020**
	Z score	*-3.25±1.51*	*-2.26±1.31*	
Cortisone 8am (microg/dl)	*Median (Range)*	*20.00 (16.00-22.00)*	*19.80 (15.00-22.00)*	*p=0.895*
Cortisone 8pm (microg/dl)	*Median (Range)*	*9.00 (5.00-9.80)*	*9.00 (4.00-9.80)*	*p=0.599*
ACTH (pg/ml)	*Median (Range)*	*20.00 (18.00-23.00)*	*20.10 (18.10-23.10)*	*p=0.692*

* for significant p value (<0.05)

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