ORIGINAL ARTICLE

Effectiveness of intralesional steroid injections with dilatation in corrosive oesophageal strictures - A Randomized Control Tiral

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Abstract

Objectives: To compare the improvement of dilatation among patients receiving intralesional steroid injection with dilatation versus dilatation alone for the management of corrosive ooesophageal strictures.

Method: The randomized controlled trial was conducted at Mayo Hospital, Lahore, Pakistan, from November 10, 2014, to November 10, 2015, and comprised patients of either gender aged 15-50years who had corrosive ooesophageal stricture. They were randomised into 2 groups by using the lottery method. In the dilatation group, only endoscopic dilation was done, while in the combination group, intralesional triamcinolone injection was injected followed by dilatation. Follow-up endoscopic dilatation was done every two weeks. Data was analysed using SPSS 21.

Results: There were 60 patients randomised into two groups of 30(50%) each. The overall mean age was 32.58±10.58 years and the male-to-female ratio was 1.7:1. At baseline, in dilatation group, the mean stricture length was 23.30±2.28cm while in combination group, it was 24.23±3.06cm. In dilatation group, the mean stricture length was 11.20±3.09cm while in combination group, it was 5.33±3.09cm (p=0.0001).

Conclusion: oesophageal Combination group was more effective than the dilatation-alone group.

Keywords: Dilation, Effectiveness, Intralesional steroid injections, Corrosive intake, oesophageal Oesophagealstrictures. (JPMA 68:1556; 2018)

Introduction

Oesophageal stricture is a commonly encountered clinical problem, especially in gastroenterology. It occurs due to narrowing of oesophagus, which results in swallowing difficulty. Oesophageal stricture has two major types: benign and malignant. Malignant type results from carcinoma but benign type has different causes.[1] Amongst benign aetiologies, gastrointestinal reflux disease (GERD), peptic injury, oesophageal webs, radiation damage, caustic swallowing and anastomotic strictures are most common. Corrosive intake is an important public health issue in developed countries and its incidence is still increasing in developing countries. The problem is largely unreported and its exact prevalence cannot be figured out due to the insufficient reporting or personal experience.[2] Corrosives materials can damage the bodies' tissues, as they come in contact with them. They are usually utilised to clean metals. It can cause severe health hazard, if swallowed accidentally or intentionally. Epidemiological studies have documented corrosive intake as the third most common cause of poisoning in adults.[3] The most common symptom of oesophageal stricture is progressive dysphagia to solids followed by inability to tolerate liquids. These strictures are diagnosed most commonly by using barium swallow, endoscopy and biopsy. Endoscopic dilatation is the most applicable method to treat oesophageal strictures, and proton pump inhibitors (PPIs) are also used to inhibit acid production.[4] Surgery is done when dilatation fails in regaining the passage of solid food through oesophagus and recurrence occurs regardless of repeated dilatations.[5] Presently, through many studies, it has been concluded that intralesional corticosteroid injections can be added to standard treatment for corrosive oesophageal stricture. International literature exhibited

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that intralesional steroid injections help in increasing the diameter because of its anti-inflammatory action.[6] But some studies showed that while corticosteroids can increase the diameter of stricture but it cannot reduce the frequency of dilatation.[7] Studies have demonstrated the usefulness of intralesional steroid injections in benign oesophageal stricture, which were resistant to bougie dilatation.[8] A study has reported that corticosteroid injection, in addition to dilatation, was successful in 100% patients.[9] A local study has reported that with dilatation alone, success was achieved in 60% cases.[10] Data of intralesional steroid injections is limited yet, so it is not in routine practice during dilatation of corrosive stricture. Further trials are required to prove or disprove the role of corticosteroids before doing dilatation of corrosive oesophageal strictures. The current study was planned to study the role of intralesional steroid injection along with dilatation in improving the stricture length in corrosive oesophageal stricture.

Patients and Methods

The randomized controlled trial was conducted at Mayo Hospital, Lahore, Pakistan, from November 10, 2014, to November 10, 2015. After approval from institutional review board, the sample size of was calculated by using 80% power of study, 5% significance level with percentage of symptomatic improvement i.e. 60% with dilation alone and 100% with dilation combined with intralesional corticosteroid injection. Informed written consent was taken from each participant. Simple random sampling was used to include all patients of either gender aged15-50years who were considered to have corrosive oesophageal stricture if the patient fulfilled all 3 elements of the criterion that entailed history of ingestion of corrosive material, stricture in oesophagus observed on barium swallow, and difficulty to pass endoscope across the stricture (10mm) in upper gastrointestinal region.

Patient with malignant disease based on histopathology of endoscopic biopsy, peptic ulcer diseases, congenital strictures, stricture due to repetitively endoscopic band ligation and achalasia cardia were excluded. Barium swallow and barium meal were administered to assess site and length of stricture and degree of contraction of oesophageal lumen. Patients were randomised into two groups. In the combination group, dilatation with 0.5cc/quadrant triamcinolone (40mg/cc) using a 23gauge, 5mm long sclerotherapy needle was done. In the dilatation group, only dilation was done. Dilatation was increased by 3mm on each session, till 15mm diameter was achieved. Standardised PPI regimen of40mg intravenous (IV) omeprazole once a day was given to all patients. Follow-up was done every 14 days till the patient was symptom free. Success of treatment was assessed by grading using following scale:[11]

Grade 0: normal diet; Grade 1: failure to swallow solid food; Grade 2: can swallow semi-solid food only; Grade 3: can take liquids only; and Grade 4: unable to tolerate liquids.

The procedure was labelled successful if grade 0 was achieved and the diameter of oesophagus widened to >15mm after 3months of procedure. Data analysis was done using SPSS 21. Effectiveness of the intervention was compared between both groups by using independent sample t-test and $p \leq 0.05$ was considered statistically significant.

Results

There were 60 patients randomised into two groups of 30(50%) each. The mean age was 32.70±10.20 years in dilatation group and 32.47±11.13 years in combination group (p=0.9338). In dilatation group, 18(60%) were males and 12(40%) were females, while in combination group, there were 20(66.6%) males and 10(33.3%) were females (p=0.599). In dilatation group, 24(80%) cases ingested acid substance, while 6(20%) ingested alkali substance.

Table-1 : Baseline characteristics of patients.

	Dilatation	Dilatation + steroid (combination group)	Total	p-value
N	30	30	60	
Mean Age (years)	32.70±10.20	32.47±11.13	32.58±10.58	0.9338
Gender (M/F)	18/12	20/10	38/22	0.5990
Corrosion type				
Acid	24	19	43	0.1547
Alkali	6	11	17	0.1556
Pulse (bpm)	75.50±8.80	75.47±8.86	75.48±8.75	0.9895
Blood Pressure (mmHg)	128.5±13.34	130.0±12.53	129.25±12.84	0.6552
Temp (oF)	99.3±0.44	99.3±0.44	99.3±0.44	1.0000
Respiratory Rate (rpm)	12.5±1.74	12.5±1.74	12.5±1.74	1.0000
Hb (g/L)	12.33±0.75	12.02±0.68	12.17±0.73	0.0989
Platelet (x103)	242.67±63.30	248.33±55.28	245.5±58.98	0.7136
Weight (kg)	67.80±8.53	66.80±10.84	67.30±9.68	0.6928

Hb: Haemglobin.

Table-2 : Comparison of symptoms in both groups after the intervention.

	Dilatation	Dilatation + steroid (combination group)	Total	p-value
Dysphagia	20	26	46	0.067
Odynophagia	20	26	46	0.067
Vomiting	21	21	42	>0.999
Weight loss	25	28	53	0.424
Chest pain	8	13	21	0.176
Back pain	7	5	12	0.519
Voice harshness	25	28	53	0.228
Dyspnoea	19	20	39	0.787

Table-3: Comparison of improved symptoms and post-procedure complications in both groups

	Study Groups			
	Dilatation	Combination	Total	p-value
Improved symptoms	7	13	20	0.100
Pallor	18	13	31	0.196
Oral Ulcer	22	16	38	0.108
Sialorrhoea& drooling	17	16	33	0.795
Posterior oropharyngeal erythema	22	12	34	0.009
Diffuse dental erosions	14	11	25	0.432
Wheezing	18	14	32	0.301
Epigastric tenderness	12	11	23	0.791

Table-1 shows the baseline characteristics of the study patients of both groups. No significant difference was observed.

The comparison of post-intervention symptoms in both groups are shown in Table-2. It can be seen that both the groups had similar improvement with no significant difference.

The mean stricture length at baseline was 23.30±2.28cm in dilatation group while in combination group, it was 24.23±3.06cm (p=0.1871). After 3 months, in dilatation group, mean stricture length was 11.20±3.09cm while in combination group, it was 5.33±3.09cm (p<0.0001).

Improvement in symptoms and post-procedure complications were also studied in both groups (Table 3). The primary outcome of decrease in the stricture length in the combination group at 3 months was achieved (p=0.0001).

Discussion

The addition of intralesional steroid injection to endoscopic dilation into the oesophageal stricture followed by dilation has been reported to prevent stricture recurrence. This modality of management has shown encouraging results in patients with peptic strictures since 1966. Nonetheless, majority of studies lacked adequate sampling size and were uncontrolled. Moreover, randomised controlled clinical trials are limited and with a compromised sample size.[12]

According to the current study, the insignificant results were obtained with study groups in terms of most of the symptoms and post-procedure complication parameters. Only significant difference was found in the posterior oropharyngeal erythema between the groups in our study. In the steroid group, fewer patients experienced posterior oropharyngeal erythemacompared to the dilation group (p=0.009)

Initially in researches, the worth of intralesional steroid injections was applied and verified in animals. In animal models of dye-induced oesophageal strictures, the effectiveness of steroid therapy in combination with dilation for the management of strictures was established.[13]

Studies established the fact that intralesional injections of steroid boost result of endoscopic dilation for the management of oesophageal strictures develop at different sites of oesophagus due to different causes.[2] It has been suggested that intralesional steroid injection must be considered in cases with refractory strictures, particularly complex strictures.[14]

A study concluded that subsequent intralesional 10mg triamcinolone injections increase the stricture diameter following oesophageal dilatation in corrosive intake.[15] Various observational studies have been conducted that suggested a possible beneficial effect of adding intralesional steroid injections to dilatation in various benign oesophageal strictures.[16] One of the observational studies concluded an improvement in dysphagia following steroid intervention for oesophageal dilatation.[17]

A trial demonstrated that the intralesional steroid injections are extremely usefulness in management of oesophageal stricture which are resistant to dilatation.[18] One small, sham randomised controlled trial (RCT) demonstrated that intralesional steroid injections in combination with dilation therapy was superior to dilation alone in the treatment of previously dilated, peptic strictures with re-do dilatation rates of 13% in steroid dilatation group and 60% in control group (p=0.01).[19]

A study reported that corticosteroid injection in addition to dilatation was successful in 100% patients.[9] A local study reported that with dilatation alone, success was

achieved in 60% cases.[10] An RCT[20] presented favourable results with a single injection of intralesional steroid injections for the inhibition of stricture after endoscopic dilatation for oesophageal cancer.

Previous research work has suggested the usefulness of intralesional steroid injections into oesophageal strictures for amplification of endoscopic dilatation effectiveness.[9,21] However, there are some cases with unmanageable stricture even with intralesional steroid injection given in combination with endoscopic dilatation.[1,22] This current study has its limitations. Firstly, this was a single-centre trial, although the study site currently receives the majority of the patients of oesophageal stricture as it is one of the largest tertiary care facilities in the region. Moreover, the results of the study can only be generalised to oesophageal strictures resulted from corrosive intake. In order to see its effectiveness in other causes of strictures, benign or malignant, further studies are warranted. Finally, the blinding process regarding the intervention among both the groups was absent. In the light of the results, the study recommends the use of intralesional steroid injections with dilatation for corrosive oesophageal stricture for better outcome in terms of dilatation.

Conclusion

The difference between the two groups was significant and the combination group showed reduced stricture length compared to dilatation alone.

Disclaimer: This manuscript is a part of Master's thesis in the field of Gastroenterology. Due to the non-existence of Randomised Controlled Trial (RCT) registration authority in Pakistan, the study carried no trial number. Instead, the study was registered with researchregistery.com with clinical trial number research registry 3340.
Conflict of Interest: None.
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