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Role of high-dose methylprednisolone in Zargar Grade IIB corrosive esophageal burns: A randomized control study

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Abstract:

OBJECTIVE: The objective of the study is to test the efficacy of high-dose methylprednisolone in the prevention of esophageal stricture after corrosive ingestion.

METHODS: This study was a single-center, randomized controlled single-blinded study. Simple randomization was done with 15 adult patients (>18 years) in each arm, who presented with a history of corrosive ingestion within the past 24 h and had esophageal injury of Zargar Grade IIB on endoscopy. Intravenous methylprednisolone 1 g/day for 3 days was given to the intervention arm while 100 mL of normal saline was given as placebo in control arm. Follow-up to diagnose esophageal stricture was done at 8 weeks.

RESULTS: Thirty patients (15 in each arm) were recruited for the study. As per the intention to treat analysis, 33% and 46.6% developed stricture in the intervention and control arm, respectively (relative risk [RR] = 0.714; 95% confidence interval 0.29–1.75; $P = 0.462$). 40% patients in control group and 7.7% in intervention group had undergone feeding jejunostomy, which was statistically significant with a p-value of 0.048. Airway injury showed significant clinical improvement in the intervention arm but the difference was nonsignificant statistically ($P = 0.674$). There was no increased incidence of hypertension, hyperglycemia, hyponatremia, hyperkalemia, or infections in intervention arm.

CONCLUSION: Methylprednisolone does not help in the prevention of stricture formation in corrosive esophageal injury, but it significantly reduces the requirement of feeding jejunostomy and has a beneficial role in treating airway injury.

Keywords:

Airway injury, corrosive ingestion, esophageal burns, steroids, stricture, Zargar classification

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Introduction

Corrosive ingestion is a grave public health problem. In contrast to pediatric population, ingestion in adults is more often suicidal in intent and frequently life threatening. It is a medical emergency and has devastating effects on the upper gastrointestinal (GI) and upper respiratory tract leading to mortality due to acute complications and esophageal stricture formation causing long-term morbidity and mortality. Majority of the esophageal strictures develop within 8 weeks of corrosive ingestion.[1]

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Box-ED section

What is already known on the study topic?

- Corrosive ingestion leads to esophageal stricture formation causing long-term morbidity
- Systemic steroids have been shown to help reduce airway edema after corrosive ingestion but its role for stricture prevention has not been established.

What is the conflict on the issue? Has it importance for readers?

- The role of systemic steroids in corrosive ingestion for stricture prevention is controversial with most of the studies done in pediatric age group
- Our study is a randomized controlled trial (RCT) in adult population to test the efficacy of steroids in Zargar Grade IIB esophageal injury.

How is this study structured?

- This single-center, randomized, parallel-group, single-blinded, placebo-controlled study was conducted at emergency department (ED) of a tertiary care hospital with a sample size of 30 (15 in each arm).

What does this study tell us?

- High-dose methylprednisolone is safe but did not reduce the incidence of stricture formation
- It reduced the requirement of feeding jejunostomy
- It might have beneficial role in reducing airway edema.

Approximately 1%–2% of corrosive ingestions develop stricture, the likelihood of which primarily depends on the depth of the burn injury.[2] Zargar classification on upper GI endoscopy (UGIE) has been used to grade the severity of corrosive injury.[3] Most of the patients with Zargar Grade I and IIA do not develop stricture.[2] Up to 70% of patients with Grade IIB and ≥90% of patients with Grade III injury will develop esophageal stricture.[4] Corticosteroid therapy in the management of corrosive substance ingestion is controversial. There is a low risk of stricture formation in lower grades of injury (Zargar IIA or lower) and high risk of infection and perforation in Zargar III or higher injuries which may be exacerbated by steroids.[5] Different corticosteroids (dexamethasone, prednisolone, and methylprednisolone) have been used at different doses through different routes of administration (oral or intravenous) in children with corrosive esophagitis with variable results.[6-8]

The utility of corticosteroids for postcorrosive stricture prevention is controversial. While various meta-analyses did not find any benefit of steroid administration in terms of stricture prevention,[9-11] few studies have demonstrated improved outcomes with steroids.[7,12-14]

Hence, we performed a randomized control trial in adult population to test the efficacy of methylprednisolone in preventing stricture formation after corrosive ingestion.

Methods

This single-center, randomized, parallel-group, single-blinded, placebo-controlled study was conducted at emergency department (ED) of a tertiary care teaching hospital from September 2020 to March 2022. The study was approved by the Institute Ethics Committee (Ref No: IECPG-212/June 24, 2020) and was registered with the National Clinical Trial Registry (CTRI/2020/09/027532).

All consecutive patients aged ≥18 years having a history of corrosive ingestion within the past 24 h of presentation to ED were screened. They underwent UGIE within 24 h of ED presentation. Patients having esophageal lesion of Zargar endoscopic Grade of IIB were recruited to the study after acquiring their valid informed consent to participate in the study. Patients with other grades of esophageal injury, i.e., Zargar Grades I, IIA, and III, hemodynamic unstable, unconscious on arrival, those who received cardiopulmonary resuscitation (CPR), needing mechanical ventilation, pregnant females, or history of corrosive ingestion of >24 h were excluded from the study [Supplementary Section 1].

On the basis of a study conducted by Usta *et al*.,[7] we estimated 11% stricture development in the intervention group and we anticipated 50% esophageal stricture development in the control group. To detect a difference of 39% with 80% power at 5% level of significance, we required 21 patients each in the intervention and control group. The total number of patients (sample size) required for this study was 42 (21 each in intervention and control group). However, due to the COVID-19 pandemic, the number of corrosive ingestion patients presenting to ED drastically reduced from August 2020 to December 2021. Hence, the sample size was reduced to 30 (15 in each arm) after getting permit for the same from Institute Ethics Committee (Ref No: F.4-1/2020 Acad. 1).

Randomization and blinding

Simple randomization allocation sequence chart was generated using online software for allocating patients to the control and intervention arm. The eligible patients were randomized to intervention and control group on 1:1 basis. The study was a single blinded (blinded to patient) with blinded endpoint (the specialist performing the endoscopy initially and after 8 weeks along with reporting radiologist for barium studies was blinded regarding the intervention and the control group) to avoid any reporting bias (PROBE design). Sequentially numbered, opaque, sealed envelope technique was

used for allocation concealment. Patients getting allocated to intervention arm received intravenous (IV) methylprednisolone 1 g/day diluted in 100 mL normal saline, which was infused over 30 min. This was administered once a day for a total of 3 days. Patients in control arm received 100 mL of normal saline (placebo) instead of methylprednisolone. Patients in both arms also received IV pantoprazole, IV antibiotics, and IV fluids along with other supportive therapy if needed. No steroids were administered to patients in control group.

Patients were monitored for complications secondary to corrosive ingestion (stridor, hoarseness of voice, upper GI bleed, acute respiratory distress syndrome, acute kidney injury, perforation peritonitis, and mediastinitis) during the ED stay. Clinical presence of hoarseness/change in voice, stridor, and/or inability to vocalize was considered for the presence of airway injury. For complications related to methylprednisolone, blood pressure and blood sugar levels (pre and postprandial levels at breakfast, lunch, and dinner) were monitored every sixth hourly. Serum electrolytes were assayed daily for evaluating the effect of methylprednisolone on electrolytes. Patients were monitored for infection with daily 6 hourly temperature charting and by rise in total leukocyte count on arrival and at day 4 were recorded [Supplementary Table 1].

Those who were hemodynamically stable and tolerating oral fluids were discharged after 5 days. Patients who were not tolerating oral fluids, GI surgery were consulted for possible feeding jejunostomy [Supplementary Section 2 and 3]. UGIE and barium swallow was done 8-week postcorrosive ingestion. At follow-up, both intervention and control group were assessed for the presence of esophageal stricture on endoscopy and radiological imaging. Patients who were not able to tolerate even fluids were not taken for barium swallow study, provided the risk of aspiration. The demonstration of stricture either on UGIE or barium swallow was labeled as having an esophageal stricture. All the endoscopies in both groups were either performed or reviewed by a single specialist (consultant gastroenterologist) and the barium swallow was interpreted by a single radiologist, both blinded to the treatment.

All the demographic profiles, symptoms, physical examination, laboratory evaluation, endoscopy, and radiological examination reports were recorded in Microsoft Excel spreadsheet. Analysis was done as per intention to treat for all the parameters except two secondary outcomes – "Underwent Invasive Procedure" and "Mortality at 8 weeks." Baseline characteristics of the patients were summarized as mean and standard deviations, median and ranges, or numbers and percentages. The endpoint (rate of esophageal stricture) was expressed as relative risk (RR). For the comparison of the quantitative data, Student's *t*-test was used to compare the normally distributed quantitative variables between the groups and the Mann–Whitney *U*-test was used to compare nonnormally distributed variables between both the groups. Chi-square test was used for the comparison of the qualitative data. All the analyses were conducted on IBM SPSS version 24, and a two-tailed $P < 0.05$ was considered statistically significant.

Results

Between July 2020 and March 2022, a total of 230 adult patients with corrosive ingestion underwent endoscopic screening, of whom 45 had esophageal Zargar Grade IIB and 30 were eligible for randomization [inclusion and exclusion criteria in Supplementary Section 1]. Details about the randomization and follow-up of the patients are provided in Figure 1. The characteristics of the patients at baseline were well balanced between the two groups [Table 1]. Most of the patients were discharged from ED at day 5 with no significant difference in admission rates between the two arms [Table 1]. None of the patients included in the study had past history of corrosive ingestion or any esophageal surgery.

Primary endpoint

On follow-up at 8 weeks, two participants could not be contacted and were lost to follow-up in the intervention arm. There was no attrition in control arm. As per intention to treat analysis, esophageal stricture developed in 5 of 15 patients (33.3%) in the intervention group and in 7 of 15 (46.6%) in the placebo group [RR = 0.714; 95% confidence interval 0.29–1.75; $P = 0.462$, Table 2 and 3]. None of the patients without stricture at 8 weeks had a history of undergoing balloon dilatation before the follow-up.

Secondary endpoint

On arrival to ED, a total of 6 patients presented with clinical airway injury, 3 each in control and intervention arm. At the time of disposition from ED, all the 3 patients in intervention arm had complete resolution of airway injury while 3 in control arm had persistent hoarseness. Although clinically there was significant clinical improvement in intervention arm, statistically this difference was nonsignificant with a $P = 0.674$. On arrival to ED, a total of six patients (3 in each arm) presented with upper GI bleed (hematemesis) which had resolved in all of them; by the time, they were disposed from ED [Table 3].

None of the patients developed infection, sepsis, acute respiratory distress syndrome (ARDS), perforation, peritonitis, or mediastinitis. On follow-up at 8 weeks, 40% patients in control group ($n = 15$) and 7.7% in

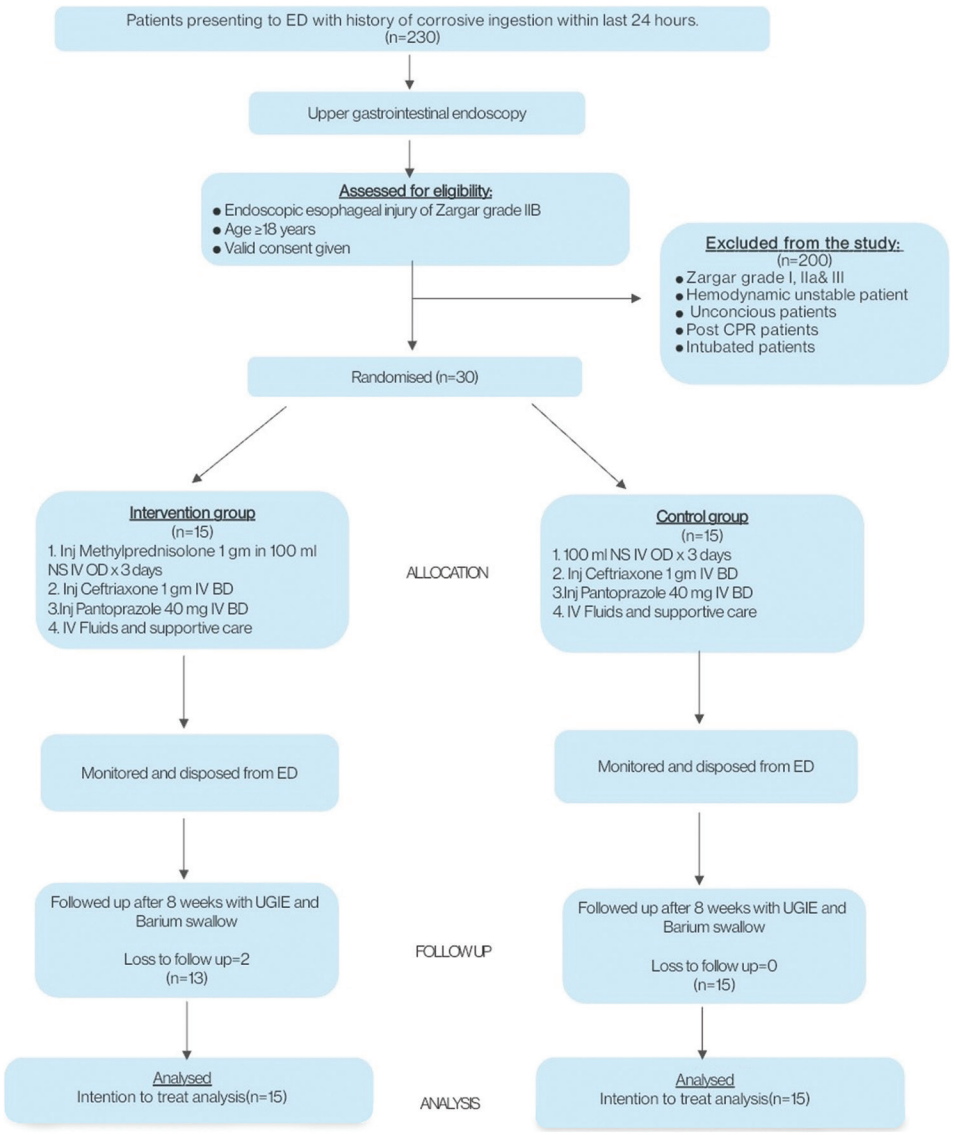

Figure 1: Consolidated Standards of Reporting Trials diagram showing progress through the phases of trial. ED: Emergency department, *n*: Frequency, Inj.: Injection, NS: Normal saline, OD: Once a day, BD: Twice a day, IV: Intravenous, UGIE: Upper gastrointestinal endoscopy

intervention group (n = 13) had undergone feeding jejunostomy, which was statistically significant with a P = 0.048. All the three cases with balloon dilatation mentioned in the study underwent the procedure before follow-up at 8 weeks. No mortality was reported in either of the groups at 8 weeks [Table 3].

No difference in the safety outcomes (rate of infection, hyperglycemia, or electrolyte disturbances) was observed between the study arms [Supplementary Figure 1 and Supplementary Table 2 and 3].

Discussion

Our study was a randomized controlled, open-label trial intended to compare the efficacy of high-dose methylprednisolone against placebo in the prevention of esophageal stricture formation in corrosive esophageal Zargar Grade IIB injury. Results from our study showed that there was no significant reduction in the development of esophageal stricture with methylprednisolone (RR = 0.714, P = 0.462). Systematic review and meta-analysis by Katibe *et al*.[9] reported no benefit of corticosteroids in the prevention of esophageal strictures following the ingestion of caustic materials. Another systematic analysis conducted by Fulton and Hoffman[10] including Zargar Grade II injury patients treated with corticosteroids versus no corticosteroids for at least 10 days also reported similar results. Pelclová and Navrátil[11] included Zargar Grades II and III injury patients treated with corticosteroids for at least 8 days also suggested that systemic corticosteroids are not beneficial for the second and third-degree corrosive

Table 1: Baseline characteristics of subjects

Characteristic	Control group (*n*=15), *n* (%)	Intervention group (*n*=15), *n* (%)	*P*
Mean age (years)	31.5±11.67	25.4±8.33	0.108
Female gender	7 (46.67)	7 (46.67)	0.642
Chemical agent ingested			
Acid	14 (93.33)	14 (93.33)	0.759
Alkali	1 (6.67)	1 (6.67)	
Intention			
Accidental	4 (26.67)	9 (60.00)	0.070
Suicidal	11 (73.33)	6 (40.00)	
Amount (mL)			
<10	0	1 (6.67)	0.169
10–50	10 (66.67)	13 (86.67)	
>50	5 (33.33)	1 (6.67)	
Presenting symptoms			
Dysphagia	12 (80.00)	14 (93.33)	NA
Vomiting	14 (93.33)	10 (66.67)	
Throat pain	10 (66.67)	10 (66.67)	
Chest pain	3 (20.00)	5 (33.33)	
Abdominal pain	10 (66.67)	8 (53.33)	
Hematemesis	3 (20.00)	3 (20.00)	
Hoarseness of voice	2 (13.33)	3 (20.00)	
Sialorrhea/drooling	5 (33.33)	6 (40.00)	
Disposition from ED			
Admission	7 (46.67)	6 (40.00)	0.500
Discharge	8 (53.33)	9 (60.00)	
Feeding status at ED disposition			
No feed	6 (40.00)	1 (6.67)	0.104
Liquid feeds	7 (46.67)	10 (66.67)	
Normal intake	2 (13.33)	4 (26.67)	

ED: Emergency department, NA: Not applicable

Table 2: Clinical, endoscopic, and radiological findings on follow-up at 8 weeks

	Control group (*n*=15), *n* (%)	Intervention group, *n* (%) (*n*=13)	RR (95% CI)	*P*
Persistence of clinical symptoms*	5 (33.3)	2 (15.3)	0.46 (0.10–1.99)	0.299
Esophageal stricture on UGIE	6 (40)	3 (23)	0.57 (0.17–1.85)	0.356
Esophageal stricture on barium swallow	4 (30.7)	2 (18)	0.59 (0.13–2.63)	0.490

*Vomiting, abdominal pain, and/or dysphagia at 8 weeks. UGIE: Upper gastrointestinal tract endoscopy, RR: Relative risk, CI: Confidence interval

esophageal burns. While prospective studies conducted by Usta *et al*.,[7] Boukthir *et al*.,[12] Bautista *et al*.,[13] and systematic analysis by Howell *et al*.[14] have suggested the beneficial role of systemic steroids in preventing stricture development in corrosive esophageal injury.

All the patients in control and intervention groups had comparable clinical profile such as presenting symptoms, disposition from ED, and feeding status at disposition. The most common complaint was dysphagia (n = 26) followed by vomiting (n = 24). Least common was hoarseness of voice (n = 4) and hematemesis (n = 6) [Supplementary Figure 2]. 57% of study subjects were discharged from ED. There was no significant difference in the ability to tolerate feeds at disposition in control and intervention groups. In a study published by Usta *et al*.,[7] vomiting and respiratory symptoms were the most and the least common symptoms, respectively. Although not statistically significant, all three patients with airway injury in intervention arm had resolution of airway symptoms after therapy while symptoms persisted in control arm at the same time interval. Systemic analysis conducted by Pelclová and Navrátil[11] and Fulton and Hoffman[10] supported the use of corticosteroids for patients with symptoms of respiratory tract edema secondary to corrosive burns.

The need for feeding jejunostomy and balloon dilation for esophageal stricture was assessed in both groups at 8 weeks. Requirement of feeding jejunostomy was significantly reduced in intervention group compared to control group (7.7% vs. 40%) with $P = 0.048$. There was no significant difference in requirement of balloon dilation at 8 weeks for both arms. Anderson *et al*.[6] reported less frequent requirement of esophageal replacement in steroid treated group. Bautista *et al*.[13] reported

Table 3: Primary and secondary endpoints of the study

	Control group (*n*=15), *n* (%)	Intervention group (*n*=15), *n* (%)**	RR (95% CI)	*P*
Primary endpoint				
Esophageal stricture development at 8 weeks after ingestion	7 (46.67)	5 (33.30)	0.714 (0.29–1.75)	0.462
Secondary endpoints				
Resolution of complications*				
Airway edema	0/3 (0)	3/3 (100)	-	0.674
AKI	1/1 (100)	0/0 (100)	-	-
Upper GI bleed	3/3 (100)	3/3 (100)	-	-
Underwent invasive procedure				
FJ	6 (40)	1 (7.7)	-	0.048
Balloon dilatation	1 (6.6)	2 (15.4)	-	0.456
Mortality at 8 weeks	0	0	-	-

*Depicted as frequency of cases with resolution on day 3 or the frequency of cases on arrival (percentage change), **For "Underwent Invasive Procedure" and "Mortality at 8 weeks" *n*=13, as two patients were loss to follow-up in intervention group. RR: Relative risk, CI: Confidence interval, AKI: Acute kidney injury, GI: Gastrointestinal, FJ: Feeding jejunostomy

decreased requirement of dilation procedure for stricture in dexamethasone-treated group in their study.

We did not observe any significant deviation in systolic or diastolic blood pressure over 3 days in both groups. The pre- and post-prandial blood sugar levels did not show an increasing trend in intervention arm. There was no increase in the incidence of electrolyte imbalances (hypernatremia, hypokalemia, and hypocalcemia) in intervention arm. These findings were consistent with studies published by Anderson *et al*.[6] and Usta *et al*.,[7] which reported no side effects associated with the high-dose methylprednisolone treatment.

Studies have shown a mortality rate of 8%–10% in corrosive ingestion secondary to upper respiratory tract injury causing airway obstruction, perforation peritonitis, esophageal perforation, and mediastinitis with delayed mortality attributed mainly to its complication of esophageal stricture formation.[15-17] In contrast to this, there was no mortality at 8 weeks in either of the groups in our study. This could be due to the exclusion of more severe grades of esophageal injuries (Zargar Grades III and IV), intubated patients, hemodynamically unstable, and post-CPR patients from our study.

Limitations

1. Reduction of sample size due to the COVID-19 pandemic further reduced the power of the study to detect a significant difference
2. It was a single-center trial conducted at a tertiary care hospital in urban setup which might affect the patient profile
3. It was a single-blinded study because of which some of the secondary outcomes could have reporting bias
4. Various studies have reported mortality 1–2 years postingestion which was not assessed in our study due to time restriction.

Conclusion

In our study, we found that IV methylprednisolone therapy does not help in the prevention of stricture formation in Zargar Grade IIB esophageal injury after corrosive ingestion, but it significantly reduced the requirement of feeding jejunostomy (though study was not powered to detect this relation) and might have a beneficial role in treating airway injury secondary to corrosive agents. Methylprednisolone use was found to be safe and was not associated with increased incidence of hypertension, hyperglycemia, and dyselectrolytemia. We did not find any increased incidence of infection or mortality with steroid use.

To better test the effectiveness of methylprednisolone in stricture prevention, role in airway injury, and reduction of need for invasive therapies, more double-blinded RCTs with larger sample size can be planned in the future.

Authors' contribution statement

- IS: Methodology, Investigation, Data curation, Formal analysis, Writing - Original Draft, Visualization
- NJ: Conceptualization, Data curation, Methodology, Writing - Review and Editing, Visualization, Supervision
- AN: Investigation, Writing - Original Draft, Review and Editing, Data curation
- PA: Conceptualization, Supervision, Resources
- SK: Data curation, Supervision, Project administration, Resources
- MK Formal analysis, Project administration, Resources
- CJD: Methodology, Supervision, Project administration
- AK: Formal analysis, Writing - Review and Editing.

Conflicts of interest

None Declared.

Ethical approval

The study was approved by Institute Ethics Committee (Ref No: IECPG-212/June 24, 2020) on June 25, 2020, and the protocol was registered with the National Clinical Trial Registry (CTRI/2020/09/027532).

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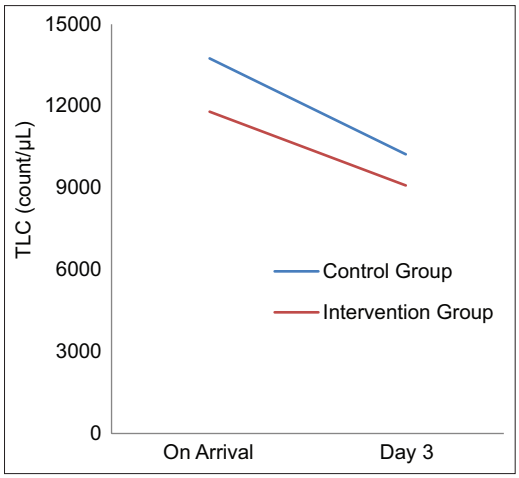
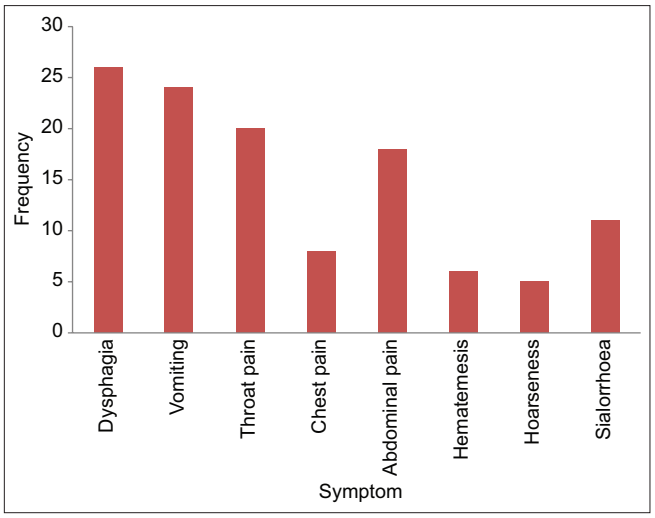


Supplementary Figure 1: Line diagram depicting the trend of TLCs. TLC: Total leukocyte counts



Supplementary Figure 2: Bar graph showing frequency of presenting symptoms

Supplementary Section

Supplementary section 1

Inclusion criteria

- All consecutive patients with a history of acute corrosive ingestion with Zargar Grade IIB esophageal injury on endoscopy
- Age ≥18 years
- Valid consent given by the patient for the study.

Exclusion criteria

- Esophageal injury other than endoscopic Zargar Grade IIB (Zargar Grades I, IIA, and III)
- Hemodynamically unstable patient
- Patients who are not conscious
- Patients who have received CPR
- Patients who need Endotracheal intubation and mechanical ventilation
- H/O corrosive ingestion of >24 h ago
- Pregnant females
- Age <18 years
- Patients who refused to give valid consent for the study.

Supplementary section 2

Admission criteria

- Complications not resolving during ED stay (stridor, hoarseness of voice, upper gastrointestinal bleed, acute respiratory distress syndrome, acute kidney injury, perforation peritonitis, and mediastinitis)
- Unable to tolerate oral liquids at disposition
- Requiring TPN (TPN was not started in our ED)
- Other concurrent injuries/conditions requiring admission and management (e.g., – ocular burns, complications secondary to comorbidities, persistent suicidal intent).

Discharge criteria

Tolerating oral liquids (trial given after Day 3 of corrosive ingestion if patient able to swallow their oral secretions).

Follow-up of patients discharged from Ed or later after admission from hospital was done on outpatient basis in Gastroenterology OPD.

Supplementary section 3

Stopping guideline

Treating physician could stop the ongoing steroid therapy if patient had features suggestive of perforation, peritonitis, mediastinitis, infection, or developed adverse effects to corticosteroids.

Supplementary Tables

UHID-

Area/bed number (in ED)

Supplementary Table 1: Monitoring chart

Date	Time	Temperature (6 hourly)	Blood pressure (6 hourly)	RBS at breakfast		RBS at lunch		RBS at dinner	
				Before	2 h after	Before	2 h after	Before	2 h after

RBS: Random blood sugar

Supplementary Table 2: Monitored clinical parameters

	Mean±SD	
	Control group (*n*=15)	Intervention group (*n*=15)
Temperature (°F)		
On arrival	98±0.55	98±0.50
Mean on day 1	97.9±0.46	97.9±0.44
Mean on day 2	97.8±0.52	97.9±0.54
Mean on day 3	97.8±0.50	97.9±0.52
SBP (mmHg)		
On arrival	119±13	120±12
Mean average SBP on day 1	119±10.8	120±12
Mean average SBP on day 2	119±12.4	119.9±12.6
Mean average SBP on day 3	118.5±12.7	119.9±12.4
DBP (mmHg)		
On arrival	73.4±6.8	77.1±7.2
Mean average DBP on day 1	74.8±5.7	76.7±6.7
Mean average DBP on day 2	73.5±6.1	76.5±0.4
Mean average DBP on day 3	74±6.6	77.06±6.8

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, SD: Standard deviation

Supplementary Table 3: Monitored laboratory parameters

	Control group (*n*=15)	Intervention group (*n*=15)	*P*
TLC, mean±SD (/μL)			
On arrival	13,744±5495	11,789±4812	0.308
On day 3	10,233±2895	9087±2102	0.224
Serum sodium (mmol/L)			
On arrival	142.6±7.3	142.3±3.6	0.858
On day 3	142.2±4.1	141.5±3.1	0.620
Serum potassium (mmol/L)			
On arrival	4.4±0.55	4.25±0.23	0.377
On day 3	4.4±0.45	4.4±0.36	0.656
Serum total calcium (mmol/L)			
On arrival	9.22±0.7	9±0.8	0.570
On day 3	9.23±0.6	9±0.8	0.591
Blood sugar levels (mg/dL)			
On arrival	150.8±65.1	123.5±36.6	0.349
Mean preprandial blood sugar levels			
Day 1	100.3±16.1	96.7±8.9	0.454
Day 2	99.7±12.8	92.5±2.0	0.072
Day 3	101.1±15	92.8±2.0	0.066
Mean postprandial blood sugar levels			
Day 1	136.6±52.0	110±13.62	0.060
Day 2	144.6±62.6	120.6±18.1	0.294
Day 3	145.6±77.2	118.2±13.8	0.297

TLC: Total leukocyte count, SD: Standard deviation