The Outcomes of Different Surgical Techniques for Esophageal Replacement in Children with Caustic Injury: A Single Center Experience

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Abstract

Introduction: Caustic esophageal injuries often lead to severe strictures untreatable with endoscopic methods, which necessitate surgical interventions. The aim of this study is to evaluate the outcomes and efficacy of these different techniques, including trans-hiatal gastric pull up, gastric pull up via thoracotomy, reverse gastric tube, and colonic interposition; and compare their complications.

Materials and Methods: This reto- and prospective study was conducted from 2014 onward at Mofid Children Hospital in Tehran. Data of patients who had undergone esophageal replacement surgery from 2007 to 2017 was retrieved from the hospital archives and the newly referred patients during the study. Required data were extracted from medical records.

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Data analysis was performed with SPSS 21 software package.

Results: 27 patients (mean age: 4.01 years, 59.3% males) were included in this survey. Average time from ingestion to surgery was 8.44 months. All patients had dysphagia. 5.8 sessions of endoscopic dilatation were performed for each patient, on average. 70.4% of patients underwent thoracotomy and gastric pull-up. ICU stay duration was 6.88 and time to extubation was 2.25 days. The most common complication was post-discharge stricture. Surgical methods were all the same regarding different parameters except post-discharge stricture.

Conclusion: Overall, surgical methods did not differ in terms of outcomes and complications.

Keywords

- Caustic ingestion
- Esophageal stricture
- Esophageal replacement
- Trans-hiatal gastric pull-up
- Esophagectomy

Introduction

Caustic agents are a group of chemicals that have the ability to cause tissue damage with direct contact to mucosal membranes. Their effects can range from a lack of physical damage to severe respiratory and gastrointestinal injuries, lifelong complications, and death. Severe complications, such as esophageal perforation and stenosis requiring multiple dilatations or esophageal replacement, have been reported extensively.[1]

The American Centers for Disease Control (AAPCC) annual report in 2015 recorded more than one million exposures to various substances in children under 6 years of age,[2] approximately 80% of which occurs in children under 5 years of age,[3] where it continues to cause major morbidity and mortality.[4-5] The extent of mucosal damage due to ingestion of caustic agent is dependent on pH, concentration, duration of tissue contact, site of contact, volume of ingested substance, viscosity of the substance, and form of ingested substance (liquid, gel, or solid).[6]

Caustic injuries are mainly due to alkalies, which are usually colorless and odorless and in liquid form, increasing the risk of

swallowing large volumes and leading to liquefying necrosis, which allow deeper penetration into the submucosa and muscular layer of the GI tract. This results in tissue scarring, vascular thrombosis, and impaired blood flow to the damaged tissue, which in severe cases, leads to perforation.[7] Acids, on the other hand, make up less than 5% of toxic ingestions. Acidic liquids have a pungent, sour taste that reduce the amount of fluid ingested in accidental or intentional swallows. Strong acids with a pH below 2 cause tissue damage due to coagulation necrosis as a result of ischemia.[8]

Clinical manifestations of caustic ingestions do not predict the presence or severity of esophageal lesions in children, and the relationship between symptoms and severity of injury in ingestion of caustic material is unclear. For example, one study found that 82% of symptomatic patients had grade 0 or 1 esophageal injury in esophagoscopy, while 12% of asymptomatic patients had grade 2 lesion.[9]

The principals of treatment in caustic ingestion are airway management and hemodynamic stabilization.[10] Fiberoptic laryngoscopy can be helpful for difficult airway management. If the airway is unstable, intubation under direct observation is required .[10-11] Airway surgery may be needed when it is difficult to establish airway through endotracheal intubation.[12]

Endoscopy is important not only in detecting the ingestion of caustic agent but also in determining subsequent management. Based on Zargar classification, Hao-Tsai Cheng et al.[13] suggested that patients with mucosal damage beyond grade 2A were at higher risk for more serious complications, while mortality and morbidity of patients with mild mucosal injury are significantly lower **Table 1.**[11-14-16]

Table 1. Classification of mucosal damage.

Grade	Definition
Grade 0	No identifiable injury
Grade 1	Erythema and edema of mucosa
Grade 2a	Noncircumferential and superficial ulceration with white plaques or hemorrhage
Grade 2b	Circumferential injury or deep ulcerations with features of 2a
Grade 3a	Small or patchy necrosis
Grade 3b	Extensive or circumferential necrosis
Grade 4	Perforation before or during endoscopy

Nasogastric (NG) tubes can be used as stents in cases of circumferential damage because the risk of stenosis is higher in these cases.[17]

Esophageal stricture is one of the most common complications of caustic injury. Up to 70% of patients with grade 2B and more than 90% of patients with grade 3 injury develop esophageal stricture.[18]

The first non-surgical treatment for stenosis is dilatation.[19] Approximately 10% of these patients cannot experience clinical improvement and are resistant to recurrent dilatations. In such patients, stent placement is a viable option.[20]

The use of stents has been reported to be hired as an alternative or complement to prevent stenosis and their mechanism is to provide continuous esophageal dilation for long periods of time.

Surgery might be necessary in cases where dilatation has failed to produce a sufficient lumen size, and symptoms of dysphagia are still unresolved. Surgical procedures include partial esophagectomy, local repair of the stenosis, and esophageal replacement. The types of esophageal replacements include gastric transposition, gastric tube esophagoplasty, colon interposition, and jejunal interposition. The most common procedures are gastric transposition (pull- up) and colon interposition.[21-24]

Endoscopic gastric dilatation has been suggested as an alternative to surgery, but dilatations were less than 50% successful in

preventing the need for surgery.[25] In cases of severe gastric adhesions and significant duodenal injuries, gastrojejunostomy should be used as an alternative to gastric resection.[26]

As mentioned previously, surgery is the last line of treatment for these patients. In this study, we aimed to compare the results of some different surgical techniques, including trans-hiatal gastric pull up, gastric pull up via thoracotomy, reverse gastric tube, and colonic interposition, for esophageal replacement in children with caustic esophageal injury.

Materials and Methods

This retro- and prospective study was performed between 2014 to 2017 in Mofid Children's Hospital in Tehran, Iran. In this study, the data of patients undergoing esophageal replacement surgery were extracted from archive files between 2007 and 2014, and the prospective cases referred to the hospital were included from 2014 to 2017. Patients' surgical method was considered as the basis for classification, and comparison of patients were based on the operation description in the hospital files and each individual surgical technique. Information about caustic injury, including type of injury, severity and extent of burn, clinical findings, severity of dysphagia, interventions such as endoscopy, dilatation and bougienage, their results, imaging results and complications and necessary treatments after surgery were extracted from the files. Study variables were recorded in pre-prepared forms.

The protocol was approved by "Shahid Beheshti University of Medical Sciences Ethics Committee", which is registered under the registration number IR.SBMU.MSP.REC.1399.601. All patient information remained confidential at all stages of the investigation, and no individual patient reports were published elsewhere. No additional costs were imposed on patients. Patients were able to leave the study whenever they wished. Routine treatment of patients did not change.

Data analysis was performed using SPSS software version 21. Descriptive analysis was performed with frequency and percentage reports. Comparisons between groups were performed using ANOVA and chi-square crosstabs according to variables. Statistical significance of p-value was considered below 0.05.

Results

In our study, 27 patients were included. The mean age of patients was 4.01 ± 2.81 years with a median of 3 years (1-14 years). 11 patients were female (40.7%) and 16 patients (59.3%) were male. The mean weight for patients was 13.50 ± 3.89 kg with a median of 12 kg (minimum 8 and maximum 24 kg). Ingestion in 11 cases (40.7%) was recorded with plunger, in 4 cases (14.8%) with hydrochloric acid, in 8 cases (29.6%) with acid (unspecified), in 1 case (3.7%) with concentrated vinegar, in 2 cases (7.4%) with battery and in 1 case (3.7%) with alkali (unspecified).

Figure 1 illustrates more information about the type of ingested caustic substances and performed surgery. The mean interval between ingestion was 8.44 ± 7.33 months with a median of 6 months (minimum 2 and maximum 36 months). All patients had dysphagia, which in 12 cases was to solids (44.4%), in 10 cases to solids and liquids (37%), and in 5 cases was unknown (18.5%). Iatrogenic esophageal perforation was present in 4 cases (14.8%), in 22 cases (81.5%) it was absent and in one case (3.7%) it was unclear.

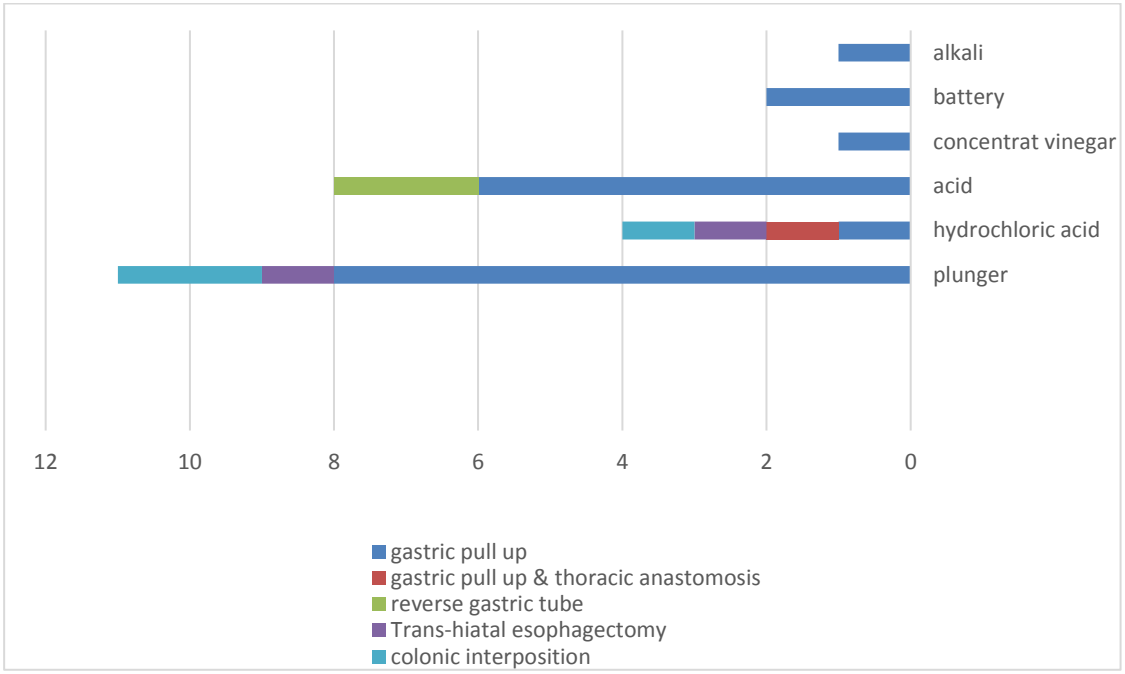

Figure 1: Comparison of ingested caustic substances in five surgical groups.

The mean number of dilatations before surgery in patients was 5.80 ± 5.11, with a median of 5 (minimum 0 and maximum 21) sessions. 20 cases (74.1%) had gastrostomy before surgery and 7 cases (25.9%) did not have gastrostomy. Jejunostomy was performed in 3 cases (11.1%), and not in 24 cases (88.9%). In endoscopy, 11 cases (40.7%) had unknown condition. 2 cases (7.4%) had grade 2 burns and 12 cases (44.4%) had grade 3 burns.

Type of surgery in 19 cases (70.4%) was thoracotomy and gastric pull-up, in 1 case (3.7%) thoracotomy and gastric pull-up and anastomosis in thorax, in 2 cases (7.4%) thoracotomy and reverse gastric tube, in 2 cases (7.4%) trans-hiatal esophagectomy and gastric pull up, and 3 cases (11.1%) had thoracotomy and colon interposition **Figure 2.**

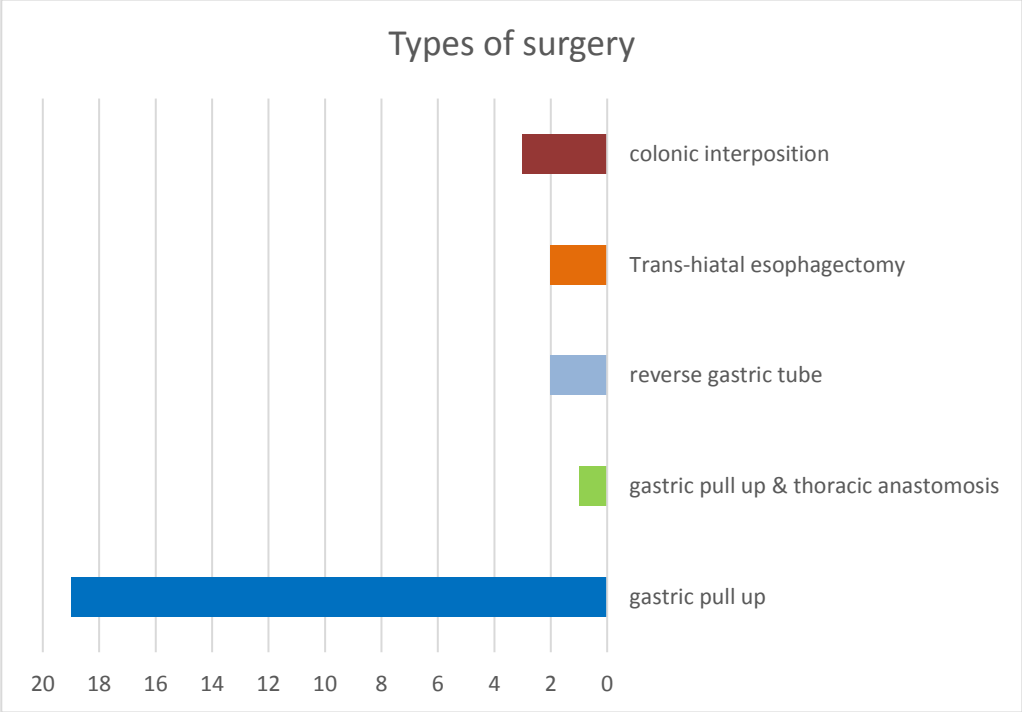

Figure 2: Frequency of different types of surgeries in the studied patients.

Preoperative chest tube was implanted in 25 patients (92.6%) and only 2 patients (7.4%) did not have a chest tube.

After surgery, 5 patients (18.5%) had a chest tube implanted and 22 patients (81.5%) did not have a chest tube. The mean duration of postoperative extubation was 2.25 ± 1.89 days with an average of 2 days (minimum 0 and maximum 8 days). The average time required for chest tube removal was 10.88 ± 6.36 days, with an average of 9 days (minimum 0 and maximum 34 days). The mean time required for NG tube removal was 10.33 ± 6.44 days with an average of 9 days (minimum 1 and maximum 35 days). The mean time required to start oral feeding was 10.81 ± 4.71 days with an average of 9 days (minimum 6 and maximum 26 days). The mean length of ICU hospitalization was 6.88 ± 7.20 days with an average of 5 days (minimum 1 and maximum 38 days).

Discharge time in patients averaged 16.33 ± 7.78 days with a median of 15 days (minimum 9 and maximum 46). The status of leakage in swallow contrast after surgery was unknown in 4 cases (14.8%). In the remaining 23 cases (85.2%) there was no leakage. Evidence of pneumothorax or pleural effusion after surgery was present in 5 patients (18.5%) and absent in 22 patients (81.5%). There was no leakage of cervical anastomosis in 23 patients (85.2%). It was present in 3 patients (11.1%) and unknown in one patient (3.7%). Anastomotic stenosis of the neck did not occur in 18 patients (66.7%). It occurred in 6 patients (22.2%) and was unclear in 3 patients (11.1%) **Figure 3.** Anastomosis revision was required in 2 patients (7.4%) and not required in 25 patients (92.6%). A comparison of the need for cervical anastomosis dilatation in different surgical groups is shown in **Figure 4** ($p = 0.298$).

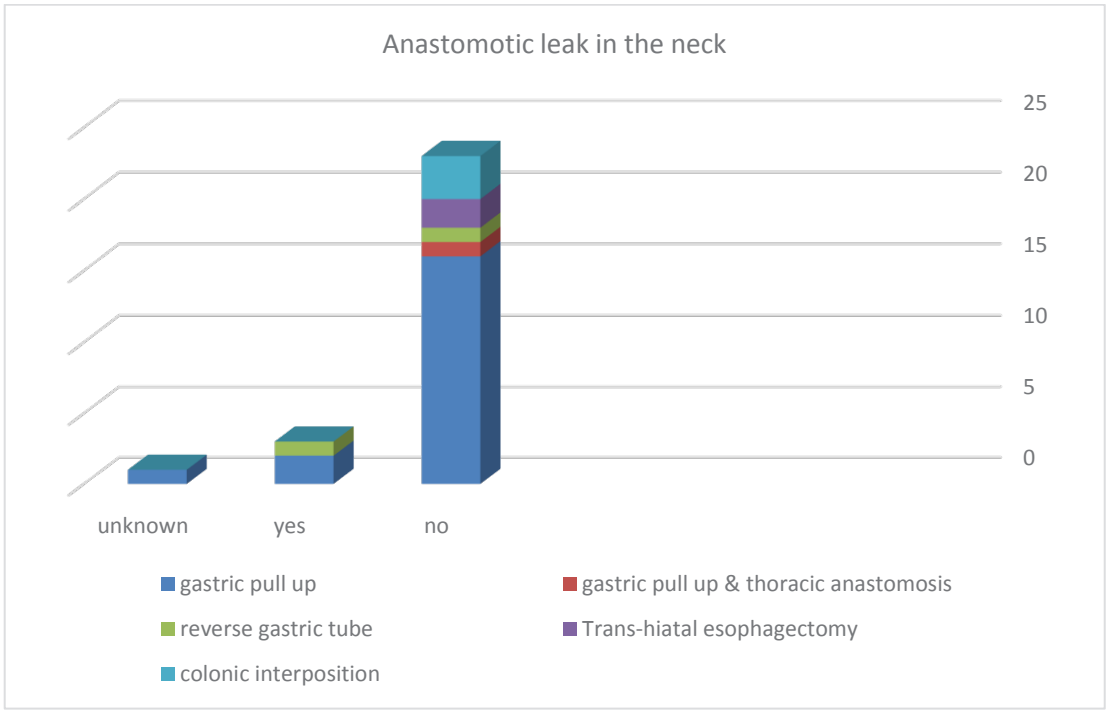

Figure 3: Anastomotic leakage in the neck in five surgical groups.

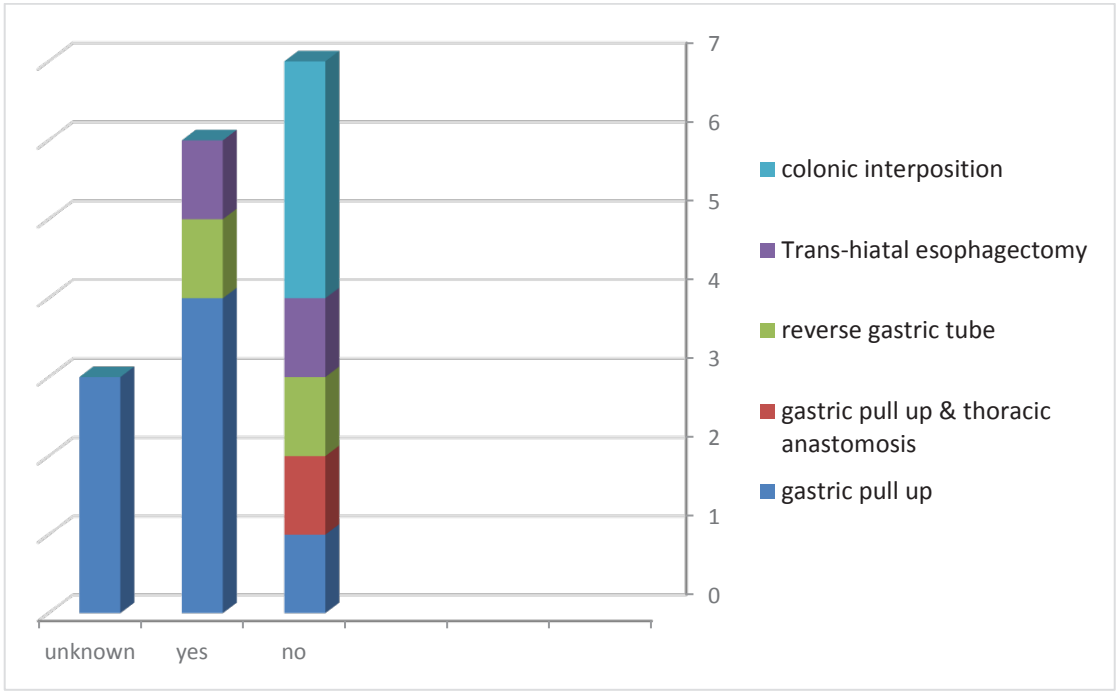

Figure 4: Anastomotic stenosis of the neck in five surgical groups.

Gastric stenosis did not occur in any of the patients. The need for revision of gastric outlet stenosis or obstruction did not occur in any of the patients. There was a need for anastomotic dilatation of the neck in 4 patients (14.8%) and not in 23 patients (85.2%). Other minor complications after surgery occurred in 10 patients (37.0%) and 5 patients (18.5%) had no complications. In 12 patients (44.4%), the incidence of complications is unknown. Postoperative stenosis (prolonged) occurred in 11 patients (40.7%) and 1 patient (3.7%) did not have stenosis. The other 15 patients (55.6%) had unknown condition. Age, gender, weight of patients and ingested substance parameters were compared between 5 groups, but the differences were not significant (p = 0.989, 0.282, 0.861 and 0.632, respectively). The severity of dysphagia was compared between surgical procedures, which are detailed in **Table 2**.

Table 2: Severity of dysphagia among the 5 groups.

Severity of dysphagia	solids	Solids and liquids	Unknown
Thoracotomy and gastric pull up	9 (47.4%)	6 (31.6%)	4 (21.1%)
Thoracotomy and gastric pull up and thoracic anastomosis	0 (0%)	1 (100%)	0 (0%)
Thoracotomy and reverse gastric tube	0 (0%)	1 (50%)	1 (50%)
Trans-hiatal esophagectomy	0 (0%)	2 (100%)	0 (0%)
Thoracotomy and colonic interposition	3 (100%)	0 (0%)	0 (0%)

The iatrogenic esophageal perforation was evaluated in different types of surgery, which can be seen in **Table 3** (p = 0.045).

The leakage status of the swallow contrast after surgery is indicated in **Table 4** (p = 0.555).

Table 3: Iatrogenic esophageal perforation among the 5 surgical groups.

Iatrogenic esophageal perforation	No	Yes	Unknown
Thoracotomy and gastric pull up	17 (89.5%)	1 (5.3%)	1 (5.3%)
Thoracotomy and gastric pull up and thoracic anastomosis	1 (100%)	0 (0%)	0 (0%)
Thoracotomy and reverse gastric tube	0 (0%)	2 (100%)	0 (0%)
Trans-hiatal esophagectomy	1 (50%)	1 (50%)	0 (0%)
Thoracotomy and colonic interposition	3 (100%)	0 (0%)	0 (0%)

Table 4: Leakage status in swallow contrast after surgery in 5 surgical groups.

Leakage status	No	Unknown
Thoracotomy and gastric pull up	16 (84.2%)	3 (15.8%)
Thoracotomy and gastric pull up and thoracic anastomosis	1 (100%)	0 (0%)
Thoracotomy and reverse gastric tube	1 (50%)	1 (50%)
Trans-hiatal esophagectomy	2 (100%)	0 (0%)
Thoracotomy and colonic interposition	3 (100%)	0 (0%)

Evidence of pneumothorax and pleural effusion after surgery is illustrated in **Table 5** ($p = 0.599$). Anastomotic leakage in the neck was compared between the surgical groups, but there was no significant difference **Figure 5** ($p = 0.833$).

Table 5: Evidence of pneumothorax pleural effusion after surgery in 5 surgical groups

Evidence of pneumothorax plural effusion	No	Yes
Thoracotomy and gastric pull up	15 (78.9%)	4 (21.1%)
Thoracotomy and gastric pull up and thoracic anastomosis	1 (100%)	0 (0%)
Thoracotomy and reverse gastric tube	1 (50%)	1 (50%)
Trans-hiatal esophagectomy	2 (100%)	0 (0%)
Thoracotomy and colonic interposition	3 (100%)	0 (0%)

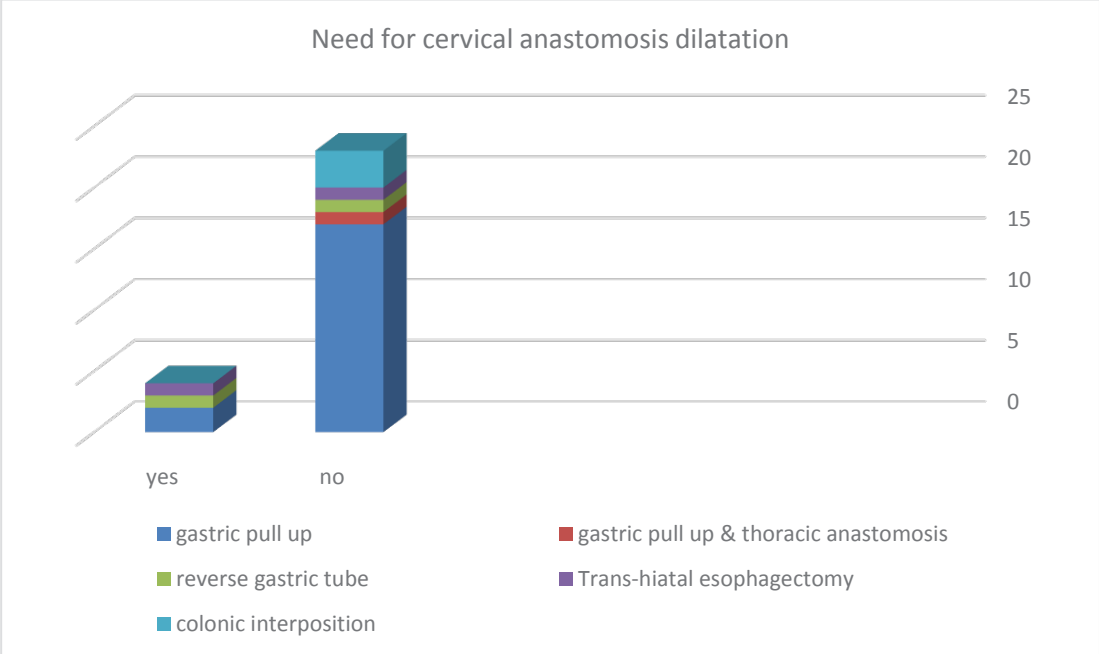

Figure 5: The need for cervical anastomosis dilatation in five surgical groups.

Complications after surgery were compared between the five surgical groups and can be seen in **Table 6** (p = 0.110). Postoperative stenosis was compared and the difference was statistically significant (p = 0.000) **Table 7.**

Table 8 gives more information about the time required for removal of NG tube (p = 0.945), start oral feeding (p = 0.722), chest tube removal (p = 0.111) and discharge of patients from hospital (p = 0.884) compared between groups, which the differences were not significant.

Table 6: Complications after surgery in 5 surgical groups.

Complications after surgery	No	Yes	Unknown
Thoracotomy and gastric pull up	4 (21.1%)	5 (26.3%)	10 (52.6%)
Thoracotomy and gastric pull up and thoracic anastomosis	1 (100%)	0 (0%)	0 (0%)
Thoracotomy and reverse gastric tube	0 (0%)	2 (100%)	0 (0%)
Trans-hiatal esophagectomy	0 (0%)	2 (100%)	0 (0%)
Thoracotomy and colonic interposition	0 (0%)	1 (33.3%)	2 (66.7%)

Table 7: Post-discharge stenosis in the 5 groups of patients.

Postoperative stenosis	No	Yes	Unknown
Thoracotomy and gastric pull up	0 (0%)	6 (31.6%)	13 (68.4%)
Thoracotomy and gastric pull up and thoracic anastomosis	1 (100%)	0 (0%)	0 (0%)
Thoracotomy and reverse gastric tube	0 (0%)	2 (100%)	0 (0%)
Trans-hiatal esophagectomy	0 (0%)	2 (100%)	0 (0%)
Thoracotomy and colonic interposition	0 (0%)	1 (33.3%)	2 (66.7%)

Table 8: Time required for NG tube removal, start oral feeding and chest tube removal in 5 surgical groups.

Type of surgery	NG tube removal	Required time (hour)		
		oral feeding	chest tube removal	discharge of patients
Thoracotomy and gastric pull up	10.84 ± 7.44	10.84 ± 7.44	11.63 ± 6.41	15.94 ± 8.82
Thoracotomy and gastric pull up and thoracic anastomosis	8.00	8.00	9.00	10.00
Thoracotomy and reverse gastric tube	11.00	11.50 ± 0.70	15.5 ± 0.7	20.00
Trans-hiatal esophagectomy	7.00 ± 2.82	7.5 ± 2.12	0.00	17.50 ± 9.19
Thoracotomy and colonic interposition	9.66 ± 4.50	13.33 ± 3.05	11.00 ± 3.00	17.66 ± 2.30

Discussion

In this study, we examined the results and consequences of different methods of esophageal replacement surgery (focusing on standard thoracotomy and trans-hiatal esophagectomy). In our study, 27 patients with a mean age of 4.01 years were studied, who were at least 1 and at most 14 years old. In similar studies, the mean age was close to our findings. In the study of Bassionny et al.[27] in 2001, the average age was 3.4 years (minimum 14 months and maximum 8 years), in other reports[28-32], the age range was from 3 months to 13.5 years. According to the mentioned findings, most injuries due to ingestion of caustic agents occur in children under 5 years of age.

In our study, 40.7% of patients were female and 59.3% were male. In other studies, a similar pattern has been reported. In the study of Bassionny et al [27], and some other studies [23-28], 62% were male and 38% were female, which was very close to our study.

In our study, 40.7% of the plunger and 14.8% of the hydrochloric acid were ingested, indicating the important role of household detergents in this complication.

In a 2005 study by Daradkar et al [28], the majority of ingestions were household detergents (41%) and cleansers (19%). Other studies have reported similar cases.

The average interval between ingestion and surgery is one of the most principal factors in the evaluation of esophageal replacement surgeries following ingestion of caustic substances. In our study, this rate was 8.44 months with a minimum of 2 and a maximum of 36 months. In the interval between swallowing and surgery, conservative treatments and esophageal dilatation are usually performed, which in case of failure or persistence of severe symptoms, surgery is used as a last resort. In the study of Gupta et al [32], the interval between injury and surgery in all cases was more than 3 months, and the average interval similar to our study was 8 months. The study by Ein SH et al.[30] however, reported a much higher time, which lasted for a minimum of 12 months and a maximum of 14 years, with an average of 5 years. These statistics show that early surgical intervention for acute esophageal burns is not justified, and that conservative treatment is always the first line of treatment.

In this survey, all subjects demonstrated dysphagia. The mean number of dilatations before surgery was 5.8 times and iatrogenic perforation occurred in 14.8% of patients. In the study of Hamza et al [33], esophageal stricture occurred in 22.8% of patients, and dilatation treatment was successful in 73.6% of patients for 7 to 36 months. The rate of perforation in the study of Hamza et al.[33] was much lower than in our study (0.3%). Another study by Gündodu HZ et al[29] reported 42% severe dysphagia and 32% moderate preoperative dysphagia. In this study, 26% of esophageal perforations were recorded. The need for multiple dilatations before surgery has been reported in numerous studies. In addition to these problems, the severity of esophageal deterioration can be seen from the high gastrostomy rate in our study of 74.1%. In more severe cases, where the stomach also suffered extensive burns, a jejunostomy was performed, which in our study the need for jejunostomy reached 11.1%. Although in our study the endoscopic findings were unclear in many cases, 44.4% had grade 3 burns and 7.4% had grade 2 burns, indicating that at least half of the patients had grade 2 and 3 burns. Overall, these findings have necessitated surgery, and conservative treatment has not been sufficient.

In our study, the surgical groups were divided into 5 categories, which include thoracotomy and gastric pull up (70.4%), thoracotomy and gastric pull up and anastomosis in thorax (3.7%), thoracotomy and reverse gastric tube (7.4%), trans-hiatal esophagectomy (7.4%) and thoracotomy and colon interposition (11.1%). In our study, comparisons were made between the surgical groups in terms of different study parameters, which were significant only in the two variables of iatrogenic esophageal perforation and stenosis after discharge, but we should be careful about interpreting this significance statistically, because the number of patients- except for the first group- were few, and their comparison cannot be statistically generalized and interpreted, and the findings can be reported only descriptively. A study by Vasseur Maurer et al.[34] compared mediastinal blind dissection and laparoscopic trans-hiatal esophagectomy, which showed only the time of the operation being longer in the laparoscopic group, and also pneumothorax more often in this group, which had no significant consequences. The mean duration of extubation was the same between the two groups.

The average time required for extubation in this study was 2.25 days. Other studies have reported same results, but in another study by Esteves et al.[35] which performed laparoscopic esophagectomy and colon interposition, they immediately extubated 4 out of 5 cases, and established oral feeding 3 to 4 days after immediate extubation; a number that is far from our study; as NGT removal and the start of oral feeding in our patients occurred approximately 10.5 days later. The average ICU admission in our study was 6.88 days, which did not differ according to the available data between the groups. A study reported that the time required for extubation and the length of hospital stay in the ICU after laparoscopic trans-hiatal esophagectomy were significantly shorter than standard procedures.[34]

In terms of occurring complications after surgery, the significance of some complications is highlighted in the literature. for example, Coopman et al.[36] reported that 84% of patients developed surgical complications in a range of over 1 year after surgery. These long-term side effects include a wide range of complications, such as gastrointestinal symptoms in 85%, abnormal lung function in 58%, eating disorders in 50%, scoliosis

in 35%, and nutritional complications in 25% of patients. In our study, evidence of pneumothorax or pleural effusion occurred in 18.5%, cervical anastomosis leakage in 11.1%, anastomotic stenosis in the neck in 22.2% **Figure 4**, need for anastomotic revision in 7.4%, need for anastomotic dilatation in the neck in 14.8%, some other complications in 37% and stenosis after discharge in 40.7% of patients. Gastric stenosis and leakage in contrast swallow studies were not recorded in our patients after surgery. In the study of Hamza et al [33], 10% leakage of cervical anastomosis, 5% proximal anastomotic stenosis and 0.6% late graft stenosis occurred. In a study by Bassionny et al.[27] trans-hiatal esophagectomy with colon interposition was performed and the anastomotic stenosis occurred in 6% of patients. The need for multiple dilatations occurred in 2% of patients, and finally 4% required surgical revision. In the study of Gündodu et al.[29] 6% had occasional dysphagia, which in our study it was classified as other complications. In the study of Spitz et al.[23] anastomotic leakage occurred in 12% and anastomotic stenosis in 20% of patients. In the study of Ein SH et al [30], early perforation after surgery were occurred in 18.18% of patients, wound infection in 18.18% of patients, paralyzed hemi-diaphragm in 9.09% and laryngeal recurrent nerve damage requiring tracheostomy in 9.09% of patients. Also, late complications included anastomotic leakage in 81.8% of patients, anastomotic stenosis in 72.7% of patients, need for anastomotic resection in 27.2% of patients, ulceration in 9.09% of patients and perforation in 9.09% of patients. In this study, 54.5% of patients also needed repeated dilatations after surgery. In a study by Erdogan et al.[37] in 2000, 61.1% of patients had leaky cervical anastomosis and 11.1% had lung problems. 16.67% had gastro-colic reflux, 11.1% had cervical anastomotic stenosis, 5.5% had intestinal obstruction due to adhesions, 5.5% had colo-gastric stenosis, 5.5% had cosmetic thoracic deformity and 5.5% had cervical protrusion. Also, 33.3% of patients of this study needed secondary surgery. In the study by Esteves et al.[35], 20% found atelectasis, 20% pneumonia, 20% cervical stenosis due to fibrotic esophagus requiring cervical revision, and 20% dilatation due to mild dysphagia. In the study by Burgos et al [31], 27% of patients needed more surgeries. As can be seen in most of studies, leakage from the cervical anastomosis was the most common complication after

surgery, which of course did not have serious consequences and was usually improved, but in our study the most common complication was stenosis after discharge.

Conclusion

The small number of patients in four of the five surgical groups was the main weakness of this study, which made statistical analysis and comparing the outcomes and results of surgical procedures difficult, limiting the findings to be generalized. Therefore, a larger sample size with a more balanced distribution in terms of surgical methods is necessary to be able to draw accurate conclusions about the results and consequences of surgical procedures in our target group. The next limitation was due to the in-part retrospective nature of the study, in which a number of patients' parameters were not recorded in the old files, and in some parameters, the "uncertain" status was frequent, which made the study analysis uninterpretable. Therefore, it is suggested to design a prospective cohort to cover these limitations and obtain more definite results.

Ethical Consideration

The protocol was approved by Shahid Beheshti University of Medical Sciences Ethics Committee which is registered under the registration number IR.SBMU.MSP.REC.1399.601.

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Conflict of interests

There are no conflicts of interest for authors.

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