Original Article

Stapler Versus Manual Suturing for Pharyngeal Closure in Total Laryngectomy

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Abstract

Background: Laryngeal carcinoma is not uncommon worldwide. We conducted this study to comprehensively compare the outcome of stapler versus conventional suturing in total laryngectomy primary or salvage.

Patients and Methods: This is a retrospective study conducted in our tertiary institute from 2015 to 2022 involving patients diagnosed with laryngeal carcinoma who underwent total laryngectomy either primary or salvage. We divided patients into 4 groups: primary or salvage laryngectomy, closed with stapler or manual suturing. The reported outcomes included : operative time, length of hospital stay, start of oral feeding, incidence of pharyngocutaneous fistula, positivity of surgical margins, and surgical site infection. Patients with multiple comorbidities and those requiring a flap for pharyngeal closure were excluded .

Results: A total of 91 patients were included in our study. Pharyngocutaneous fistula rate was 19% in conventional patient group in comparison to 6.7% in stapler group for primary total laryngectomy while it was 12.5% for salvage with stapler and 25% for salvage with conventional. Hospital stay was 6 ± 1.5 days for stapler and 11.4 ± 2.9 days for conventional suturing in primary laryngectomy. It was 8.8 ± 1.3 days for stapler and 13.1 ± 1.8 for conventional suturing in salvage laryngectomy. There was highly significant difference found as regard mean operative time, start of oral feeding and hospital stay in favor of stapler use.

Conclusion: Stapler use in total laryngectomy is is a simple, fast, and effective technique with tension free watertight closure, better hemostasis, less contamination of surgical field than manual suturing

Keywords

total laryngectomy, pharyngeal closure, stapler, pharyngocutaeous fistula

Introduction

Laryngeal carcinoma is not uncommon malignancy worldwide[ref]. Although organ preservation protocols have been used widely, still surgery is considered main line of treatment especially in cases of advanced tumor, non-functional larynx, residual, or recurrent tumor.[1] Pharyngeocutaneous fistula is a common and serious complication in cases of total laryngectomy and pharyngeal closure thus a critical step in surgery. Conventional methods of pharyngeal closure carry the risk contamination of surgical site with saliva and can lead to surgical site infection. The frequent trauma to tissues by forceps and ischemia with suture tightening affecting microcirculation of the mucosa increase the risk of a subsequent PCF with longer hospital stay, more complications,increased patient morbidity and more burden on the health system. Pharyngeal closure by surgical staplers can avoid all these drawbacks with preservation of mucosa vitality.[2,3] Although stapler use in total laryngectomy is an easy and well tolerated technique, it is not very popular and there is a dearth of comparative studies in the literature. This study compares the outcome of stapler versus conventional suturing in total laryngectomy primary or salvage. The primary outcome measure was the incidence of pharyngocutaneous fistula, secondary outcomes included: operative time, length of hospital stay, start of oral feeding, positivity of surgical margins and surgical site infection.

Patients and Methods

This is a retrospective study conducted in our tertiary institute on patients with laryngeal squamous cell carcinoma who underwent total laryngectomy in the period from 2015

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to 2022. Included patients are advanced laryngeal carcinoma (T3 or T4a) in cases of primary laryngectomy or any stage in salvage laryngectomy. All included cases were endolaryngeal tumors. Exclusion criteria included patients with extralaryngeal extension, patients needing a flap reconstruction for pharyngeal reconstruction (local or free flap), and patients with multiple comorbidities.

All patients were subjected to full history taking, head and neck examination, videolaryngoscopy, contrast enhanced CT scan neck, and direct laryngoscopy under GA and biopsies. The cases were discussed in MDT board and were scheduled for total laryngectomy. Patients were followed up for 2 years after surgery.

The study was done in accordance with the ethical standards the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by approved by Ain Shams University, Faculty of Medicine institutional review board FMASU R266/2023. As it was a retrospective study no patient consent was required. All patients' data were dealt with complete confidentiality and anonymity.

The primary outcome measure was the incidence of pharyngocutaneous fistula, secondary outcomes included: operative time, length of hospital stay, start of oral feeding, positivity of surgical margins, and surgical site infection.

Our study cases (91 cases) divided into 4 groups:

Group 1: primary total laryngectomy and pharyngeal repair by stapler (30 cases)
Group 2: salvage total laryngectomy, pharyngeal repair by stapler (24 cases)
Group 3: primary total laryngectomy, manual pharyngeal repair by suturing (21 cases)
Group 4: salvage total laryngectomy, manual pharyngeal repair by suturing (16 cases)

All manual repairs and stapling were performed in the vertical direction in 3 layers using Vicryl 4/0 and 3/0 sutures on a rounded needle. For stapler closure we used a linear 75 to 80 mm stapler (Ethicon Echelon Surgical Stapler or the Medtronic GIA 80MTC) and 4 to 5 mm long staples (Figures 1 and 2). No flaps neither local nor free were used. Mean operative time was calculated from the start of laryngeal exposure to the end of pharyngeal repair. Primary tracheoesophageal puncture was only performed in some of the primary cases and none in salvage cases.

Statistical Analysis

The required number of patients needed to achieve statistical significance was calculated by the on the prevalence of PCF after total laryngectomy as it was the primary outcome measure and was 60 patients. The collected data was revised, coded, tabulated, and introduced to a PC using

Figure 1. Stapler is inserted above pharyngeal mucosa and is ready for firing.

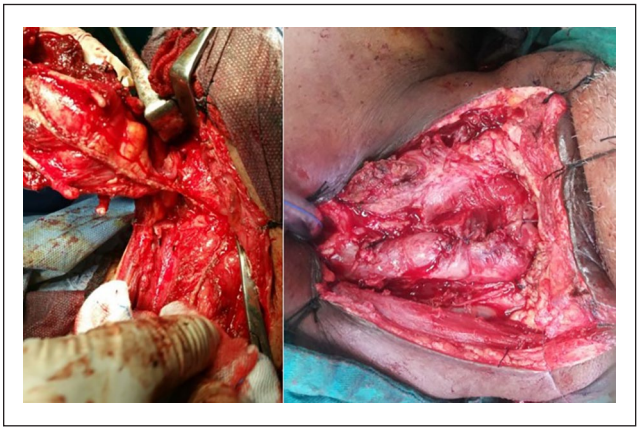

Figure 2. Suture line is shown after separation of the larynx by stapler.

Statistical package for Social Science (SPSS 25.0.1 for windows; SPSS Inc, Chicago, IL, 2001). Shapiro wilk's test was used to evaluate normal distribution of Quantitative variables which was expressed as mean and Standard Deviation. Qualitative variables are expressed as frequencies and percents. Student t test was used to compare a Quantitative variable between 2 study groups. ANOVA Test was used to assess the statistical significance of the difference between more than 2 study group mean with Bonferroni post hoc test for pairwise comparisons. Fisher's exact test was used to examine the relationship between Categorical variables. A P-value$<.05$ was considered statistically significant.

Results

This study included 91 patients aged 43 to 73 years (59.05 ± 7.37 years), there were 85 males and 6 females. Only 6 patients were not smokers, and none reported alcohol or drug use. About 30% of cases had a pre-operative tracheostomy. The mean operative time, start of oral feeding, and

Table 1. Description of Personal and Clinical Characteristics Among All Cases.

Personal and Clinical Characteristics	Mean	±SD	Min	Max
Age	59.03	7.37	43.00	73.00
Operation time (min)	92.11	30.66	35.00	151.00
Start of oral feeding (d)	8.70	4.20	3.00	25.00
Hospital stay (d)	9.22	3.30	5.00	20.00
Gender				
Male	85	93.4%		
Female	6	6.6%		
Tracheostomy pre total				
No	64	70.3%		
Yes	27	29.7%		
Fistula				
No	78	85.7%		
Yes	13	14.3%		
Surgical wound infection				
No	79	86.8%		
Yes	12	13.2%		
Positive margin				
No	89	97.8%		
Yes	2	2.2%		
Voice rehabilitation				
Failed	16	17.6%		
Valve	75	82.4%		

hospital stay was 92.1 ± 30.6 minutes, 8.7 ± 4.2 days, and 9.2 ± 3.3 days respectively. Fistula and surgical wound infection occurred in 14.3% and 13.2% of cases respectively. Most cases had no positive margins (97.8%), while among 17.6 % of cases voice rehabilitation failed (Table 1)

There was a no significant difference between the 4 study groups as regard age and sex, however a highly significant difference significant difference was found as regard mean operative time, start of oral feeding and hospital stay. Pairwise comparisons between all study group pairs revealed a highly significant difference between the 4 groups regarding operative time, while for the start of oral feeding, the significant difference was between Conventional Salvage group and each of stapler total and stapler Salvage groups. For hospital stay, a highly significant difference was found between all study pairs, except between Conventional Salvage and Conventional total groups. There was a no significant difference between the 4 study groups as regard tracheostomy pre total, fistula, positive margin and voice rehabilitation respectively. However, a significant difference was found between the 4 study groups as regard wound infection (Table 2; Figure 3).

There was a no significant difference between cases with and without fistula as regard age, sex, and operative time, however a significant difference significant difference was found as regard start of oral feeding and hospital stay, with higher mean among fistulated cases. There was a near significant difference between cases with and without Tracheostomy pre total as regard occurrence of fistula as 25.9% of cases with Tracheostomy pre total developed fistula compared to only 9.4% of cases without Tracheostomy pre total. There was no significant difference between cases with and without Positive margin as regard occurrence of fistula, however a significant difference was found between cases with and without surgical wound infection as regard occurrence of fistula, as 41.7% of cases with infection developed fistula compared to only 10.1% of cases without (Table 3)

Discussion

Pharyngocutaneous fistula is common and serious complication in total laryngectomy. Its incidence varies between 5% and 65%. It is a challenging complication as it is associated with prolonged hospital stay, delayed oral feeding, and increased patient morbidity and mortality.[3-6]

In our study, the incidence of fistula was directly related to the length of operation time, and preoperative tracheostomy . Fistula incidence is more in patient with conventional suturing than stapler patients. Patient with fistula had more complications with longer hospital stay. We found PCF rate was 19% in conventional patient group in comparison to 6.7% in stapler group for primary total laryngectomy while it was 12.5% for salvage with stapler and 25% for salvage with conventional.

Bedrin et al[7] found that with stapler use, PCF is about 11.9% in primary total laryngectomy cases and 19.4% in salvage patients. Galli et al[8] concluded that rate of PCF in their study with stapler use is 16%.[3] Lee et al found PCF rate is 13.7 % in stapler group and 27.2% in another group.

Gonçalves et al[6] found that none of 14 patients developed PCF after salvage laryngectomy with stapler use while all salvage patients developed PCF in conventional suturing group. In their study on 30 patients, Babu et al[9] found that stapler use in total laryngectomy gave better results and less PCF in both primary and salvage patients

In our study, hospital stay was 6 ± 1.5 days for stapler and 11.4 ± 2.9 days for conventional suturing in primary laryngectomy. It was 8.8 ± 1.3 days for stapler and 13.1 ± 1.8 for conventional suturing in salvage laryngectomy.

Aires et al[4] found PCF is 8.7% in stapler group and 22.9% in conventional group with 80 minutes less in operation time and 8 days earlier in start of oral feeding for stapler group. In their study on 59 patients, Algargaz et al[10] found no statistically significant difference between stapler and conventional groups as regard PCF rates, hospital stay

Chiesa-Estomba et al[11] found PCF rate is 9.5% in stapler group and 23.4% in manual group with less operation time and hospital stay in stapler group. Also, Aires et al[4] found the same in stapler group early oral feed with less hospital stay.

Table 2. Comparison Between 4 Study Groups as Regard Personal and Clinical Characteristics.

Personal and Clinical Characteristics	Stapler primary total (Gr 1)		Stapler salvage (Gr 2)		Conventional total (Gr 3)		Conventional salvage (Gr 4)		*P*
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	
Age	57.47 ± 8.29	43–73	60.3 ± 7.1	48–70	59.2 ± 6.6	48–73	59.7 ± 6.9	48–70	.52* (NS)
Operation time	65.4 ± 19.2	35–95	81.7 ± 22.2	50–112	109.6 ± 9.2	90–125	134.9 ± 9.3	120–151	.001* (HS)[a]
Start of oral feeding	6 ± 2.9	3–17	8.2 ± 3.2	6–20	10.9 ± 4.6	7–24	11.6 ± 3.9	9–25	.001* (HS)[b]
Hospital stay	6 ± 1.5	5–11	8.8 ± 1.3	8–13	11.4 ± 2.9	9–20	13.1 ± 1.8	11–19	.001* (HS)[c]
Gender									
M	27	90.0%	23	95.8%	21	100.0%	14	87.5%	.36** (NS)
F	3	10.0%	1	4.2%	0	0.0%	2	12.5%	
Tracheostomy pre									
No	20	66.7%	18	75.0%	14	66.7%	12	75.0%	.862‡ (NS)
Yes	10	33.3%	6	25.0%	7	33.3%	4	25.0%	
Fistula									
No	28	93.3%	21	87.5%	17	81.0%	12	75.0%	.31** (NS)
Yes	2	6.7%	3	12.5%	4	19.0%	4	25.0%	
Wound infection									
No	29	96.7%	22	91.7%	17	81.0%	11	68.8%	.03** (S)
Yes	1	3.3%	2	8.3%	4	19.0%	5	31.3%	
Positive margin									
No	30	100.0%	22	91.7%	21	100.0%	16	100.0%	.12** (NS)
Yes	0	0.0%	2	8.3%	0	0.0%	0	0.0%	
Voice rehabilitation									
Failed	4	13.3%	3	12.5%	5	23.8%	4	25.0%	.6** (NS)
Valve	26	86.7%	21	87.5%	16	76.2%	12	75.0%	

[a]Gr 1 vs Gr 2(HS), Gr 1 vs Gr 3(HS), Gr 1 vs Gr 4(HS), Gr 2 vs Gr 3(HS), Gr 2 vs Gr 4(HS), Gr 3 vs Gr 4 (HS) using post hoc test.
[b]Gr 1 vs Gr 2(NS), Gr 1 vs Gr 3(NS), Gr 1 vs Gr 4(HS), Gr 2 vs Gr 3(NS), Gr 2 vs Gr 4(S), Gr 3 vs Gr 4 (NS) using post hoc test
[c]Gr 1 vs Gr 2(HS), Gr 1 vs Gr 3(HS), Gr 1 vs Gr 4(HS), Gr 2 vs Gr 3(HS), Gr 2 vs Gr 4(HS), Gr 3 vs Gr 4 (NS) using post hoc test.
*ANOVA test. **Fisher's Exact Test. ‡Chi square test.

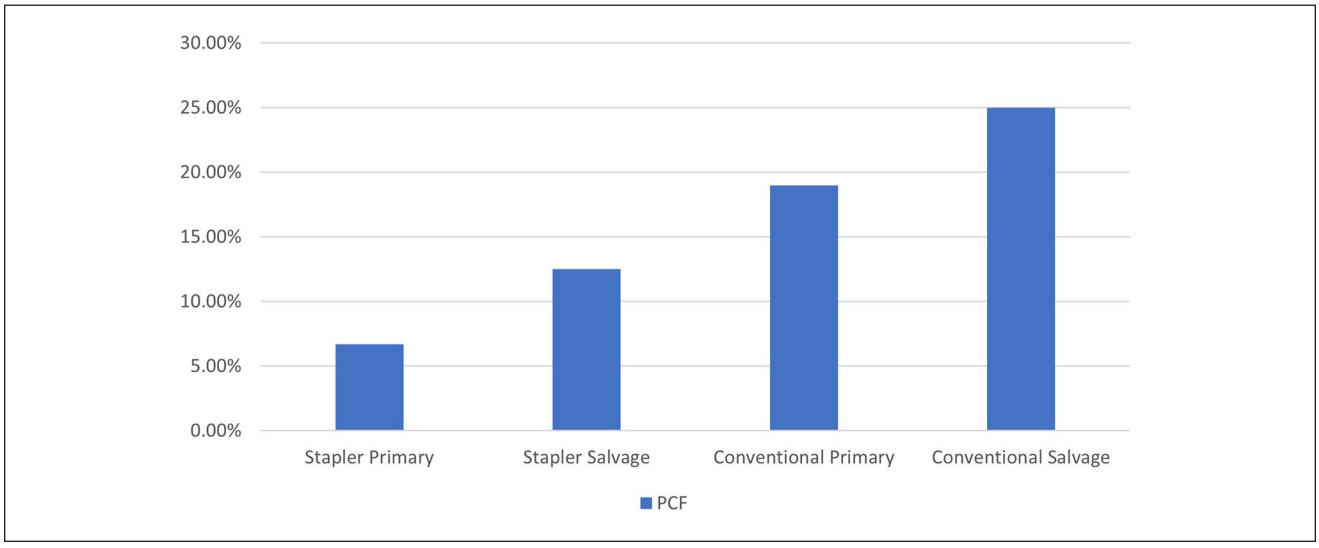

Figure 3. Percentage of pharyngocutaneous fistula in each group.

Calli et al[5] found that PCF in 4.9% in stapler group and 19.8 % in conventional suturing group. Also, PCF closed in 1 week with conservative management in stapler group while it took 2 to 3 weeks for closure with conservative treatment and surgery in the other group. Hospital stay was 14.33 ± 3.48 days in stapler group and 18.29 ± 5.62 in

Table 3. Comparison Between Cases With and Without Fistula as Regard Personal and Clinical Characteristics.

	Fistula					
	No (n = 42)		Yes (n = 6)			
Personal and Clinical Characteristics	Mean	±SD	Mean	±SD	*P*	Sig
Age	59.37	7.41	57.00	7.04	.280*	NS
Operation time (min)	91.24	30.08	97.31	34.78	.512*	NS
Start of oral feeding (d)	7.65	2.55	15.00	6.35	.001*	HS
Hospital stay (d)	8.55	2.75	13.23	3.56	.0001*	HS
Gender						
Male	72	84.7%	13	15.3%	.588**	NS
Female	6	100.0%	0	0.0%		
Tracheostomy pre total						
No	58	90.6%	6	9.4%	.052**	NS
Yes	20	74.1%	7	25.9%		
Surgical wound infection						
No	71	89.9%	8	10.1%	.012**	S
Yes	7	58.3%	5	41.7%		
Positive margin						
No	77	86.5%	12	13.5%	.267**	NS
Yes	1	50.0%	1	50.0%		

*Student *t* test. **Fisher's Exact Test.

conventional suturing group. Also, operative time was less in stapler group.[5]

In our study, operation time is 65.4 ± 19.2 minutes for stapler and 109.6 ± 9.2 minutes for conventional suturing in primary laryngectomy. Operation time in salvage laryngectomy is more than in primary due to meticulous dissection needed in salvage laryngectomy due to excessive fibrosis and to preserve blood supply as much as possible.

Ozturk et al[12] stated that stapler closed pharyngeal mucosa in only 3 minutes while it took 37.5 minutes in conventional technique. Zhang et al[13] found stapler use consumed 45 minutes less than conventional group in operation time. In their study on 41 patients, Calli et al found pharyngeal; closure time was 3 minutes in stapler group versus 37.5 minutes in conventional group. PCF rate is 14.3% in stapler group versus 35 % in conventional group[12]

There were 2 patients with positive margins in salvage group with stapler. This positive margin was on the supraglottis area. This is one of the drawbacks of using stapler blindly in the upper end of the tumor especially in extensive lesions. In insertion of the stapler at the tumor upper end, we should withdraw the epiglottis with forceps to be included in the tumor specimen. Stapler doesn't allow tumor view intraoperatively. So, patients should be meticulously chosen and assessed in stapler use especially in cases with difficult anatomy.

Ismi et al[14] stated that stapler use decreases PCF rate, surgical site infection, operation time, but no relation with systemic complications. PCF rate is 3.3% in stapler group in comparison to 25% of manual group.[14] In a systematic review of 4 studies per formed by Aires et al. authors examined the effects of stapler-assisted pharyngeal closure after TL. Aires et al reported a lower incidence of PCF, a shorter time to starting oral feeding, and a shorter hospitalization period when compared to hand-suture closure.[12] Galli et al[15] found stapler group had less PCF rate, less operation time, and early oral feeding

In our study, there is highly significant difference found as regard mean operative time, start of oral feeding and hospital stay in favor of stapler use. Stapler use in total laryngectomy leads to early start of oral feeding with less time of hospital stay. Although stapler is more expensive than manual suturing, it is cost effective due to less operation time and less hospital stay.

Conclusion

Stapler use in total laryngectomy is is a simple, fast, and effective technique with tension free watertight closure, better hemostasis, less contamination of surgical field than manual suturing.

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Declaration of Conflicting Interests

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