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# Stapler Pharyngeal Repair Versus Conventional Suturing After Laryngectomy in Jordanian Laryngeal Cancer Patients

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## ABSTRACT

**Background:** The use of staplers in surgical repair of the pharynx after laryngectomy has gained traction in recent years, with differing results. **Objective:** In this study, we compare the use of stapler suturing (SS) after laryngectomy in comparison with the manual suturing (MS) technique in laryngeal cancer patients regarding pharyngocutaneous fistula (PCF) formation, operative time, blood loss, margin status, and length of hospital stay. **Methods:** We conducted a retrospective cohort study of laryngeal cancer patients undergoing pharyngeal repair after total laryngectomy by either a stapler or manual suturing. Demographic data, stage of disease, postoperative complications, duration of hospital stay, and operative time were collected. **Results:** A total of 59 laryngeal cancer patients were included, of which 22 underwent SS and 37 had MS. Our cohort was predominantly males (98%), and similar mean ages were observed across both suturing groups (60.5 vs 59.9,  $P = 0.83$ ). Negative margins were more frequent with SS (100% vs 86.5%,  $P = 0.13$ ) yet this difference was not statistically significant, whereas preoperative tracheostomy procedure was present more in MS patients (43.2% vs 0,  $P = 0.003$ ). Lymph node involvement was higher in the manual suturing cohort, yet this difference was statistically insignificant (41.2% vs 25%,  $P = 0.49$ ). The muscle flap procedure was significantly higher in the MS cohort (70.3% vs 20%,  $P = 0.001$ ). In both groups, comparable PCF rates were noted (13.3% vs 10.8%) and there was no association between salvage laryngectomy and PCF occurrence in the entire cohort. For surgery details, there was no statistical difference between both groups in blood loss, hospitalization length, or oral feeding start. Only surgical time was significantly lower in the stapler cohort (277 vs 372.6 minutes,  $P = 0.000$ ). **Conclusion:** Both suturing techniques did not show any statistically significant difference in PCF rates. However, was markedly reduced with stapler use in comparison to manual suturing. Further randomized studies with larger sample size are needed to validate the role of stapler suturing for pharyngeal repair.

**Keywords:** Total laryngectomy, laryngeal cancer, stapler, pharyngocutaneous fistula, neopharynx.

## 1. BACKGROUND

Since the introduction of surgical staplers in 1908, their use has increased due to their ability to suture wounds more efficiently and with more sterility, gaining popularity initially in gastrointestinal surgery (1). The stapler was first used in total laryngectomy (TL) in 1971 (2) and has since then been used more frequently.

Over the last few decades, organ preservation protocols have prioritized laryngeal cancer treatment and as a result, more and more laryngectomies have been performed as a salvage treatment when the initial therapy fails. Pharyngocutaneous fistula (PCF) is the most common complication after TL. PCF most commonly occurs between day 3 and day 8 post-TL, and its presence is associated with higher morbidity and a longer hospital stay (3). The presence of a PCF significantly delays the initiation of postoperative radiotherapy, which leads to worse outcomes (4).

Following TL, the pharyngeal defect can be closed either by manually suturing (MS) or by using a stapler for closure (SC). Previous reports have shown that SS is associated with decreased incidence of PCF, decreased operative time, and decreased hospital stay.

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The use of staplers in repairing the pharynx after laryngectomy has recently gained traction, with differing results. In this study, we hope to shed more light on the use of stapler pharyngeal repair after laryngectomy in comparison with the conventional suturing technique regarding PCF formation, operative time, blood loss, margin status, and length of hospital stay in Jordanian patients.

## 2. OBJECTIVE

In this study, we compare the use of stapler suturing (SS) after laryngectomy in comparison with the manual suturing (MS) technique in laryngeal cancer patients regarding pharyngocutaneous fistula (PCF) formation, operative time, blood loss, margin status, and length of hospital stay.

## 3. MATERIAL AND METHODS

This study was conducted in accordance with the 1964 Helsinki Declaration and ethical approval was received by the ethical board at King Hussein Cancer Center.

### Patient Cohort

This is a retrospective descriptive study including all patients who underwent TL between January 2014 to December 2018 at a tertiary referral cancer center in Amman, Jordan. Patients with involvement of the base of the tongue, vallecular, pyriform sinus, and preoperative tracheostomy were excluded to guarantee clear resection margins. Patients with tumors well-contained within the boundaries of the larynx and those with anterior extra laryngeal extension were included for stapler use whether surgery was the initial treatment or was a salvage option following radiotherapy failure.

Demographic data, stage of disease, postoperative complications, duration of hospital stay, and operative time were collected. Patients were grouped into two groups depending on the type of surgical closure of the pharyngeal defect. This study was carried out per the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement (5).

### Surgical Technique

After TL, the pharyngeal defect was closed with the linear 60 mm Ethicon stapler (Ethicon, Inc., Cincinnati, OH) in SC patients (Figure 1) and with interrupted 3/0 vicryl sutures in MS patients. In SC cases, once the resection is complete and the stapler jaws are released the water tightness of the closure line is tested by filling the pharynx with methylene blue. Should any leak develop in the stapler line, reinforcing vicryl stitches were applied (Figure 2). Patients listed for total laryngectomy and found to meet the inclusion criteria of using the stapler were included in this study. A thorough review of imaging and direct laryngoscopy immediately before surgery was performed on all patients. This helped the surgeon visualize the three-dimensional nature of the tumor in the larynx. Once the larynx had been separated from the surrounding structures and skeletonized, the trachea was transected and further dissection up in the pyriform sinuses was carried out. The posterior border of the thyroid cartilage and the hyoid bone were skele-

tonized. A bone cutter was used to remove the greater wings of the hyoid bone and superior thyroid horns for. This helped the jaws of the linear stapler to fit snugly between the larynx and the pharynx, therefore, maximizing the preserved pharyngeal mucosa at the end of the resection. Once the larynx was fully mobilized, we directed our attention to voice prosthesis insertion. A rigid esophagoscope was gently inserted into the pharynx by an assistant and guided by the surgeon's hand into the appropriate place for the tracheoesophageal puncture site. We then utilized a trochar over a cannula to create the fistula and then the voice prosthesis was pulled through the mouth via a guide wire in a similar fashion when secondary placement of the prosthesis was performed. Once the voice prosthesis was in place, the epiglottis was pulled in between the vocal cords using a hook inserted through the tracheal end of the specimen before applying the stapler in a completely closed technique. This was later replaced by a semi-closed technique when we noted some technical difficulties when the epiglottis was partly caught between the stapler jaws in a couple of cases. This entailed creating a small, key-hole-like incision, superior to the hyoid bone enough to insert a small hook and fish out the epiglottis and then apply the jaws of the stapler making sure the epiglottis and the small hole surgically created in the pharynx are lying above the stapler jaws. A 60 mm three rows linear Ethicon stapler was used in all cases and operated by the same surgeon. A pectoralis major muscle flap was used in patients undergoing salvage laryngectomy in the two groups.

### Statistical analysis

Mean and Standard Deviation (SD) were used to describe quantitative variables and counts and percentages for categorical variables. We used the independent sample T-test to compare means if data was normally distributed (investigated using the Shapiro-Wilk test) and the Mann-Whitney U test was used for non-normal data. We also used the Chi-square test, or Fisher's exact test if cell count was less than 5, to compare proportions for categorical variables across both suturing groups. We assigned a two-sided p-value of less than 0.05 as statistically significant. IBM SPSS version 26 was used for all statistical analyses.

## 4. RESULTS

### Patients Characteristics

A total of 59 laryngeal cancer patients were included, of which 22 underwent stapler suturing and 37 had manual suturing. Our cohort was predominantly males (98.3%), and similar mean ages were observed across both suturing groups (60.5 vs 59.9,  $P = 0.83$ ). As for the disease stage, the majority of patients were stage 4 in both groups, whereas glottic and supraglottic involvement were most frequent in the stapler and manual suturing groups, respectively. Table 1 shows patients' characteristics.

### Manual Versus Stapler Suturing

Negative margins were more frequent with stapler suturing (100% vs 86.5%,  $P = 0.13$ ), whereas preoperative

Characteristics	Stapler Suturing (n=22)	Manual Suturing (n = 37)	P value
<b>Margins</b>			
Free	22 (100%)	32 (86.5%)	0.134
Positive	0 (0.00%)	5 (13.5%)	
<b>Fistula Post Op</b>			
Yes	3 (13.6%)	4 (10.8%)	1
No	19 (86.4%)	33 (89.2%)	
<b>Fever Post Op</b>			
Yes	2 (9.1%)	5 (13.5%)	0.659
No	20 (90.9%)	32 (86.5%)	
<b>Lymph nodes involvement</b>			
Yes	5 (22.7%)	14 (41.2%)	0.489
No	17 (77.3%)	20 (58.8%)	
<b>Muscle Flap</b>			
Yes	4 (18.2%)	26 (70.3%)	0.001
No	18 (81.8%)	11 (29.7%)	

**Table 1. Included patients characteristics. Abbreviations: SD: Standard Deviation, DM: Diabetes Mellitus**

	Stapler Suturing (n=22)		Manual Suturing (n = 37)		Total (n = 52)	
	PCF	No PCF	PCF	No PCF	PCF	No PCF
Salvage						
Yes	1 (20%)	4 (80%)	2 (12.5%)	14 (87.5%)	3 (15%)	17 (85%)
No	2 (11.8%)	15 (88.2%)	2 (9.5%)	19 (90.5%)	3 (9.4%)	29 (90.6%)

**Table 2. Surgical outcomes comparison between suturing techniques**

tracheostomy procedure was needed more in manual suturing patients (43.2% vs 0, P = 0.003). Regarding post-operative fistula formation or fever, similar results were observed in both groups. Lymph node involvement was higher in the manual suturing cohort, yet this difference was statistically insignificant (41.2% vs 22.7%, P = 0.49). Muscle flap procedure was significantly higher in the manual suturing cohort (70.3% vs 18.2%, P = 0.001). Table 2 compares various surgical details between both groups.

In both groups, similar PCF rates were reported (13.6% vs 10.8%) and there was no association between salvage radiotherapy and PCF occurrence in the entire cohort (Table 3). For surgery details, there was no statistical difference between both groups in blood loss, hospitalization length, or oral feeding start. Only surgical time was significantly lower in the stapler cohort (277 vs 372.6 minutes, P = 0.000). Details are presented in Table 4.

## 5. DISCUSSION

Our study describes the outcomes and surgical complications in patients undergoing TL using two methods for pharyngeal repair, the first group was repaired using the stapler technique and the second with manual suturing. PCF is the commonest complication after TL,

and in our study, we found comparable results in PCF rates in the two groups. Surgical time in the stapler group was significantly lower. Pre-operative tracheostomy and muscle flaps were observed more in the MS group.

Both groups included salvage and primary laryngectomies and yet there was no statistically significant difference in fistula rates. In our study negative margins were obtained more in the stapler group (100%), while this did not reach statistical significance due to the small sample size, this might be explained by the strict inclusion criteria in the stapler group. It is worth mentioning, that while hospital stay, and intraoperative blood loss were less in the stapler repair group both did not reach statistical significance.

Since introducing organ preserving treatment for laryngeal carcinoma, surgical treatment by TL has decreased and is now reserved

	Stapler Suturing (n=22)	Manual Suturing (n = 37)	P value
Start of Oral Feeding (Post Operative Days)	12.67 (8.58)	16.11 (12)	0.320
Hospitalization Length (Days)	15.8 (6.35)	18.46 (9.1)	0.300
Surgical Time (minutes)	277 (65.19)	372.62 (82.48)	0.000
Blood Loss (mL)	203.33 (102.59)	254.59 (125.4)	0.167

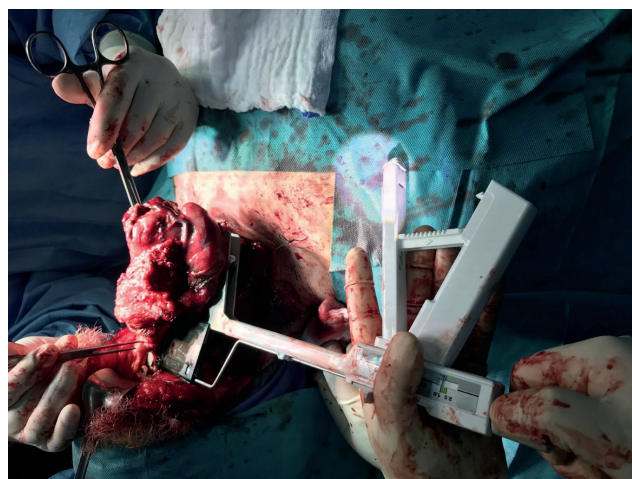
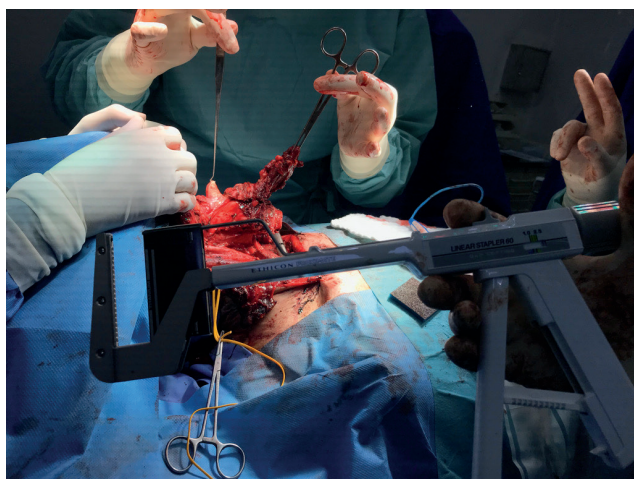
**Table 3. Comparison of percutaneous fistula (PCF) occurrence between both suturing groups**

	Stapler Suturing (n=22)	Manual Suturing (n = 37)	P value
Start of Oral Feeding (Post Operative Days)	12.67 (8.58)	16.11 (12)	0.320
Hospitalization Length (Days)	15.8 (6.35)	18.46 (9.1)	0.300
Surgical Time (minutes)	277 (65.19)	372.62 (82.48)	0.000
Blood Loss (mL)	203.33 (102.59)	254.59 (125.4)	0.167

**Table 4. Surgery details comparison between stapler and manual suturing**

for advanced cases or when organ preservation fails. During TL, a large pharyngeal defect is created, which is then repaired manually or mechanically using staplers. SS has become a more frequently used technique, providing watertight closure and reducing the risk of surgical site contamination. The stapler is indicated in tumors confined to the larynx where safe oncologic margins can be achieved. Preoperative assessment such as direct laryngoscopy and recent imaging help to assess the suitability of stapler use in pharyngeal repair.





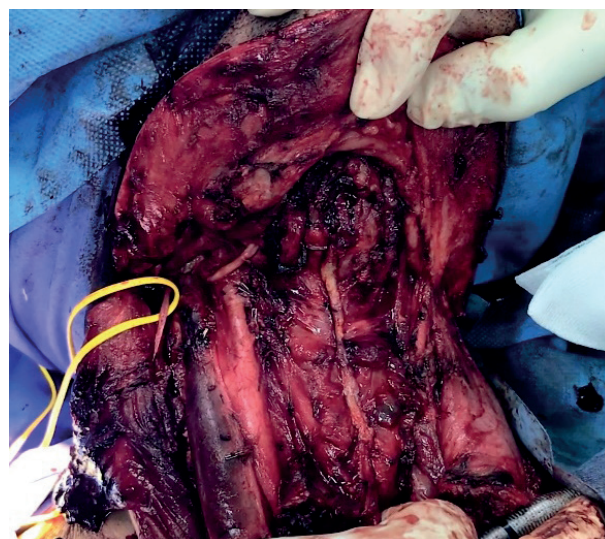
**Figure 1. (a) Preparing the larynx for the application of the stapler jaws. Please note how the epiglottis has been delivered through a vallecule keyhole incision (b) Stapler jaw applied snugly for laryngectomy, notice the inclusion of the keyhole incision in the stapler line.**

Multiple techniques have been described for SS. In the closed technique, the stapler is applied between the larynx and pharynx after skeletonization of the larynx and the trachea is cut (7). In the semi-closed technique, a mini-pharyngostomy is made in the vallecule mucosa to retract the suprahyoid part of the epiglottis and avoid trapping it between the jaws of the stapler (8). In the open technique, the mucosal edges are directly closed with the stapler after laryngectomy (9).

The use of a muscle flap was significantly higher in the MS group. One of the advantages of SS is the ability to preserve the blood supply better when compared to MS, due to the repetitive trauma occurring during manual suturing techniques (10). The development of a PCF is the most common complication following TL, with its incidence reaching 65% in one study (11). In the presence of PCF, postoperative radiotherapy (PORT) is delayed, which significantly decreases survival (4). The association between the suturing technique and the development of PCF has been previously studied. Individual studies reported variable incidence of PCF when comparing MS and SS.

In our study, PCF incidence was comparable between both groups, with only a minority of patients in both groups developing PCF. Dedivitis et al. reported similar findings (6). Some authors reported a higher rate of PCF formation in the MS group, although this was not statistically significant (14, 15). Others reported a significantly lower incidence of PCF in the SS group (16, 17), which is supported by a recent meta-analysis (10). These variations could be explained by multiple factors, such as a small sample size, as well as patient characteristics that may impair wound healing, such as DM, smoking history, and prior irradiation. It is interesting to note that while radiotherapy is a risk factor for PCF formation, there was no association between PCF and salvage radiotherapy in our entire cohort.

Another advantage of stapler use over MS is the reduced operation time and overall hospital stay. We report that operation time is significantly reduced in SS when compared to MS, which is supported by other



**Figure 2. Stapler line demonstrated after laryngectomy**

studies (15, 17). An important component to consider with the reduced operation time is the time needed to close the pharyngeal defect. Ahmad et al. reported that stapler closure took an average of 3 minutes, compared to manual suturing which took 44 minutes on average (18). Reducing operation time has been shown to reduce the risk of postoperative systemic complications, and every additional half-hour of surgery increases the risk of complications by 14% (19). Furthermore, patients undergoing stapler closure spend less time in the hospital. We report that those undergoing stapler closure spent less time in the hospital, as is supported by other studies (10, 18). Reduced hospital time can contribute to the cost-effectiveness of the stapler. While the use of the stapler is more expensive than manual suturing, the reduced operation time, reduced hospital stay, and decreased administrative costs allow the stapler closure technique to be more cost effective (18), which is especially important in a developing country such as Jordan where resources are limited for both the patients and the healthcare system. This also saves theater time for other patients. While some surgeons initiate oral intake, ear-

ly at the third or fourth post-operative day, we elected to wait until the seventh post-operative day. This might explain the lack of statistically significant difference in hospitalization days between the two groups.

In our study, the SS group started oral feeding 3 days earlier than the MS group, however, this did not reach statistical significance. Ahmad et al. similarly reported that the stapler group started feeding earlier, however, their finding was significant (18), and Montoya et al. also reported that the stapler group started oral feeding 8 days on average earlier than the manual suturing group (20). It is important to note that oral refeeding time is dependent on postoperative complications, and as we previously mentioned, the reduced operation time results in a reduced risk of complications.

#### Limitation of the study

Our study was limited by the small sample size, the retrospective nature of our design, and the involvement of a single institute. Staplers are not designed for the purpose of laryngectomy; therefore, we feel that a stapler designed specifically to follow the shape of the larynx would be easier to use. In this study, we did not compare the swallow and quality of voice production between the two groups.

## 6. CONCLUSION

PCF rates were comparable between the two groups and SS had significantly decreased operation time. Despite the closed technique in the stapler pharyngeal repair, this did not risk surgical margins as strict inclusion criteria has been followed for the use of the stapler. While the use of stapler resulted in earlier oral feeding and reduced hospital stay, this did not reach statistical significance in our cohort.

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- **Conflict of interest:** The authors declare no conflict of interest
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