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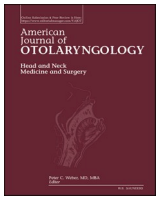

Revisiting the closed stapler laryngectomy: Technique and review of recent evidence

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ABSTRACT

Objective: To review the current literature regarding stapler-assisted closed total laryngectomy (TL), present a case series, and provide details on operative technique.
Finding: Several meta-analyses and randomized controlled trials have demonstrated lower rates of pharyngocutaneous fistula (PCF) with closed stapler-assisted TL compared to traditional manual closure. Operative time, hospital stay, and time to oral feeding also appear to be lower. We present a five-patient case series of stapler-assisted closed TL with successful outcomes, including the first reported salvage case with free flap reconstruction, and provide technical detail including intraoperative photographs.
Conclusion: Stapler-assisted closed TL appears to be a safe alternative to traditional manual closure in select patients with endolaryngeal tumors with potential for lower rates of PCF and shorter operative time, hospital stay, and time to oral feeding.

1. Introduction

The use of the surgical stapler in pharyngeal closure during total laryngectomy (TL) has been the subject of some controversy since its inception. Originally conceived in 1908 in Hungary [1], the surgical stapler was more widely adopted in gastrointestinal surgery in the 1950s after Russian and American advancements [2]. Its use was first described for pharyngeal closure in Zenker's diverticulum in 1969 [3] and shortly after was reported during TL in Russian literature in 1971 [4]. In Western literature, in the 1980s, several case reports described the staple pharyngeal closure of an open post-TL defect [5–8], and the method of a closed technique, in which the stapler is applied prior to removal of the larynx, was described in 1990 and 1998 [9,10]. An initial case series of 7 patients utilizing this technique was reported by Agrawal and Schuller at our institution in 2000 [11], and shortly thereafter by Sofferman [12]. While the surgical stapler today is commonly used in gastrointestinal surgery, its acceptance in the use of pharyngeal closure during TL has been less enthusiastic.

The successful closure of the neopharynx in TL depends on several factors: lack of tension on the closure, preservation of healthy mucosa, and a watertight seal to prevent swallowed pharyngeal secretions from entering the surgical bed [10,13]. In contrast to traditional manual closure with Connell-style sutures in which the edges of the mucosa are inverted into the neopharynx, the stapler works by everting the mucosa [13]. After positioning between the targeted tissue, the stapler places two parallel lines of staples that are evenly placed without gaps. The staples are titanium and do not react to magnetic fields, imparting MRI safety [14,15]. Additionally the titanium creates minimal surgical trauma and inflammatory response [16]. Theoretically, this leads to less tissue necrosis at the closure line, whereas manual suturing may increase necrosis due to manipulation with forceps, knots, and inclusion of the mucosa in the suture line. The stapler closure is watertight, and in pharyngeal closure specifically, is thought to reduce the contamination of the surgical field by oral cavity and oropharyngeal secretions [11].

The stapler has continued to be used sparingly in TL, particularly in Western literature, despite evidence indicating benefit in select patient populations. This is possibly due to persistent conflicting evidence regarding the rate of pharyngocutaneous fistula (PCF). PCF is the most

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common surgical complication following TL, occurring between 2.6 and 65.5 % of cases [17,18]. (Higher rates were historically reported.) PCF has been associated with longer hospitalization, increased morbidity, delay to adjuvant treatment, delay to oral feeding, and increased cost of care [17–21]. Many risk factors have been associated with the development of PCF including prior radiation, neck dissection, pre-operative albumin and hemoglobin, thyroid function, and technique of pharyngeal closure [22–29]. Given the significant consequences of PCF development, the closure of the pharyngeal defect in TL is perhaps the most important portion of the procedure, and the optimal method of closure remains a point of debate and inter-surgeon variability [24,30–35].

In this study, we sought to investigate recent literature on outcomes related to the use of the surgical stapler in TL in the interim since the first-described series at our institution. We also sought to report on a series of patients for whom our technique was recently performed, including successful use in a salvage case with free flap reconstruction, and provide details of our technique with intraoperative photography.

2. Methods

2.1. Study identification and inclusion

A comprehensive review was performed using PubMed and Google Scholar (key words “stapler,” “pharyngoplasty,” and “laryngectomy”) to identify literature analyzing outcomes related to the use of the surgical stapler in pharyngeal closure during TL. This search was performed on articles published between 2000 and 2024 (since the initial case series performed at our institution by Agrawal and Schuller) with emphasis on reporting results of meta-analyses and relevant studies not included in these meta-analyses.

In total, 73 studies were identified using these criteria, including 4 meta-analyses, 65 retrospective reviews, 1 prospective non-randomized trial, and 3 prospective randomized trials.

2.2. Operative technique and case series inclusion

The operative technique described is the current method by which our team performs stapler-assisted closed TL. The five patients described in our case series had this technique performed between July 2022 and June 2023. All cases were performed by the senior author.

3. Literature review

Numerous outcomes have been evaluated in the use of stapler assisted TL. Among these, the most frequently evaluated and impactful outcome measurements are rate of PCF, operative time, length of hospitalization, and time to oral feeding.

There have been several meta-analyses comparing outcomes of stapler-assisted TL to manual closure [36–39] (Table 1 A). Most recently, Ding et al. conducted a systematic review, which included 9 studies and 803 patients. Stapler closure had 46 % lower odds of developing PCF with moderate heterogeneity between studies [36], which is consistent with each of the prior meta-analyses. Interestingly, Chiesa-Estomba found that, although there was a higher percentage of salvage cases in the stapler group, the incidence of PCF in stapler-assisted TL was 9.5 % versus 23 % in the manual closure group [37]. Prior meta-analyses also found significantly shorter hospital stay (about 4 days) and shorter operating time (70–80 min shorter) for stapler closure [37–39]. Time to removal of nasogastric tube was only measured in two of the studies [40,41], and in one indicated a significant improvement in time to oral feeding [41]. Importantly, this meta-analysis did note that there was significant heterogeneity among the studies, which limited the validity of the results. There were also flaws with data collection, bias in selection criteria, and technical differences.

Our literature review identified three additional prospective studies and five retrospective studies that have been published more recently or were not included in the most recent meta-analysis (Table 1B). Two prospective randomized controlled trials from Egypt were recently published. Ahmed et al. reported on 60 patients with endolaryngeal

Table 1
Literature Review.

A. Meta-analyses

First Author	Year	Studies included	Number of patients	PCF	Hospital stay	Operating time	Time to oral feeding
Aires	2014	4	417	15 % absolute risk reduction	6 days shorter in stapler group	80 min shorter	–
Lee	2021	7	535	62 % lower odds in stapler gropu	3 days shorter in stapler group	63 min shorter	–
Chiesa-Estomba	2022	8	622	14 % absolute risk reduction in stapler group	4 days shorter in stapler group	80 min shorter	10 days shorter[a]
Ding	2024	9	803	46 % lower odds in stapler group	–	–	–

B. Select prospective and retrospective studies

First Author	Year	Studies design	Number of patients	PCF	Hospital stay	Operating time	Time to oral feeding
Ahmed	2022	Prospective rano differenceomized	60	No difference	3 days shorter in stapler group	31 min shoter	4 days shorter[b]
Mandor	2024	Prospective randomized	58	18 % absolute risk reduction in stapler group	–	19 min shorter	–
Zhang	2013	Prospective case series	21	1 of 21 (repaired intraoperatively)	–	NR	–
Algargaz	2022	Retrospective review	59	No difference	No difference	105 min shorter	No difference
Sansa-Perna	2020	Retrospective review	126	No difference	3 days shorter in stapler group	–	–
Wang	2020	Retrospective review	55	22 % absolute risk reduction	5 days shorter in stapler group	235 min shorter	4 days shorter

Abbreviations: PCF, pharyngocutaneous fistula. -, not reported.
[a] Only one study commented on time to oral feeding.
[b] All patients in manual closure group started oral feeding on postoperative day 14.

tumors [13]. Both primary and salvage TL were included. Patients were randomized to vertical stapler closure or manual closure. There was no significant difference in PCF rate between stapler and manual closure. Pharyngeal closure time was significantly lower in the stapler group (3 versus 44 min). Length of hospitalization was also significantly lower in the stapler group (11.9 versus 14.7 days). Similarly, Mandor et al. reported on 58 patients with endolaryngeal tumors undergoing primary or salvage TL randomized to vertical stapler closure or manual closure [42]. Both primary and salvage TL were included. PCF occurred in one stapler patient (3.3 %) versus six manual closure patients (21.4 %), which was a significant difference. Pharyngeal closure time was lower in the stapler group (1.7 versus 21 min). EAT-10 scores were also better in the stapler group, as were rates of stricture and cricopharyngeal spasm. A non-randomized prospective trial published by Zhang in 2013 [43] tracked 21 patients undergoing stapler-assisted TL, 9 of which had undergone prior organ-preservation treatment, without a comparator arm. In this cohort, one patient had intra-operative leakage of methylene blue which was overseen, and only one patient developed a post-operative PCF, which healed with conservative management.

Regarding retrospective studies, Algargaz performed a retrospective study of 59 patients with endolaryngeal tumors undergoing primary or salvage TL, 22 of which underwent stapler closure [44]. PCF rates were similar in the primary setting (13.3 % in stapler, 10.8 % in manual) and slightly higher in the salvage setting (20 % in stapler, 12.5 % in manual). There was no difference in hospitalization length or start of oral feeding. Operative time was significantly lower in the stapler group (277 vs 372 min). Sansa-Perna et al. compared 126 patients, 46 of whom underwent stapler closure [45]. Stapler closure was more common in glottic tumors and had less local extension. PCF rates were similar between groups. Finally, Wang et al. found stapler closure had significantly lower operative time (239 versus 474 min), time to oral feeding (12.8 versus 17.3 days), length of hospitalization (15 versus 20 days), and incidence of PCF (4 % versus 26.1 %) [46].

4. Operative technique

Patient selection and tumor location are critical when performing closed stapler-assisted TL. The utility of the stapler is primarily in patients with anterior endolaryngeal tumors. Patients in which there is base of tongue, hypopharyngeal, or pyriform sinus extension are at risk for margin compromise due to the location of the staple line. Appropriate pre-operative imaging and flexible nasal laryngoscopy can assist with determination of lesion extent (Fig. 1). However, direct laryngoscopy and esophagoscopy must be performed at the start of the case to ensure that the tumor is entirely endolaryngeal. If concern for involvement of these regions exists, the stapler-assisted technique must be aborted in favor of manual closure to ensure oncologically-appropriate resection margins.

Key surgical steps are shown in Fig. 2. The larynx is first fully skeletonized, a tracheal incision is made at an adequate position below the larynx and the stoma is partially formalized to establish a safe airway. We then take care to bluntly dissect the mucosa of the pyriform sinus off from the deep surface of the thyroid cartilage to preserve as much pharyngeal mucosa as possible. The stapler is the inserted from the bottom upward. In some cases, due to the shape of the stapler, the greater cornua of either or both the hyoid bone and thyroid cartilage are cut or bent to facilitate positioning of the stapler at the superior extent of the staple line. This can be performed with scissors, or simply application of manual pressure. A single-prong hook is inserted into the specimen through the trachea and used to grasp the epiglottis, which may be visualized in relief, pulling it inferiorly, away from the line of the stapler. Of note, if the epiglottis is not pulled adequately inferiorly, some of the cartilage may partially be captured within the staple line. In our experience when this has occurred it does not appear to impair the quality of the closure, but this step is important to note if there is any concern for supraglottic tumor involvement. Finally, the larynx is pulled anteriorly, the stapler is positioned, and the staple line is placed between the larynx and pharynx. The staple line can be placed vertically as in traditional manual pharyngeal closure. However, if there is adequate pharyngeal tissue, we prefer to rotate the stapler 90 degrees to create a horizontal closure, thereby preventing a long segment of potentially stenotic pharyngoesophageal tissue [47,48]. Once the stapler is deployed, a scalpel is used to sharply separate the specimen from the neopharynx, and the TL is complete.

The stapler that is used by our team is the Medtronic Covidien TA™ 60 mm stapler. This stapler comes pre-loaded with 3.5- or 4.8-mm titanium staples. The jaws of the stapler are placed around the tissue at the site of transection, and the sliding handle on the side of the instrument is advanced to secure the locking pin in place, aligning the cartridge to the distal limb of the device to ensure proper firing. The handle may be partially squeezed to compress the tissue and plan the placement of the staples. After proper positioning, two full squeezes of the handle are required which places a staggered, double line of staples. The handle then locks in the back position to confirm that it has been fired appropriately. A cutting guide on the side of the stapler indicates the site utilized for sharp transection. The stapler is then released by pressing the black button on the top of the instrument (medtronic.com/covidien/).

5. Case series

Our team recently performed a series of five closed stapler-assisted TLs. Three were salvage TL after failure of radiation/chemoradiation. One case was a primary TL for glottic cancer, and one case was performed for non-functional larynx. Of those performed for cancer, all masses were endolaryngeal with no base of tongue or hypopharyngeal involvement confirmed on direct laryngoscopy at the beginning of the case.

Key patient demographic, surgical, and postoperative information are included in Table 2. The five oncologic cases included bilateral selective neck dissections without free flap reconstruction. The median

Fig. 1. View on flexible laryngoscopy and select CT imaging of an endolaryngeal tumor, ideal for stapler closure total laryngectomy.

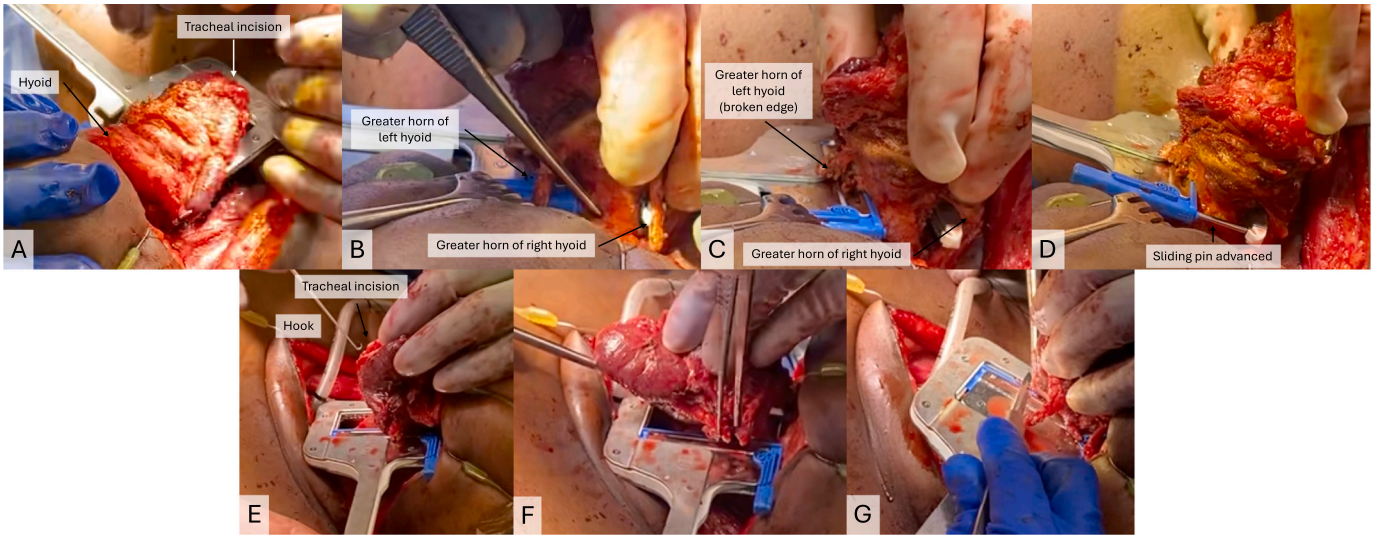

Fig. 2. Surgical Steps for Stapler Closure. A. Following TL completed in standard fashion, prior to the pharyngotomy incision, the stapler is inserted from the bottom of the specimen upward. B. (View from superior) Sliding of the stapler upward along the entire planned length of the pharyngotomy. Placement of the stapler is limited by the hyoid on the side of the stapler. C. After breaking a portion of the greater horn of the hyoid on the left, the stapler is easily advanced past the planned cut in the vallecula. D. Sliding pin is placed to lock the specimen in place. E. (View from the left) Hook advanced through tracheal incision to pull the epiglottis inferiorly prior to stapler deployment. F. Stapler deployed. Some areas may automatically separate. G. Specimen sharply excised anterior to the staple line.

Table 2
Case Series Overview.

Age	Sex	Primary?	Tumor size (cm)	Primary site	Cartilage involved (pathologic)	Type of closure	Free flap?	Operative time (minutes)
69	F	Salvage	2.4	Glottis	No (abuts)	Vertical	No	239
83	M	Primary	3.0	Glottis	Yes (through)	Vertical	No	382
62	F	Salvage	2.1	Supraglottic (false fold)	No	Vertical	No	466
65	M	Salvage	2.8	Glottis	No	Horizontal	No	281
60	M	Non-functional larynx s/p CRT	–	–	–	Horizontal	Yes (ALT muscle only)	398*

No patients had a pharyngocutaneous fistula (PCF) postoperatively. All patients were tolerating a regular diet at 6 months.
* Operative time included free flap harvest, microvascular anastomosis, and inset.

operative time for these patients was 331.5 min. The shortest operative time waws 239 min. No patients developed a PCF, and all patients were tolerating a regular diet at 6 months.

6. Discussion

Our review showed that recent literature predominantly indicates good outcomes in patients undergoing stapler-assisted TL. In many studies, the rate of PCF is superior or at least non-inferior in those undergoing stapler closure. The closure of the pharynx is significantly faster in the stapler-assisted technique, leading to reduced operative time, which could be beneficial in high-risk patients. Patients also appear to have a shorter length of hospitalization when undergoing stapler-assisted TL, potentially secondary to reduced risk of PCF development. While time to oral feeding and swallow function have only been evaluated on a limited basis, this also appears to favor the stapler-assisted technique. From our limited series, these findings were also evident; none of our patients developed a PCF, operative time was below average, and length of hospitalization was comparable to prior studies.

As mentioned in the operative technique, patient selection is of paramount importance when deciding when to employ this method. It should be noted that in existing literature, there may be bias favoring the use of stapler-assisted TL because only select patients can be candidates for this technique. By nature of the design of the stapler, the tumor must not extend to the hypopharynx or pyriform sinus. Furthermore, while some supraglottic extension is not necessarily an absolute contraindication, the method by which the epiglottis is pulled inferiorly may not be adequately precise in supraglottic lesions which encroach on the epiglottis. While in our experience inclusion of epiglottis in the stapler line did not appear to impact outcomes, it has been reported previously that this may lead to increased risk for PCF [49]. The feasibility of obtaining frozen margins in stapler-assisted TL is also a noteworthy consideration. With the stapler, obtaining a frozen pharyngeal or base of tongue margin from the tumor bed is not advised. Specimen based margins should be taken in these cases. Alternatively, a semi-closed technique has also been described in which a small pharyngotomy is performed at the vallecula to visualize the epiglottis prior to placing the staple line [50].

Patients in our series had anterior endolaryngeal tumors. In the salvage setting there is literature that indicates that the use of free transfer of well-vascularized, non-irradiated tissue during TL may improve wound healing and reduce the risk of PCF formation [51–53]. In our practice, this is frequently employed, and in our case series this was performed on one patient. Additional layers of tissue sutured over the staple line has been described, as well as the use of a pectoralis muscle flap [44], but the use of a vascularized free tissue transfer in a patient undergoing stapler-assisted TL has not previously been reported. Our patient underwent an anterolateral thigh, muscle-only free flap that was placed over the stapler closure.

At our institution, there are a number of patients who undergo TL for

non-functional larynx in which the stapler method would also likely be beneficial. For this patient population, preservation of a functional swallow and the option of voicing are essential in maintaining quality of life. In our method, when possible, we utilized a horizontal staple line to preserve maximum native pharyngeal mucosa and prevent a long stenotic segment of neopharynx. A recent meta-analysis looking at different techniques of pharyngeal closure [54] described five studies in which horizontal closure was performed and found that horizontal closure had the lowest PCF rate in salvage surgery [45,55–58]. Several studies have also evaluated the effect of closure shape on swallow function, which found that horizontal and T-shaped closure were superior to that of vertical closure [47,59]. Horizontal closure with stapler closure has been described once previously by Allegra et al [48] in a group of 33 patients in which they found a low rate of post-surgical complications in early stage tumors in all age ranges. While only noted in several studies, this low rate of PCF and improvement in swallow function may be due to a wider neopharynx, while not having the trifurcation that the T-shaped closure produces. Horizontal closure, however, is not possible in all patients as this requires a short pharyngeal defect, and bias should be considered as these defects are likely more often in patients with less advanced disease.

Performing primary tracheoesophageal puncture (TEP) was reported in the original series at our institution. While this may be an appropriate option for some patients and has been reported successfully [45,60,61], this requires that the freshly-stapled neopharynx be instrumented, which may lead to disruption of the staple line, and it is unknown if this may increase the risk of PCF development. In our series, primary TEP was not performed on any of the patients and is typically offered in a delayed, secondary fashion if desired.

An additional unanswered question in stapler-assisted TL is the non-degradability of the staplers used in pharyngeal closure, and the possibility of delayed complications related to retained surgical material. In manual closure, all sutures used are typically dissolvable while in this method, the staples remain in situ for the duration of the patient's life. Delayed fibrosis around staple lines and loose staples causing intestinal obstruction and internal herniation has been reported in surgical literature [62–65]. Rarely, hypersensitivity reactions have been reported to titanium in the neck [66]. Additionally, there have also been reports of retained surgical clips acting as a nidus for infection [67–69]. There has been no report of this in patients who have previously had stapler-assisted TL, but long-term follow-up would be required to ascertain if this may occur, especially in close proximity to the neopharynx.

7. Conclusion

Stapler pharyngeal closure during TL remains a controversial, but potentially beneficial technique in select patient populations and is currently rarely used in the United States. Prior studies have found faster operative time, reduced length of hospitalization, and reduced risk of PCF in stapler-assisted TL. Our recent series of patients is small, but also supports that the use of the stapler is safe and efficient, even in patients with previous organ-preservation treatment and those undergoing free flap reconstruction. Horizontal pharyngeal closure may lead to reduced rates of PCF and improved swallowing outcomes. We present a practical review of the literature and a detailed description of technique for surgeons interested in utilizing this technique.

CRediT authorship contribution statement

Ryan T. Judd: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Jeremy Godsell:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Hannah Kuhar:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Hilary McCrary:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Janice Farlow:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. **Amit Agrawal:** Conceptualization, Investigation, Methodology, Writing – original draft, Writing – review & editing. **Enver Ozer:** Conceptualization, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing.

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Declaration of competing interest

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