25-YEAR EXPERIENCE OF USING A LINEAR STAPLER IN LARYNGECTOMY

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Accepted 16 April 2005
Published online 1 November 2005 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/hed.20280

Abstract: Background. Stapler application for pharyngeal closure after total laryngectomy allows for rapid watertight closure without field contamination and for potentially reduced fistula rate.

Methods. One thousand four hundred fifteen patients underwent laryngectomy with linear stapler closure. In 98.6%, laryngectomy was performed after radiation failure.

Results. A relatively high incidence of pharyngeal fistulae (12%) was seen, although these rates were reduced to 5.5% during the recent decade. Simultaneous creation of tracheoesophageal fistula and myotomy by a novel technique was introduced. Swallowing problems were observed in 11 patients and local recurrences in nine patients (0.6%).

Conclusion. The advantages of mechanical sutures with the closed stapling technique are simple and rapid application, watertight closure with good hemostasis, prevention of field contamination, good speech and deglutition, no increase in fistula rate, and low local recurrence rates. Operating room expenses may also be significantly reduced, rendering this method cost-effective as well. © 2005 Wiley Periodicals, Inc.

Keywords: mechanical suturing; stapler; larynx; laryngectomy; fistula; stapling device

The history of laryngectomy spanning more than 150 years reveals a quest for the preferred method for pharyngeal closure. The basic requirements for favorable results are based on non-tension watertight closure, hemostasis, and preservation of mucosal viability. In the late 1950s, the Russians pioneered the use of mechanical sutures in abdominal and thoracic surgery. This technique was embraced by head and neck surgeons, and stapler use in laryngectomy was initiated during the 1960s.

In 1971, Lukyanenko reported in the Russian literature the first clinical experience of closing 16 laryngectomy defects using a stapling device, with results defined as “satisfactory” and “without complications.” His method involved placing the two-row tantalum staples on the mucosa of the laryngopharynx before resection...
of the larynx, thus providing “hermetization, asepsis, and hemostasis.” A year later, Paches et al.\(^2\)\(^,\)\(^3\) reported their experimental work in dogs and clinical experience since 1965. They compared the open and closed technique and found the latter advantageous. They also compared stapler with hand suture closure and found almost a twofold decreased incidence of fistula in the former. In these reports, a single application of the \(\text{YK}_1/\text{C}_3\)-60 (comparable to the \(\text{TA}-60\)) was found to be optimal.

The first reports of sporadic stapler use in the West only emerged in the early 1980s. Halevy and Sadé\(^4\) reported a case of laryngectomy defect closure with stapler by the open technique, and Westmore and Knowles\(^5\) reported their experience with the open technique in four patients.

Only a few additional articles describing mechanical suture device use in laryngectomy in a total of 152 patients were reported in the Western literature.\(^6\)\(^–\)\(^11\)

One of our group used stapling devices for Zenker diverticulectomy\(^12\) and for postlaryngectomy pharyngeal closure with the open technique.\(^13\) Although this technique is effective, we firmly believe in the additional benefits of the closed technique. We described our favorable preliminary results\(^14\) with stapler use in 1998. After this, the technique was adopted and successfully implemented by Agrawal and Schuller in seven patients.\(^15\) During this same period, Sofferman and Voronetsky\(^16\) independently applied the closed technique in 12 patients.

We present the first major bi-institutional study in which a uniform approach by the closed technique was used during a 25-year period in more than 1400 cases of laryngectomy with pharyngeal closure in a patient cohort, in which most patients either did not respond to radiation treatment or experienced treatment failure. Therefore, this is a high-risk group for postoperative complications.

This technique is routinely performed in the Regional Oncological Center in Ekaterinburg in the Russian Federation, and with the instruction of the senior author, we have been using this technique since 1997.

The aims of the study were to describe the indications and contraindications for the technique, to explain the fine points and pitfalls, to evaluate fistula rates in light of former radiation treatment, to present functional and oncologic results, and to present our novel technique for performing tracheoesophageal fistula (TEF) or tracheoesophageal puncture (TEP) adapted for closed mechanical suturing.

**PATIENTS AND METHODS**

Patients undergoing total laryngectomy either as primary procedure for radiation lack of response after a dose of 40 to 45 cGy or radiation failure after a full 60- to 65-cGy dose with stapler use were included in the study. Endolaryngeal (T3) and T4 tumors were indicated for the procedure. Excluded were patients with suprahypoid vallecular, pyriform sinus, and postcricoid extension.

One thousand three hundred eighty-seven patients were from the Department of Head and Neck Surgery, the Regional Oncological Center in Ekaterinburg in the Russian Federation (ROC) and 28 were from the Sheba Medical Center in Tel Hashomer, Israel (ShMC). The ROC patients were treated between the years 1978 and 2002, and the ShMC patients were treated between the years 1997 and 2002. Data obtained included primary tumor staging according to the TNM staging system available at the time of diagnosis, radiation dose and treatment course, fistula rates, and local recurrence rates. Speech and swallowing data were marked in the charts but were not comprehensively evaluated.

The staplers used in Russia were TA-compatible devices \(\text{YK}_1/\text{C}_3\)-60 or a specially adapted device for laryngectomy, the \(\text{YI}-70\) (Krasnogvardeez Co., St. Petersburg, Russian Federation). The Ethicon (Ethicon Endo-Surgery, Inc., Cincinnati, OH) or Autosuture (United States Surgical, Norwalk, CT) devices were used in the ShMC.

The therapeutic approach in Russia was based on organ preservation modality. This consisted of irradiating practically all patients with T3 and T4 disease and reevaluating the effects of radiation after a dose of 40 to 45 cGy. Responders were referred for continuation of radiation treatment, and nonresponders were scheduled for surgery.

There were 1329 male and 86 female patients, with age ranging from 32 to 89 years with mean age unavailable. Disease in 1160 patients was staged as pT3 (82%) and in 255 as pT4 (18%). One thousand four patients (71%) received a radiation dose of 40 to 45 cGy and underwent total laryngectomy for lack of satisfactory response to radiation. Three hundred ninety-one patients (27.6%) had radiation dose of 60 to 65 cGy and underwent total laryngectomy as a salvage procedure.
and 20 patients (ShMC) only underwent primary total laryngectomy (1.4%).

**SURGICAL PROCEDURE**

Endoscopy is done in all patients to verify tumor extent and eliminate hypopharyngeal involvement. Total laryngectomy is performed traditionally but with comprehensive skeletonization of the laryngeal framework. The hyoid bone is released from the suprathyroid musculature and its lateral attachments. The greater cornu of both the hyoid bone and thyroid cartilage are transected with scissors for easier application of the stapling device. Special attention is placed on complete release of the suprathyroid region and on good visualization of the contour of the suprathyroid part of the epiglottis. This scrupulous release, although somewhat time consuming, is the key to successful performance of the procedure. Stylopharyngeus muscle fibers inserting into the hypopharyngeal wall bilaterally are transected. After completion of skeletonization of the larynx, the trachea is entered in the preplanned level, and a sterile tube is inserted into the distal part. The larynx and the proximal tracheal rings are separated from the esophagus and anterior hypopharyngeal wall with complete release of the both pyriform sinuses up to the level of cricoarytenoid joints. At this stage, the laryngeal specimen remains connected to the hypopharynx by thin mucosa–submucosal layer only. This allows for uniform thickness of the stapled tissue and promotes even closure.

Stabilizing the mobilized larynx with one hand, the surgeon inserts a tracheal hook through the tracheal lumen into the larynx and grasps the epiglottis, thus evertting it and preventing its disruption of the staple suture line. A depression appearing in the vallecular area is an indication for successful retraction of the epiglottis. The importance of this maneuver cannot be overemphasized. The next step is transferring the larynx with the tracheal hook to the assistant instructed to maintain mild tension cephalad and the application of the linear stapler (60 MM or AKM-60) by the surgeon. The stapler is orientated with its open jaws cephalad and parallel to the esophageal lumen diameter (Figures 1 and 2). In case of YK-70 use, the frame is opened, the released larynx is inserted, and the frame is secured. The dismountable frame is then compressed against the anvil, and the stapler is activated after compression of the tissue. If a nasogastric tube was previously inserted, it is removed to prevent its hindering stapler application.

The stapler is activated, automatically forming a hemostatic double-row suture line, and the laryngeal specimen is separated by incising flush with a scalpel on the device rim (Figure 3). A single stapling application is all that is required for complete pharyngeal closure. At this stage, removal and closure are completed, and the specimen’s surgical margins must be evaluated and frozen sections obtained if deemed necessary, although this is rarely the case. In extreme cases of suspected or verified positive margins, part
(usually the upper section) or even all of the mechanical suture line may be resected and re-closed by the open technique or by hand suture.

A second intermuscular suture layer was usually applied in the ROC patients. In ShMC patients, this is felt to be superfluous, and a second layer is not closed.

In 28 ShMC patients, a single-step voice restoration procedure was done simultaneously with the total laryngectomy. An original atraumatic technique using two or even three-channel Foley catheter (20 F) was introduced by the senior author (L. B.). This was done to obviate the need for mini-esophagotomy as was formerly done and a difficult-to-perform transoral procedure with rigid instruments. This method also allows performing a leak test confirming watertight closure and facilitates cricopharyngeal myotomy when indicated.

The Foley catheter (recommended with an inner guide wire) is gently inserted transorally by an assistant into the hypopharynx and upper esophagus, placed with the tip corresponding with the stomal site, and the guide removed. Dyed saline is now insufflated under pressure (up to 50 mL) with simultaneous compression of the distal esophagus to enhance back-pressure. If a leak exists, it will usually manifest itself and is repaired with sutures. The catheter is now advanced approximately 1 cm, and the balloon is now inflated with air until a bulge is recognized in the projection of membranous part of the trachea. This acts as a visual landmark for the TEP site by local mild, but sufficient, tissue expansion; prevents creation of a false route; and further protects the posterior wall of the esophagus. At this point, the trachea is retracted cephalad by stay sutures and stabilized on the inflated balloon. An incision is performed with a bovie vertically 7- to 10-mm deep to the tracheostomy line until the balloon membrane is visualized (Figure 4). The balloon is heat resistant and usually will not rupture. The edges of the esophageal mucosa are grasped by fine hemostats, balloon pressure is decreased, the Foley catheter is removed, and a feeding tube is inserted through the newly formed opening and its position verified. To facilitate voice prosthesis use, the sternal attachments of the sternocleidomastoid muscle may be cut, resulting in a more flat stoma formation. The wound is routinely drained and closed.

Feeding in the ROC patients was achieved by nasogastric tube for a period of 10 to 12 days, and oral intake was resumed after a normal barium swallow. The ShMC patients were fed by feeding tube inserted into the TEP for 1 week in non-irradiated patients and after 10 to 12 days in those with prior irradiation. Patients are typically discharged within 24 hours of initiating oral food intake. Insertion of voice prosthesis is done in an ambulatory setting.

RESULTS

The records indicated persisting swallowing problems in 11 patients that were resolved with bougienage. Local recurrence was seen in only nine
patients (0.6%). These cases occurred, for the most, during the early phases of stapler use (ROC).

Speech was defined as fair to good in 96% of TEP patients (ShMC) and in 94% of ROC patients. It should be noted that because of financial constraints in this group, only esophageal speech was used.

Pharyngeal fistulae were encountered in 168 of 1395 irradiated patients (12%). Of these, 116 healed spontaneously, and 52 required surgical measures for closure. Fistula rates in primary surgery were 5% of cases. It should be noted that although fistula rates were near 15% during the years 1978 to 1982, they dropped to 5.5% during the years 1998 to 2002. Fistula rates, type of treatment, and radiation doses are presented in Table 1.

### DISCUSSION

Mechanical suture devices—staplers are in wide use today because of the exponential increase in endoscopic and open thoracoabdominal and vascular surgery. They usually deliver a double, staggered row of staples that are designed to minimize tissue damage while allowing watertight closure and optimal healing.

Results presented here are in a large series of patients from two medical centers that used comparable instrumentation in a similar technique, albeit with many influencing factors evolving along the study period. These patients are, for the most part, considered compromised by prior partial or full-course irradiation and are, therefore, considered at high risk for complications and increased postoperative morbidity according to accepted standards. It should be noted that staplers were also used for partial pharyngeal closure in patients excluded from the study group, increasing the overall numbers of stapler use in our patients.

In the open technique of stapling first applied in the West, after a routine laryngectomy is carried out, the mucosal edges of the vertically directed defect are aligned by evenly spaced holding sutures placed between the jaws of the stapler, and the device is activated. According to our own experience with the open technique and that of others according to the scant available literature, other than time-saving, no clear benefit over traditional suturing is reported. Although fistula rates are not seemingly decreased, a clear benefit of this approach lies in the ability to assess the tumor extent and verify all margins in cases that are not indicated for the closed technique. It is our belief that the role for the open technique is in fact quite limited.

The indications for the closed technique as reflected by practically all authors are endolaryngeal (T3) and T4 tumors without suprathyroid vallecular, pyriform sinus, and postcricoid extension. Careful preoperative assessment is necessary to select the appropriate patients as reflected by our extremely low local recurrence rate of 0.6%. Most of these patients are also eligible for undergoing the closed TEP procedure as well.

The closed technique described herein is consistent with the original method illustrated by Paches et al. This differs from former reports in several aspects. Once the skeletonization of the larynx is properly completed, a single application of the 60-mm stapler suffices to close the pharyngeal defect without problems. Agrawal and Schuller used a TA-90 long disposable stapler and achieved good tension-free closure. We believe this stapler length is excessive in most cases but may be used if warranted. On the basis of the anatomy of the laryngopharynx and on our experience, we suggest that if proper release is done including the suprahyoid region as described, there is no need for an elongated device. Sofferman and Voronetsky’s technique also differs in that they use two applications of the stapler, which is superfluous in our experience as well. This also required hand suturing the connecting point of the two staple lines to fortify this midpoint area. These authors also perform the epiglottic retraction under endoscopic vision. Although perhaps beneficial during a learning curve, we find this unnecessary and cumbersome. Although this retraction is important, it is readily performed in our proposed manner without hindrance.

Although many surgeons advocate a second layer closure of the constrictor muscles, this was deemed unnecessary. We do not routinely apply second layer closure in stapling or in hand suturing and see no change in fistula rates. We have

<table>
<thead>
<tr>
<th>Course of treatment</th>
<th>No. of patients (%)</th>
<th>Fistula incidence</th>
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<tbody>
<tr>
<td>No radiation</td>
<td>20 (1.4)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Nonresponders (40–45 cGy)</td>
<td>1004 (71)</td>
<td>92 (9.2)</td>
</tr>
<tr>
<td>Salvage (60–65 cGy)</td>
<td>391 (27.6)</td>
<td>76 (19.4)</td>
</tr>
<tr>
<td>Total</td>
<td>1415</td>
<td>169 (11.9)</td>
</tr>
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not critically evaluated the issues of speech and swallowing when second layer closure is obviated.

A major complication of laryngectomy is a pharyngocutaneous fistula. Complication rates increase after irradiation treatment and organ preservation therapy and also depend on the patient parameters, extent of surgery, technique and individual surgeons’ expertise, and postoperative care. Fistula rates after total laryngectomy in nonirradiated and irradiated patients vary and were reported to be from 4% to 70%.\(^ {13}\)

In essence, the use of staplers is the “great equalizer” in laryngectomy. Once a surgeon is proficient in stapler use, the individual factor is nearly eliminated, and fistula rates potentially reflect the true tissue-dependent incidence.

Sessions et al\(^ {6}\) studied laryngectomy defects created in dogs and closed with staples. No union occurred between the apposed mucosal surfaces, and tensile strength was decreased compared with the control animals. These isolated results controvert those of Paches et al,\(^ {3}\) who found good mucosal closure in a similar experimental setting. Indeed, the beneficial effects of mechanical suturing in a wide variety of surgical procedures are well recognized. In virtually all stapling instruments used on parenchymal organs and the aerodigestive tract, a double-staggered row of staples is deposited with varying length, according to the device’s specifications. The staple begins in a squared “U” and closes to a “B” shape that is non-strangulating and non-necrosing and permits vessels to pass through the staple loops with minimal tissue injury.

Simoncelli and Altissimi\(^ {8}\) presented their experience with the closed technique. None of their 13 patients had fistulae develop. It should be noted that none of their patients were formerly irradiated. Santaolalla Montoya et al\(^ {9}\) studied the efficacy of mechanical suture closure of the pharyngeal defect after a total laryngectomy. Three random groups of nonirradiated patients were compared: those with manual suture (n = 50), those who had stapling with the closed technique (n = 38), and those who had a mechanical suture with an open technique (n = 12). Use of staplers in the closed technique significantly improved the procedure length, initiation of the oral feeding, and the length of in-hospital stay. This technique reportedly also reduced fistulae rates (5.26%), infection, and hemorrhage comparable to our results in the recent decade. Sofferman and Voronetsky\(^ {16}\) had two fistulae in a series of 12 patients (17%) in whom the closed technique was used. Agrawal and Schuller\(^ {15}\) had one fistula occur in a formerly irradiated patient in a series of seven laryngectomies only.

Our results do not exceed accepted fistulae incidence rates. Also, improved results are observed in the past decade that may be attributable to better equipment, technique, and wound care and possibly also to improved irradiation methods in these patients.

Another significant benefit of mechanical suture use is expedition of the overall procedure time. Sofferman and Voronetsky\(^ {16}\) compared the duration of hand suturing to stapler use. The former took 5 minutes only, whereas the latter was timed at 45 minutes. Although we have not timed and compared our different procedures, our experience supports these results. Moreover, whereas a single-use stapling device costs approximately $100 US in our institution, this compares with a calculated 7 minutes of operating room costs. A single application of the 60-mm stapler was demonstrated in all our cases as adequate for the closed technique. In this day and age of limited budgets, the price factor should be taken into account. Also, many of the laryngectomy patients are elderly, heavy smokers, and high anesthetic risks. Shortening operative time may reduce the incidence of perioperative complications and morbidity.

The main drawback of the technique is that the tumor itself is not visualized during resection, and this harbors the potential for oncologic compromise if applied in unsuitable cases. Tumors that are not entirely endolaryngeal are evidently at risk for compromise with this technique. Frozen section analysis of margins is difficult but feasible. Another concern that may arise is the ability to learn and implement the technique. Although a learning curve exists, the primary reported results of experienced teams adopting this technique are favorable.\(^ {15,16}\) Once the principal concept is understood, the fine points of the technique are readily implemented.

The “gold standard” of laryngectomy also includes speech rehabilitation in most patients. Compared with the open technique, the closed procedure presents some difficulties in creating the TEF. The novel TEP technique with Foley catheter use described is especially adapted for the closed stapling procedure. It readily allows for observing the suture line for leaks, for safe and rapid creation of the fistula, and a reliable option for myotomy. Our experience of a large bi-institutional series of patients supported by the
literature provide us with the ability to confirm the advantages of mechanical sutures with the closed stapling technique: simple and rapid application, watertight closure with good hemostasis, prevention of field contamination, good speech and deglutition, no increased fistula rates, and very low local recurrence rates. Operating room expenses may also be significantly reduced, rendering this method cost-effective as well.

REFERENCES