

Is open tracheotomy performed by residents in otorhinolaryngology a safe procedure? a retrospective cohort study

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Abstract Surgical or percutaneous tracheotomy is one of the commonest operations in the ENT practice and one of the first procedures to be taught to residents. No study exists that demonstrates the safety of this surgical procedure performed by unexperienced surgeons. The purpose was to compare outcomes of tracheotomies performed by supervised residents and surgeons in terms of postoperative complications and mortality, and identify risk factors for the onset of complications. Retrospective cohort study. Otolaryngology-Head and Neck Surgery Department, University of Florence, Italy. We included all patients undergoing tracheotomy from July 2008 to January 2013 and compared tracheotomies performed by supervised residents or surgeons. During the study period, 304 patients were submitted to tracheotomy. Patients operated by surgeons had a significantly higher number of tracheal rings fracture ($p = 0.05$), subcutaneous emphysema ($p = 0.003$) and tracheostomy tube displacement ($p = 0.003$), while supervised residents had a higher number of tracheitis/pneumonia ($p = 0.04$) as early complications. Patients operated by supervised residents had a significantly higher number of tube obstructions as late complication ($p = 0.04$). Using multivariate model, risk factors for early postoperative complications were male sex ($p = 0.04$) and delayed time to substitution with cuffless tube ($p = 0.01$), while only a trend to statistical significance was observed for urgent tracheotomies concerning the risk for late postoperative complications ($p = 0.08$). The current practice where residents perform tracheotomies supervised by a surgeon should not

be disheartened. Our study demonstrates that it is safe and does not lead to higher risk of complications nor negatively affects the quality of care.

Keywords Surgeon · Supervised resident · Tracheotomy · Surgical training · Complication · Quality of care

Introduction

Surgical or percutaneous tracheotomy is one of the most common operations in the field of otorhinolaryngology, with about 100,000 procedures performed annually in the United States.

Since the first “incision of the artery” was performed, about 4,000 years ago, tracheotomy has expanded and gained popularity.

Today, main indications to tracheotomy include acute dyspnea due to head and neck trauma or to iatrogenic vocal cords paralysis and other events causing upper airway (UA) obstruction, weaning from long-term mechanical ventilation (MV) and prevention of UA obstruction in major head and neck oncologic procedures.

The operative technique of tracheotomy was refined by Chevalier Jackson, who standardized the procedure, reducing the mortality rate from 25 to 2 % [1, 2].

Surgical tracheotomy is usually considered an easy and straightforward procedure, nevertheless fearsome complications may arise in the early postoperative course, i.e., tracheal rupture [3], major bleeding, neck/mediastinal infections [4], or later on, i.e., laryngotracheal stenosis [4, 5].

Surgical tracheotomy is one of the first procedures to be taught to residents in otolaryngology, however, whether tracheotomies performed by residents are related to a higher incidence of complications and a higher mortality rate or not,

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has never been studied. Several studies have been carried out for other surgical procedures [6–11] comparing surgeons with residents in terms of complications and mortality rate. Some of them demonstrate that the resident's inexperience does not affect the outcome of the procedure [12], while other studies show that the decreasing number of operations performed by residents due to work hour restrictions may affect the quality of care that they would deliver [6–11, 13, 14].

The aim of this retrospective study was to compare outcomes in patients operated by surgeons (S) to those operated by supervised residents (SR), in terms of early and late postoperative complications and mortality. The secondary aim was to identify risk factors for the onset of complications.

Methods

After the institutional review board approval, a retrospective review was performed on all patients undergoing open tracheotomy at the Otolaryngology-Head and Neck Surgery Department of Florence University Hospital from July 2008 to January 2013.

All tracheotomies performed in our operation room (OR) were included in the analysis. In very few cases, we did not perform the tracheotomy at our OR, whenever it was impossible to transfer patient for logistic reasons, or in emergency situations; since these cases were not registered in our database, and also included few emergency cricothyrotomy and/or tracheotomy, they were excluded from this study.

Our Department is part of a University hospital, where seven surgeons and nine residents take part, tracheotomies are performed by surgeons or by supervised residents as part of the institutional training program. The individual skills and personal experience of the resident are generally not an issue, since tracheotomy is one of the first operations to start with. The resident is allowed to start and carry on the procedure as long as the supervising surgeon judges that everything remains within a range of safety, otherwise the senior surgeon takes over the procedure; in this study, when surgeons did take over the procedure this was assigned as performed by surgeons.

The surgical technique in this study was standard: transverse skin incision in the Jackson's triangle, sharp dissection through the subcutaneous tissue, blunt separation of the strap muscles from the midline, superior displacement of the thyroid isthmus with exposure of the anterior tracheal wall, intercartilaginous horizontal tracheal incision (usually between 2nd and 3rd tracheal ring), creation of the inferiorly based Björk flap, anchorage of the Björk flap to the subcutaneous tissue, introduction of the cannula. Creation and anchorage of the Björk flap was performed also

in surgical conversions of percutaneous tracheotomies. We usually prefer to retract the thyroid isthmus superiorly performing a sub-isthmic tracheotomy, supra-isthmic or trans-isthmic tracheotomies were seldom performed.

Since 2008, an electronic patient record (BEST) for surgical reports was introduced, in which all relevant patient data are included: indication for surgery, patient's age, sex, American Society of Anesthesiologists (ASA)-classification score [15], date of surgery, starting time, duration of the operation, name of operators, and a detailed description of the operative procedure including intraoperative complications. All other information concerning the whole hospitalization were recorded using information within clinical charts, postoperative complications and the management of the tracheostomy tube were registered in detail.

To define a complication, we refer to the definition given by the Association of Surgeons of the Netherlands: "A complication is any condition or event, unfavorable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy" [16].

For the purpose of this study, we differentiated between immediate postoperative complications occurring within the first postoperative week from late complications, occurring after the seventh day or during the follow-up period.

To identify late postoperative complications, we fully reviewed the outpatient files where postoperative follow-up information of all patients were meticulously recorded, for oncologic patients follow-up was routinely scheduled, while all not oncologic patients received a follow-up consultation at first, third and sixth postoperative month.

We also checked the database of our Specialistic ENT Emergency Service for possible secondary accesses.

Statistical analysis

All data were analyzed using Stata/SE 9.1 (StataCorp, College Station, TX). Differences between groups were analyzed by the Fisher's exact test. Logistic regression multivariate analysis was used to calculate the risk for every single complication for patients operated by supervised residents compared to those operated by surgeons; Cox multivariate analysis was used to calculate the hazard ratio of early and late postoperative complications. A $P < 0.05$ was considered statistically significant.

Results

Study population

During the study period, a total of 304 patients underwent tracheotomy at our Otolaryngology-Head and Neck

Table 1 Indications to open tracheotomy

	Surgeons, <i>n</i> (%)	Supervised residents, <i>n</i> (%)	<i>p</i> **
Patients	72 (23.7)	232 (76.3)	
Weaning from MV*	14 (19.5)	84 (36.2)	0.009
Head and neck cancer	40 (55.5)	106 (45.7)	0.1
Acute airway obstruction	14 (19.5)	38 (16.4)	0.5
Conversion of percutaneous tracheotomy	4 (5.5)	4 (1.7)	0.09

* MV mechanical ventilation

** All *p* values calculated by the Fisher's exact test**Table 2** Baseline patient characteristics

	Surgeons, <i>n</i> (%)	Supervised Residents, <i>n</i> (%)	<i>p</i>
Patients	72 (23.7)	232 (76.3)	
Age, year (mean ± SD)	79.5 ± 10.60	68 ± 7.07	0.06
Sex, male	52 (72.2)	148 (63.8)	0.2
Comorbidity, yes	52 (72.2)	180 (77.6)	0.3
Neck stiffness	32 (44.5)	72 (31.03)	0.04
BMI, <i>n</i> (mean ± SD)	24.6 ± 4.38	27.3 ± 2.90	0.03
Smoking status, yes	36 (50)	64 (27.6)	0.001

All *p* values calculated by the Fisher's exact test

Surgery Department: 72 (23.7 %) were operated by S and 232 (76.3 %) by SR. Surgical indications included: acute dyspnea (52 cases), weaning from MV (98 cases), temporary tracheotomy for major head and neck oncologic procedures (146 cases) and surgical conversion of percutaneous tracheotomies because of bleeding (8 cases). SR performed a significantly higher number of tracheotomies indicated for weaning from MV ($p = 0.009$) (Table 1).

Patients operated by S and SR were matched for sex, age, comorbidity, neck stiffness, BMI and smoking status. A significantly higher number of patients with stiff neck ($p = 0.04$) and smokers ($p = 0.001$) was found in the group operated by S, while SR had a greater number of patients with a higher BMI value ($p = 0.03$) (Table 2).

With regards to elective or urgent tracheotomies, no differences were observed between S and SR (62 and 10 for S vs 202 and 30 for SR, $p = 0.8$).

Study outcome

Table 3 describes the type of complication for every indication. Intraoperative, early and late postoperative complications are shown in Table 4 and divided between S and SR. We observed 2 (0.6 %) intraoperative complications, 44 (14.5 %) early postoperative and 58 (19.1 %) late postoperative complications. Hemorrhage and

tracheostomy tube obstruction due to mucous plug were the early postoperative complications most frequently observed (3.9 % each), while the most frequent late postoperative complication was tracheal stenosis (5.9 %). Using univariate analysis, patients operated by surgeons had a significantly higher number of tracheal rings fracture ($p = 0.05$), subcutaneous emphysema ($p = 0.003$), tracheostomy tube displacement ($p = 0.003$) and tracheitis/pneumonia ($p = 0.04$). Using multivariate analysis, we observed a trend to the statistical significance for SR concerning the number of tube obstructions due to mucous plug ($p = 0.06$). When concerning late postoperative complications, SR had a significantly increased number of tube obstructions due to mucous plug only at univariate analysis ($p = 0.04$). No differences were observed between the two groups using multivariate analysis. The rate of complications requiring further surgery was 1 %, 1 SR patient needed surgical revision for early bleeding, 1 S and 1 SR patients presented a persistent tracheotomy opening and received closure under local anesthesia. In 12 patients, we recorded a tracheal stenosis, however, in none of them the stenosis was symptomatic since it appeared as a minimal (<20 %) antero-posterior lumen reduction at the tracheotomy site.

Tables 5 and 6 represent the hazard ratios for early and late postoperative complications. The variables significantly associated with an increased risk for early postoperative complications are sex ($p = 0.04$) and a delayed time of substitution with a cuffless tube ($p = 0.01$). When concerning the risk for late postoperative complications, a trend to the statistical significance was observed for urgent tracheotomies ($p = 0.08$).

Table 7 describes the management of patients with tracheostomy tube, comparing patients operated by surgeons and supervised residents. The time to cuff deflation was significantly longer in the group operated by supervised residents ($p = 0.03$). No statistically significant difference was observed concerning time to substitution with a cuffless or fenestrated tube and time to decannulation, even though they all resulted longer in the group operated by supervised residents.

No patient died during the surgical procedure or follow-up.

Table 3 Complications on the basis of the indication

	Total, <i>n</i> (%)	Head and neck cancer, <i>n</i> (%)	Weaning from MV, <i>n</i> (%)	Acute airway obstruction, <i>n</i> (%)	Conversion of PT, <i>n</i> (%)
Intraoperative	2 (0.6)	0 (0)	2 (2.0)	0 (0)	0 (0)
Tracheal rings fracture		0 (0)	2 (2.0)	0 (0)	0 (0)
Early postoperative complications	44 (14.5)	26 (17.8)	8 (8.1)	8 (15.4)	2 (25)
Hemorrhage		8 (5.4)	0 (0)	2 (3.8)	2 (25)
Subcutaneous Emphysema		4 (2.7)	0 (0)	2 (3.8)	0 (0)
Tube obstruction due to mucous plug		8 (5.4)	2 (2.1)	2 (3.8)	0 (0)
Tracheostomy tube displacement		0 (0)	3 (3.1)	1 (1.9)	0 (0)
Tracheitis/pneumonia		6 (4.1)	3 (3.1)	1 (1.9)	0 (0)
Late postoperative complications	58 (19.1)	28 (19.2)	10 (8.2)	16 (30.7)	4 (75)
Tube obstruction due to mucous plug		6 (4.1)	4 (4.1)	4 (7.7)	0 (0)
Incomplete tracheotomy closure		4 (2.7)	0 (0)	2 (3.8)	0 (0)
Tracheal stenosis		2 (1.4)	3 (3.1)	5 (9.6)	2 (25)
Wound dehiscence		6 (4.1)	0 (0)	0 (0)	2 (25)
Hemorrhage		2 (1.4)	1 (1.0)	1 (1.9)	0 (0)
Tracheostomy tube displacement		2 (1.4)	0 (0)	4 (7.7)	0 (0)
Tracheitis/pneumonia		6 (4.1)	2 (2.0)	0 (0)	0 (0)

MV mechanical ventilation, PT percutaneous tracheotomy

Table 4 Complications

	Total, <i>n</i> (%)	Surgeons, <i>n</i> (%)	Supervised Residents, <i>n</i> (%)	<i>p</i>	<i>p</i> [§]
Intraoperative	2 (0.6)	2 (0.6)	0 (0)		
Tracheal rings fracture		2 (2.8)	0 (0)	0.05	–
Early postoperative complications	44 (14.5)	14 (19.5)	30 (12.9)		
Hemorrhage		2 (2.8)	10 (4.3)	0.5	0.8
Subcutaneous emphysema		4 (5.5)	2 (0.9)	0.003	0.1
Tube obstruction due to mucous plug		4 (5.6)	8 (3.4)	0.2	0.06
Tracheostomy tube displacement		4 (5.6)	0 (0)	0.003	–
Tracheitis/pneumonia		0 (0)	10 (4.3)	0.04	–
Late postoperative complications	58 (19.1)	10 (13.9)	48 (20.7)		
Tube obstruction due to mucous plug		0 (0)	14 (6.03)	0.04	–
Incomplete tracheotomy closure		2 (2.8)	4 (1.7)	1.0	0.7
Tracheal stenosis		4 (5.6)	8 (3.4)	1.0	0.7
Wound dehiscence		2 (2.8)	6 (2.6)	0.7	0.6
Hemorrhage		0 (0)	4 (1.7)	0.5	–
Tracheostomy tube displacement		0 (0)	6 (2.6)	0.3	–
Tracheitis/Pneumonia		2 (2.8)	6 (2.6)	0.3	0.4

^a All *p* values calculated by the Fisher's exact test

[§] Multivariate analysis' *p* value

Table 5 Cox multivariate analysis: early complications

	HR	<i>p</i>	95 % CI
Smoke	1.85	0.23	0.66–5.16
BMI	1.18	0.68	0.52–2.68
Age	1.65	0.24	0.70–3.92
Sex	2.78	0.04	1.03–7.48
Comorbidity	1.50	0.40	0.57–3.95
Indication: elective vs urgent	2.25	0.31	0.46–10.93
Neck	1.0	0.99	0.47–2.14
Time to cuff deflation	0.52	0.56	0.06–4.65
Time to substitution with cuffless tube	5.43	0.01	1.47–19.96
Operator	1.71	0.23	0.70–4.16
Indication: cancer	1.64	0.53	0.34–7.84
Indication: weaning from MV	3.88	1.0	0
Indication: dyspnea	1.05	0.96	0.12–8.67

Table 6 Cox multivariate analysis: late complications

	HR	<i>p</i>	95 % CI
Smoke	0.86	0.75	0.36–2.07
BMI	1.43	0.42	0.59–3.42
Age	0.91	0.83	0.38–2.16
Sex	1.04	0.91	0.47–2.3
Comorbidity	0.78	0.62	0.28–2.1
Indication: elective vs urgent	5.57	0.08	0.8–38–47
Neck	1.15	0.69	0.56–2.34
Time to cuff deflation	0.33	0.33	0.03–3.05
Time to substitution with cuffless tube	2.23	0.20	0.64–7.79
Operator	0.59	0.3	0.22–1.61
Indication: cancer	2.03	0.33	0.48–8.55
Indication: weaning from MV	7.06	1.0	0
Indication: dyspnea	0.75	0.81	0.07–7.41

Discussion

The main goal of this study was to compare outcomes in patients operated by S to those operated by SR, in terms of postoperative complications and mortality. We found no differences in the incidence of complications between tracheotomies performed by S and SR for: head and neck cancer surgery, weaning from MV, acute airway obstruction

and conversion of percutaneous tracheotomies. No significant differences were seen in the two groups concerning the total number of complications, however, patients operated by surgeons had a higher incidence of early postoperative complications (19.5 vs 12.9 %). This could be partially justified by the patient characteristics. Infact, S operated a greater number of patients with a stiff neck ($p = 0.04$) that results in a more difficult exposure of the trachea. Patients operated by S had a significantly higher number of tracheal rings fracture during the procedure ($p = 0.05$), subcutaneous emphysema ($p = 0.003$), and tracheostomy tube displacement ($p = 0.003$) in the early postoperative period, while SR had a higher number of tracheitis and pneumonia ($p = 0.04$), but we must consider that a higher BMI was seen in patients operated by SR ($p = 0.03$). In contrast, the incidence of late postoperative complications resulted higher in the group operated by SR (20 vs 14 %), even though no statistically significant differences were observed concerning the overall and individual late postoperative complications between the 2 groups. It must be highlighted that in this series, we recorded 12 cases of late tracheal stenosis, but all these patients were asymptomatic and in all cases, the minimal stenosis was incidentally detected at fiberoptic routine investigation.

The results presented are in agreement with studies in literature that investigate complications for other surgical procedures. Acun et al. [17] demonstrated that no differences exist concerning the incidence of complications after subtotal thyroidectomies performed by S or SR. Emre et al. [18] found the same results for total thyroidectomies. Mehall et al. [12] found that complications after laparoscopic colecistectomy were comparable in patients operated by S and SR. The above-mentioned studies refer to surgical procedures that require a specific technical ability and surgical skills, however, their results are as encouraging as ours.

Numerous studies demonstrated the efficacy of laparoscopic appendectomy performed by residents, with the same risk for the onset of complications [12, 19–22] as senior surgeons. Finally, in a recent work, Graat et al. [7] reported no differences in terms of complications after appendectomy among surgeons, supervised and unsupervised residents. All these results seem to confirm that neither the degree of preparation of the surgeon nor his

Table 7 Postoperative management of patients with tracheostomy tube

	Surgeons	Supervised Residents	<i>p</i>
Patients, <i>n</i>	72 (23.7 %)	232 (76.3 %)	
Time to cuff deflation, days (mean ± SD)	2.5 ± 0.7	3.1 ± 1.4	0.03
Time to substitution with cuffless tube, days (mean ± SD)	3.3 ± 1.4	3.9 ± 0.7	0.7
Time to substitution with fenestrated tube, days (mean ± SD)	6.2 ± 2.1	8.3 ± 6.4	0.6
Time to decannulation, days (mean ± SD)	10.8 ± 3	14.6 ± 16.3	0.5

All *p* values calculated by the Fisher's exact test

personal attitude may influence the efficacy and safety of these surgical procedures. In another previous study [23], we compared the incidence of complications after tonsillectomy performed by S and SR, and found the procedure to be safe. To the best of our knowledge, this is the only other study that refers to a head and neck surgical procedure.

In this study, among 304 patients submitted to open tracheotomy, the incidence of overall complications was 34 %. The incidence of intraoperative, early and late postoperative complications was 0.6, 14.1 and 19.1 %, respectively. Our results slightly differ from other recent studies of Zhu et al. [24], who had 3.2 % of overall complications, and Halum et al. [25] who had 1.4 % of intraoperative, 5.6 % of early postoperative, and 7.1 % of late postoperative complications. However, we found the same commonest early postoperative complication, hemorrhage (4.6 %), and late postoperative complication, tracheal stenosis (5.9 %) as Zhu and Halum [25]. The only intraoperative complication that we had was tracheal rings fracture in two cases (0.6 %).

The secondary aim of this study was to define risk factors for the onset of intraoperative, early and late postoperative complications. Males and patients with a delayed substitution with a cuffless tube demonstrated an increased risk for the onset of early complications ($p = 0.04$ and $p = 0.01$, respectively). A trend to the statistical significance was observed for urgent tracheotomies ($p = 0.08$) concerning the risk for the onset of late complications. Because we registered only two intraoperative complications, no statistical analysis on the risk factors for their onset and no comparison between the two groups could be performed.

In literature, the delayed substitution of the cuffed tracheostomy tube correlates with late onset of tracheal stenosis, tracheoesophageal fistula or innominate artery erosion [26–28]. Our experience suggests that the persistent compressive action of the tracheostomy tube cuff on the tracheal wall also determines flogosis. For this reason, we believe that efforts should be made towards the early, but safe weaning from the tracheostomy tube, whenever no absolute or relative contraindications exist.

About 76 % of our patients, in the study period, was operated by supervised residents. This reflects the tendency in our university hospital to let residents perform the “easiest” operations. The open technique allows the prompt intervention of the surgeon whenever necessary, so that every surgical act always remains in a range of safety.

We recognize that our study presents some limitations. First, it is observational, nonrandomized, and retrospective in design. Residents with different years of experience were included and compared with surgeons with a variable degree of experience as well. The differences in experience have not been accounted for. It is not unlikely that several

other confounding factors may have influenced our results. One of the confounding factors is that patients with a trachea that is difficult to expose due to neck stiffness were operated by surgeons and not by supervised residents.

In our Academic Institution, one of the responsibilities of the ENT surgeon is to train beginner surgeons, teaching them the anatomy of the head and neck structures, improving their technical skills, and educating them to adhere to the principles of basic surgery. In the present study, the rate of complications was not significantly different between the two groups. The better complications rates of tracheotomies performed by residents might be attributed to their meticulous technical refinement as well as their ambition to succeed and the good teaching principles of the educators.

Conclusion

Current practice where residents perform tracheotomies supervised by experienced surgeons should not be discouraged. We found this safe and that it does not lead to a larger number of complications nor negatively affect quality of care.

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