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REVIEW ARTICLE

Surgical versus percutaneous tracheostomy: an evidence-based approach

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Abstract The choice between surgical (ST) and percutaneous tracheostomy (PT) is not often based on evidence. The aim is to evaluate the quality of evidence in published articles comparing the two methods. A MEDLINE search was done. From 298 articles found, 37 fulfilled the inclusion criteria and 35 were further analyzed. No study was based on type I evidence, 13 (37%) represented type II, in 1 (3%) a clear-cut definition between type II or III was not possible and 21 (60%) represented type III or IV evidence. Taking into account the complication rate of the 13 type II evidence studies, 7 are in favor of PT and 3 in favor of ST. The majority of studies comparing PT with ST are of type III or IV level of evidence. Even if only type II studies are analyzed, outcomes are controversial. Any claims by clinicians in favor of a particular treatment are still debatable.

Keywords Tracheostomy · Surgical · Percutaneous · Evidence-based medicine · Complications · Outcome

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Introduction

Tracheostomy is a surgical procedure performed to establish airway in patients with upper respiratory tract obstruction. Although it is one of the oldest surgical operations, it has been associated with numerous severe complications until the nineteenth or even the twentieth century, as the procedure had not been clearly understood and the indications had not been properly defined.

The first instance of tracheotomy was portrayed way back in 3600 BC on Egyptian artifacts by engravings in Abydos and Sakkara regions of Egypt depicting tracheostomy. Homer around 1000 BC reported that Alexander the Great saved the life of a soldier from suffocation, by making an opening in the trachea using the tip of his sword. However, the father of medicine, Hippocrates (460–377 BC) condemned tracheotomy because of fear of carotid artery damage. He knew that laceration or ligation of carotid vessels could cause death and advocated intubation in such cases.

In 1921 Chevalier Jackson codified indications and techniques for modern tracheostomy [1].

Today tracheostomy is most commonly performed in patients with difficulty weaning off a ventilator, followed by those who have suffered trauma or neurologic disorders. Infectious and neoplastic diseases are less common as indications for tracheostomy.

The classical surgical tracheostomy (ST) is a standard surgical procedure performed all over the world by general surgeons and otolaryngologists. However, during the last decades, new techniques of percutaneous tracheostomy (PT) have been gradually developed and widely accepted, especially in intensive care unit (ICU) patients. The reasons for this evolvement are considered to be some evident weaknesses of the standard ST (time consuming, usually

requiring an operating theater, and significant staff utilization).

Nevertheless, the adoption of one or the other method is usually done based on physician's individual opinion or experience, patient's clinical condition, availability of surgeon, theater and staff, etc. In addition, there are still several dogmatic opinions against or in favor of each method and many prefer one against the other, based on personal experience rather than evidence, and the debate still continues.

However, the twenty-first century is the century of evidence-based medicine. This demands that medical treatment is based on the best available scientific evidence. The expectation is that patients should receive the health care option that offers the greatest likelihood of conferring a benefit. When added to conscientiously practiced clinical skills and constantly developing clinical expertise, sound evidence derived from systematic research can be applied efficiently and effectively to patients' problems [2]. This can be accomplished only by integrating clinical expertise with research evidence whose quality is known and has been properly evaluated. Therefore, the choice should be based not on dogmatic opinions or personal experience but on sound and clear evidence.

The aim of the current study was to evaluate the quality of published evidence in comparison with the two methods of tracheostomy.

Materials and methods

An extensive search of the English literature was performed using Medline and other available database sources, with the primary goal of identifying all available studies comparing surgical to percutaneous tracheostomy published until February 2009. The keywords "Tracheostomy", "Surgical", "Percutaneous", "Evidence based medicine", were used and the search was confined only to adults (aged 13 and above). Conference reports, simple comments, editorials or experimental studies in animals were excluded. In addition, reference lists from the retrieved articles were manually searched.

The quality of evidence in each article was classified according to the levels of evidence as defined in Table 1 which has developed from the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001) in conjunction with the AACE protocol for guidelines [3, 4]. The Oxford criterion for type I well-conducted randomized control trials is the follow-up of at least 80% of patients. In order to assess, at least, the early and some of the long-term complications following tracheostomy, we considered as type I well-conducted randomized control trials the ones with the above criterion and at least 3 months follow-up.

Table 1 Levels of evidence

Level of evidence	Description
I	Well-controlled, generalizable randomized trial
	Adequately powered
	Well-controlled multicenter trial
	Large meta-analysis with quality ratings
	All or none evidence
II	Randomized controlled trial (low quality, e.g., limited body of data, ≥80% of patients lost to follow-up, follow-up less than 3 months)
	Well-conducted prospective cohort study
	Well-conducted meta-analysis of cohort studies
III	Methodologically flawed randomized clinical trials
	Observational studies
	Case series or case reports
	Conflicting evidence with weight of evidence supporting the recommendation
IV	Expert opinion based on experience
	Expert consensus
	Theory-driven conclusions
	Unproven claims

Results

The search produced 298 articles but only 37 fulfilled the inclusion criteria of the current study and were further analyzed. Only two studies could not be retrieved. The results are illustrated in Table 2.

From the 37 studies, 4 (11%) were meta-analyses, 17 (46%) were randomized controlled trials (RCT), 13 (35%) comparative studies (CS), 2 (5%) prospective nonrandomized studies (PNR) and 1 (3%) prospective randomized (PR).

Most of the studies (35/37) concerned perioperative and postoperative complication rates after percutaneous or surgical tracheostomies, but some of them were also comparing operative time, staff utilization, availability and cost effectiveness. In one study [5] oxygenation index was also examined and in another [6] the efficiency of a modified technique of percutaneous tracheostomy with bronchoscopic guidance in comparison to the open technique was examined.

Of the 35 tracheostomy studies analyzed, none was based on type I evidence, 13 (37%) represented type II evidence, in 1 (3%) a clear-cut definition between type II or III evidence was not possible, 20 (57%) represented type III evidence and 1 (3%) represented type IV evidence. All four of the meta-analyses were type II evidence. From the 17 RCT, 9 (53%) were characterized as type II evidence, 6 (35%) as type III and 2 (12%) could not be retrieved. 12 of

Table 2 Studies comparing surgical with percutaneous tracheostomy and their level of evidence

	Reference Paper	Type of study	Evidence type	Reason for classification
1	Beltrame et al. [21]	Comparative study (CS)	III	No power analysis; comparison with historical data; methodologically flawed
2	Türkmen et al. [10]	Comparative study (CS)	III	No power analysis; small number
3	Lukas et al. [22]	Randomized controlled trial (RCT)		Paper not found
4	Oliver et al. [16].	Meta-analysis	II	No power analysis; no adequate follow-up
5	Higgins and Punthakee [18]	Meta-analysis	II	No power analysis; no adequate follow-up
6	Silvester et al. [15]	Randomized controlled trial (RCT)	II	No power analysis; no adequate follow-up
7	Delaney et al. [19]	Meta-analysis	II	No power analysis; no adequate follow-up
8	Gravvanis et al. [23]	Comparative study (CS)	III	No power analysis; retrospective; methodologically flawed
9	Bacchetta et al. [24]	Comparative study (CS)	III	No power analysis; retrospective; methodologically flawed
10	Antonelli et al. [20]	Randomized controlled trial (RCT)	II	No power analysis; <80% follow-up
11	Tabaee et al. [25]	Randomized controlled trial (RCT)	III	No power analysis; methodologically flawed; no adequate follow-up
12	Wu et al. [26]	Randomized controlled trial (RCT)		Paper not found
13	Goldenberg et al. [27]	Comparative study (CS)	III	No power analysis; nonrandomized; methodologically flawed
14	Kaylie et al. [11]	Randomized controlled trial (RCT)	III	No power analysis; not blinded randomization; small number; methodologically flawed
15	Khalili et al. [28]	Comparative study (CS)	III	No power analysis; not well conducted
16	Sustić et al. [12]	Randomized controlled trial (RCT)	III	No power analysis; small number; methodologically flawed; no adequate follow-up
17	Melloni et al. [29]	Randomized controlled trial (RCT)	II	No power analysis; <80% follow-up
18	Freeman et al. [30]	Randomized controlled trial (RCT)	II	No power analysis; no follow-up
19	Levin and Trivikram [31]	Comparative study (CS)	III	No power analysis; methodologically flawed
20	Grover et al. [32]	Comparative study (CS)	IV	No power analysis; based on experience; theory-driven conclusions
21	Massick et al. [14]	Randomized controlled trial (RCT)	II	No power analysis; no adequate follow-up
22	Bowen et al. [33]	Comparative study (CS)	III	No power analysis; retrospective; methodologically flawed
23	Heikkinen et al. [34]	Randomized controlled trial (RCT)	III	No power analysis; methodologically flawed; <80% follow-up
24	MacCallum et al. [35]	Comparative study (CS)	III	No power analysis; unequal sample (50 open vs. 13 PDT); not well conducted
25	Gysin et al. [36]	Randomized controlled trial (RCT)	II	No power analysis; <80% follow-up
26	Freeman et al. [17]	Meta-analysis	II	No power analysis; no follow-up
27	Westphal et al. [5]	Comparative study (CS)	III	No power analysis; no randomization; methodologically flawed
28	Porter and Ivatury [37]	Randomized controlled trial (RCT)	III	No power analysis; unequal sample; small number; methodologically flawed
29	McHenry et al. [13]	Comparative study (CS)	III	No power analysis; retrospective; methodologically flawed
30	Holdgaard et al. [38]	Randomized controlled trial (RCT)	III	No power analysis; methodologically flawed
31	Stoeckli et al. [39]	Prospective nonrandomized	II or III	No power analysis; nonrandomized; ? methodologically flawed
32	Graham et al. [40]	Comparative study (CS)	III	No power analysis; retrospective; methodologically flawed
33	Friedman et al. [41]	Randomized controlled trial (RCT)	II	No power analysis; no follow-up
34	Barba et al. [6]	Prospective randomized study	III	No power analysis; small number; methodologically flawed; nonrandomized
35	Crofts et al. [42]	Randomized controlled trial (RCT)	II	No power analysis; no adequate follow-up
36	Griggs et al. [43]	Prospective nonrandomized	III	No power analysis; methodologically flawed; nonrandomized; no adequate follow-up
37	Hazard et al. [44]	Randomized controlled trial (RCT)	II	No power analysis; <80% follow-up

the 13 CS represented type III evidence and 1 type IV. From the two PNR one was type III and the other could not be clearly defined as II or III. The PR was type III. The above-mentioned studies and the reasons for the above classification are illustrated in Table 2.

Discussion

Recently evidence-based medicine emerged as a way to improve and evaluate patient care. It involves combining the best research evidence with the patient's values to make decisions about medical care. The most essential prerequisite in evidence-based medicine is that all studies should be critically and systematically appraised and their validity and usefulness determined [7].

The results are in agreement with the basis of common sense and statistical principles, which define the well-conducted and suitably powered multicenter double-blind placebo, controlled randomized trial as the apex of the pyramid of evidence. In the absence of such a trial, many would also regard a high-quality systematic review and meta-analysis as high evidence. However, systematic reviews require cautious interpretation and may not warrant placement on the apex of the hierarchy of evidence, due to inclusion of evidence from trials of poor quality [8].

Moreover, single-center trials and multicenter studies have their own weaknesses relating to grading the quality of evidence [9]. Last but not least, studies comparing surgical data and methods may be assigned in high evidence based level although serious weaknesses may be hidden under the mathematical figures or the criteria of evidence-based medicine.

No actual data from the studies analyzed were included in the present paper and there was no attempt to make any synthesis of the data. Perhaps this is a weakness of the present study although more details of each paper and other lengthy methods of assessment might have been tiring and out of the scope of the present paper. Moreover, any synthesis of nonhomogenous data of studies with selection bias would produce the same weak results following a vicious circle.

The aim of the present study was to assess the quality of published evidence supporting either percutaneous or surgical tracheostomy for elective cases. Although several meta-analyses in the literature have already attempted to compare the two methods, none has analyzed the quality of the evidence supporting the conclusions of the various studies.

The results revealed that there are no type I studies to establish a sound advantage of one method against the other. On the other hand, there are 13 studies comparing the two different methods of management based on type II evidence. Still the majority (21/35) of studies found were of type III or type IV evidence.

It has to be highlighted that PT is mainly used in intensive care unit or intensive treatment unit (ICU/ITU) patients who have a lot of medical problems and can easily deteriorate, developing clotting disturbances or other medical conditions that could affect the results of the tracheostomy. However, most of the comparisons between ST and PT are made in ICU/ITU patients and therefore the related outcomes are valid, at least in these patients.

In most of the studies both procedures were performed either by an experienced surgeon or an experienced ICU/ITU physician or by a person with accreditation to perform tracheostomy, or under senior supervision. Nevertheless, in some studies this was not taken into serious account and for that reason the validity of the results, especially concerning complications, procedure time, etc., is under consideration.

None of the studies analyzed had a documented power analysis; therefore, we do not know whether the number of patients used was adequate to support the published outcomes, especially when no statistical difference was found. In many studies [10–13], the number of patients used was extremely low making the related conclusions rather unreliable.

Another important issue is the selection of patients for either PT or ST. The criteria commonly used are in favor of the PT and this decreases substantially the strength of the comparisons. For example, Massick et al. [14] in their study excluded 64 out of 164 patients, who could not be candidates for PT due to anatomical or other problems. This, even if it has been done unwillingly, makes PT the procedure of choice for the easiest or at least for certain cases and the comparisons are valid only for such cases. In addition, even if the analysis of the studies had taken into account the various subgroups (e.g., patients undergoing head and neck surgery), the same selection bias would have been again found.

It was interesting to note that none of the studies analyzed fulfilled the criteria for adequate follow-up (more than 80% of the patients followed-up for 3 months or more). Unfortunately, a considerable number of patients in ITU/ICU do not survive long enough in order to establish the rate of long-term complications following tracheostomy. This is another weakness for the comparisons between ST and PT in such patients. Moreover, in the studies included in the present analysis, patients are followed-up for various time periods and this further decreases the reliability of the related outcomes.

Taking into account the complication rate of the 13 type II evidence studies identified in the present study, 7 seem to be in favor of percutaneous tracheostomy and 3 in favor of surgical tracheostomy (Table 3). However, this is not as simple as that, because these outcomes in favor of the one

Table 3 The 13 type II evidence studies comparing surgical with percutaneous tracheostomy

	Paper	In favor of PT	Against PT	No difference
1	Oliver et al. [16]	Faster ($p = 0.01$)	Early minor complications ($p = 0.04$) (for randomized trials only) Cost (bedside surgical tracheostomy less expensive)	Perioperative death ($p = 0.33$) Early complications ($p = 0.1$) or serious early complications ($p = 0.25$) Late complications ($p = 0.24$)
2	Higgins and Punthakee [18]	Wound infection ($p = 0.0002$) Scarring ($p = 0.01$)	Decannulation/obstruction ($p = 0.009$)	False passage ($p = 0.08$) Minor hemorrhage ($p = 0.77$) Major hemorrhage ($p = 0.17$) Subglottic stenosis ($p = 0.19$) Death ($p = 0.50$) Overall complications ($p = 0.05$)
3	Silvester et al. [15]	Shorter time from randomization to procedure ($p = 0.006$) Scar length ($p = 0001$) Infection day 7 ($p = 0.044$)	Larger tube ($p = 0.0001$)	Procedure duration ($p = 0.58$) Bleeding ($p = 0.2$) Infection day 3 ($p = 0.15$) Median duration of cannulation Number of patients discharged with the TT in situ ($p = 0.8$) Hospital mortality rate ($p = 0.74$)
4	Delaney et al. [19]	Wound infection ($p < 0.0005$)		Mortality ($p = 0.13$) Minor complications ($p = 0.35$) Major incidence ($p = 0.59$)
5	Antonelli et al. [20]	Procedure duration ($p = 0.003$) Major postoperative bleeding ($p = 0.03$)		ICU stays ($p = 0.52$) Hospital ($p = 0.46$) and ICU ($p = 0.8$) mortality rates Phonetic or respiratory problems ($p = 0.53$)
6	Melloni et al. [29]	Early postoperative complications ($p < 0.0001$) Procedure duration ($p < 0.0001$)		
7	Freeman et al. [30]	Faster ($p = 0.0001$) Less expensive ($p = 0.0001$)		Trend toward a higher mortality rate in patients undergoing ST vs. PT, which did not reach statistical significance ($p = 0.06$)
8	Massick et al. [14]		Post operative complications ($p < 0.05$)	Perioperative complications ($p > 0.05$)
9	Gysin et al. [36]		Minor perioperative complications ($p = 0.02$)	Early postoperative complications ($p = 0.20$) Total postoperative complications
10	Freeman et al. [17]	Faster All postoperative complications Stomal infections Post operative bleeding		All operative complications Mortality rates
11	Friedman et al. [41]	Faster ($p < 0.001$) Logistically superior Post procedural total complication rate ($p = 0.008$)		
12	Crofts et al. [42]			Adverse events (no statistical analysis)
13	Hazard et al. [44]	Pre-decannulation adverse events ($p < 0.01$) Procedure duration Post decannulation complications ($p < 0.05$)		

or the other method are sometimes based on a single, even minor, complication whereas the remaining and serious complications do not have any significant difference. For example, in the study conducted by Silvester et al. [15] there was a significant reduction in the scar length and the infection rate at day 7 using the PT compared with the

ST technique, whereas there was no significant difference in hospital mortality rate, bleeding, infection rate at day 3, or other complications. This finding is further supported by the fact that, although PT seems to outperform ST in the conclusions of the majority of single-center trials, the situation is not the same when we take into account the four meta-analyses.

In the meta-analysis of Oliver et al., the authors reported no significant difference for either early complications or serious early complications when all prospective study designs were analyzed. However, when the analysis was limited to randomized, controlled studies, a different picture emerged in favor of ST as it was associated with a 60% lower likelihood of early minor complications compared with PT, although there was no difference in serious early complications. The authors suggested that long-term outcome data are incomplete and deserve additional studies [16].

In the second meta-analysis by Freeman et al., the conclusion is in favor of PT as postoperative complications, stomal infections, and bleeding are found to be less in PT. However, there was no difference between the two methods with regard to all operative complications (those occurring during the procedure) and mortality [17].

In the third meta-analysis by Higgins et al., ST outperforms PT in decannulation/obstruction rate whereas PT outperforms ST in wound scarring or infection. Bleeding, subglottic stenosis, false passage, mortality, and overall complications have no significant difference in the two methods [18].

In the fourth meta-analysis conducted by Delaney et al., the situation is no different. A significant reduction was found only in wound infection using the PT compared with the ST technique, whereas there was no significant difference in mortality, minor, and major incidences [19].

With regard to cost effectiveness, it would be very reasonable to assume that PT would easily outperform ST, being faster and less costly. However, even in this area the evidence is not clear. Supporting PT, Friedman et al. demonstrated that PT is logistically superior to ST, as operating time does not need to be scheduled and PT can be performed sooner once the decision to perform a tracheostomy is made. This is due to schedule problems that presumably exist in many hospitals [20]. In addition, Higgins et al. [18] in their meta-analysis reported logistical overall pooled results that seem to favor the percutaneous technique by $456.61 USD and PT was also found faster by an average of 4.5 min. On the other hand, Oliver et al. [16] in their meta-analysis agreed that PT maybe 50% faster to perform than ST but bedside surgical tracheostomy is on average 50% less costly than PT by means of the associated bronchoscopy and disposable device charges of PT.

With regard to long-term complications, the evidence is even weaker. Antonelli et al. [20] reported that 1 year after the tracheostomy procedure, 5 of the 13 PT respondents (38%) and 6 of the 18 from the ST group (33%) had subjective phonetic or respiratory problems described as mild or moderate. The fact that only 31 (22%) were assessed 1 year after the procedure out of the 139 patients who were included in the beginning of the study further highlights the inherited weaknesses of the related studies.

Although the results of the present study revealed that there is no strong evidence to suggest that the one method is superior to the other, PT seems to have been found to be faster and less expensive than ST, as the latter requires theater time and more staff. Moreover, there was an overall trend in the literature of fewer complications in the PT method. Therefore, if the proposed tracheostomy is the first performed to the patient and theater time or surgeons are difficult to be found, PT seems to be the method of choice in experienced hands. However, there are certain contraindications for the PT method (e.g. swollen neck, anatomical problems, etc.) and an experienced surgeon may perform tracheostomy under local anesthesia or at the bedside of the patient in a very short time with minimum cost.

Conclusions

The present evidence-based study has demonstrated that the majority of the studies in the literature comparing percutaneous with surgical tracheostomy are of type III or IV level of evidence. Even if only type II studies are included in the analysis, the outcomes are still controversial, especially taking into account the serious weaknesses in the study design (selection of patients, no long-term follow-up, lack of power analysis, significant number of patients lost to follow-up, etc.). Any claims by clinicians in favor of a particular treatment are still debatable.

The necessity of a well-conducted, adequately powered, and with long-term follow-up, studies is even more prominent now that medicine is based on evidence.

An additional effort will be needed in order to address and quantify dimensions of evidence such as biological plausibility, reproducibility and generalizability. This effort could be especially beneficial on current clinical practice regarding tracheostomy. However, randomized control studies should not put in risk quality of care in critically ill patients.

Since the present paper assesses the quality of evidence already published in the literature, there was no need of approval by our hospital ethics committee.

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