*The Laryngoscope*
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# Meta-Analysis Comparison of Open Versus Percutaneous Tracheostomy

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***Objectives/Hypothesis:*** **Multiple studies have been performed to characterize differences in complications and cost-effectiveness of open and percutaneous tracheostomy; however, large enough studies have not been performed to determine a clearly superior method. Our primary objective was to compare complication rates of open versus percutaneous tracheostomy in prospective, randomized-controlled trials using meta-analysis methodology. Secondary objectives included cost-effectiveness and procedure length analyses.** ***Study Design:*** **Meta-analysis.** ***Methods:*** **From 368 abstracts, 15 prospective, randomized-controlled trials involving nearly 1,000 patients were reviewed to extract basic demographic data in addition to complications, case length, and cost-effectiveness. Pooled odds ratios (OR) with confidence intervals (CI) were calculated in addition to subgroup analyses and meta-regression.** ***Results:*** **Pooled OR revealed statistically significant results against percutaneous tracheostomy for the complication of decannulation/obstruction (OR 2.79, 95% CI 1.29–6.03). There were significantly fewer complications in the percutaneous group with respect to wound infection (0.37, 0.22–0.62) and unfavorable scarring (0.44, 0.23–0.83). There was no statistically significant difference for complications of false passage (2.70, 0.89–8.22), minor hemorrhage (1.09, 0.61–1.97, $P$ = .77), major hemorrhage (0.60, 0.28–1.26), subglottic stenosis (0.59, 0.27–1.29), death (0.70, 0.24–2.01), and overall complications (0.75, 0.56–1.00). However, the overall complications trended toward favoring the percutaneous technique. Percutaneous tracheostomy case length was shorter overall by 4.6 minutes, and costs were less by approximately $456 USD.** ***Conclusions:*** **Our meta-analysis illustrates there is no clear difference but a trend toward fewer complications in percutaneous techniques. Percutaneous tracheotomies are more cost-effective and provide greater feasibility in terms of bedside capability and nonsurgical operation.** ***Key Words:*** **Meta-analysis, percutaneous, open, tracheostomy, complications, cost-effectiveness.**

***Laryngoscope,*** **117:447–454, 2007**

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Editor's Note: This Manuscript was accepted for publication October 23, 2006.

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**DOI: 10.1097/01.mlg.0000251585.31778.c9**

## INTRODUCTION

Securing the airway by way of a tracheotomy has been reported back to ancient times. The procedure was popularized in the early 1900s by Chevalier Jackson and is currently used in intensive care units (ICU) across the world. Major indications include upper airway obstruction, pulmonary toileting, and prolonged endotracheal intubation. Standard tracheotomy using an open surgical approach has been accompanied by the percutaneous technique in the past 15 years. Percutaneous techniques are emerging as a common method of securing definitive airways in adult ventilated patients. Advocates for this technique cite various advantages including smaller skin incision, less tissue trauma, and lower incidence of wound infection and peristomal bleeding complications. Furthermore, the procedure can be performed at the bedside in the critical care unit, reducing risks associated with patient transfer and releases operating room resources including time and personnel. It is also believed to be faster, requires less personnel, and allows nonsurgeons to perform the procedure with resultant implications related to cost savings both direct and indirect.

Multiple studies have compared the open and percutaneous tracheotomy technique in addition to reviews and two prior meta-analyses;[1,2] however, there is no consensus at this time as to the optimal approach in terms of minimizing complications. In addition, past studies have had limited systematic methodology, bias related to unknown confounders, and review of only few randomized trials. Our primary objective was to compare complication rates of open versus percutaneous tracheostomy in adult ventilated patients using meta-analysis methodology. Cost-effectiveness and procedure length comparisons were included as secondary objectives. To ensure an appropriate quantitative analysis, we examined the pooled data for heterogeneity and assessed for publication bias using funnel plot methodology.

## MATERIALS AND METHODS

### *Study Selection and Identification*

Study inclusion and exclusion criteria were established and can be seen in Table I. The following computerized bibliographic

TABLE I.
Study Selection Inclusion and Exclusion Criteria.

| | |
|---|---|
| Inclusion criteria | |
| Population | Elective consenting adult ventilated patients |
| Intervention | Percutaneous technique compared with open technique |
| Method | Experimental design: random or quasi-random clinical trials only |
| Outcome | Complications described and numbers reported |
| Published English language | For ease of reporting and shown to not lead to biased estimates of effectiveness of treatments[3] |
| Exclusion criteria | |
| Emergency airway | Tracheotomy is not considered standard of care |
| Pediatric population | Immaturity of larynx and varied position in neck restricting choice of intervention[4] |

databases were comprehensively searched using the maximally sensitive strategy developed by the Hedges team[5]: Medline, EMBASE, Cochrane Central Register of Controlled Trials, Cumulative Index to Nursing and Allied Health Literature, and Web of Science. The reference lists of all papers obtained were reviewed with any additional relevant papers identified and photocopied. Additional strategies were used to attempt to uncover unpublished material including Biosis Preview, ClinicalTrials.gov, and Conference Papers Index. Finally, the following organizations were contacted concerning knowledge of any research funded by or associated with their organization: Canadian Society of Otolaryngology–Head and Neck Surgery, Canadian Critical Care Society, Trauma Association of Canada, Canadian Critical Care Trials Group.

Two reviewers (K.H., X.P.) screened the titles and the abstracts for initial relevance independently. Any title or abstract that either reviewer believed met the eligibility criteria was then obtained in full text form for differential photocopying with blinding to journal source, author, and institution to minimize selection bias. Interobserver agreement was analyzed with quadratic-weighted kappa scores. The relevance forms were initially pilot tested with the a priori criterion of a kappa statistic greater than 0.65 before full searching proceeded. Disagreement was resolved by eventual consensus governance.

### Validity Assessment

The Agency for Health care Research and Quality Evidence[6] reports and summaries were searched electronically for systems to rate the strength and validity of scientific evidence. The Downs and Black checklist was selected as a baseline template for tool creation,[7] with measures for internal and external validity that were applicable to randomized and quasi-randomized studies. The same reviewers who judged eligibility rated the methodologic quality of the primary research and conducted a blinded review of fully relevant studies. Agreement for the quality assessments was calculated and disagreement resolved. Interobserver agreement was analyzed with quadratic-weighted kappa scores.

### Data Abstraction

Information concerning important clinical baseline variables, primary, and secondary outcome data were abstracted in duplicate to minimize random error (Table II).

TABLE II.
Clinical Baseline Variables, Primary, and Secondary Outcome Data Gathered.

| Clinical Baseline Variables | Details |
|---|---|
| Age | |
| Sex | |
| Length of ICU stay | After procedure/indwelling period |
| Duration of endotracheal intubation | |
| Ventilator settings | FiO2, PEEP |
| Coagulopathy | INR, PT, PTT |
| Total number of personnel involved | |
| Length of follow-up | |
| Setting of procedure | ICU, bedside, OR |
| Medical comorbidities | ASA, APACHE score |
| Economic evaluation | Cost, case length |
| Primary and secondary outcome data | |
| Complications* | Procedural, perioperative, postoperative |
| Patient neck anatomy described | Circumference, length, landmarks |
| Percutaneous method used | |
| Open method used | Horizontal, vertical, u-shaped, Bjork flap |
| Type of primary personnel involved | Intensivist, respirologist, anesthesia, medical surgical, other |
| Monitoring method applied | Endoscopic control, capnograph, ultrasound guided |
| Percentage lost to follow-up | |

*Complications included death, cardiac arrest, pneumothorax, pneumomediastinum, tracheo-innominate fistula, mediastinitis, sepsis, major hemorrhage, minor hemorrhage, subglottic stenosis, desaturation, false passage, posterior tracheal wall injury, decannulation/dislodgement, pneumonia, atelectasis, conversion to open technique, aspiration, subcutaneous emphysema, wound infection/stomatitis, delayed closure, unfavorable scar.

ICU = intensive care unit; FiO2, fraction of inspired oxygen; PEEP, positive end-expiratory pressure; INR, International Normalized Ratio; PT, prothrombin time; PTT, partial thromboplastin time; OR, operating room; ASA, American Society of Anaesthesia; APACHE, Acute Physiological and Chronic Health Evaluation.

### Analysis

Dichotomous results were summarized as pooled odds ratios (OR) and 95% confidence intervals (CI) around the point estimates. The test for overall pooled effect used the Z statistic with significant $P < .05$. Continuous outcome variables were compared using weighted mean or standardized normal differences. The homogeneity of the estimates was formally tested using the chi-square statistic with degrees of freedom and $P$ values reported. The $I^2$ test will be used to measure the extent of inconsistency among results and the proportion of total variability accounted for by heterogeneity rather than chance alone. The predetermined significance level of heterogeneity was $P < .10$. Both the typical effect size and the effect size relative to specific study characteristics will be interpreted cautiously if there is significant heterogeneity. The statistical packages used included Review Manager 4.2 (The Cochrane Collaboration, Oxford, UK), Minitab 14 Statistical Software (Minitab, Inc., State College, PA), and Statsdirect (Statsdirect Ltd., Chesire, UK). Subgroup analyses

| TABLE III. Electronic Search Results. | |
|---|---|
| Cochrane Central Register of Controlled Trials | 20 |
| CinAHL | 25 |
| EMBASE | 149 |
| Medline | 55 |
| Biosis | 83 |
| Conference Papers Index | 36 |
| Total | 368 |

CinAHL = Cumulative Index to Nursing and Allied Health Literature.

were planned a priori to examine the impact of methodologic quality, type of personnel performing percutaneous procedure, and procedure location using a $P$ value of .001.

### *Publication Bias*

Funnel plot testing was performed to examine for the presence of publication bias by comparing the magnitude of the treatment effect against sample size. Egger's method was used to estimate funnel plot asymmetry using linear regression with effect size/standard error dependent on the precision estimate, with significant publication bias detected if the intercept differed significantly from 0.[8]

## RESULTS

The electronic search yielded a total of 368 citations (Table III). The relevance screening yielded 50 papers with consensus governance (weighted kappa 0.77) with the exclusion of duplicates; 31 papers were subjected to full text comprehensive relevance assessment by the two authors. After relevance testing, 15 papers[9–23] were considered eligible for inclusion (weighted kappa 0.80) and validity testing. The validity agreement for weighted kappa scores were 0.78 (overall score), 0.90 (randomization component), and 0.67 (blinding component).

The total number of patients included was 973 (490 percutaneous, 483 open). Baseline characteristics of the studies including case number, method of monitoring, number of personnel involved, procedure setting, length of follow-up, and proportion lost to follow-up are illustrated in Table IV. The average number of personnel was 3.25 in the percutaneous group and 4.375 in the open group.

Pooled ORs revealed statistically significant results against percutaneous tracheostomy for complications of decannulation/obstruction (pooled OR with 95% CI, 2.79, 1.29–6.03, $P$ = .009). There were significantly fewer complications in the percutaneous group with respect to wound infection (0.37, 0.22–0.62, $P$ = .0002) and unfavorable scarring (0.44, 0.23–0.83, $P$ = .01) (Figs. 1–3).

There was no statistically significant difference in terms of false passage (2.70, 0.89–8.22, $P$ = .08), minor hemorrhage (1.09, 0.61–1.97, $P$ = .77), major hemorrhage (0.60, 0.28–1.26, $P$ = .17), subglottic stenosis (0.59, 0.27–1.29, $P$ = .19), and death (0.70, 0.24–2.01, $P$ = .50). Overall complications trended toward favoring the percutaneous technique; however, this only approached statistical significance (0.75, 0.56–1.00, $P$ = .05) (Fig. 4). Minor hemorrhage analysis was adjusted to reduce heterogeneity and accounted for outlying definitions. Conclusions could not be generated for the following because of minimal events or lack of reporting: cardiac arrest, pneumomediastinum, tracheo-innominate fistula, mediastinitis,

TABLE IV.
Baseline Characteristics of Included Studies.

| Study | n (perc/open) | Monitoring | Total Personnel (perc/open) | Procedure Setting (perc/open) | Length of F/U | Percentage Lost to F/U (total, perc, open) |
|---|---|---|---|---|---|---|
| Antonelli | 67/72 | PO | 4/6 | Bedside/OR | 1 yr | 77.6, 73, 82 |
| Crofts | 25/28 | None | 2/2 | Bedside/OR | 2 wk | NS, 36, 50 |
| Freeman | 40/40 | Bronch | NS | Bedside/OR | NS | NS |
| Friedman | 26/27 | None | 2/4 | Bedside/OR | NS | NS |
| Gysin | 35/35 | Bronch | NS | 8 bedside, 27 OR/13 bedside, 22 OR | 3 mo | 57, NS, NS |
| Hazard | 22/24 | None | NS | Bedside/bedside, OR (numbers not specified) | 12 wk | NS |
| Heikkinen | 30/26 | None | 3/5 | Bedside/bedside | 18 mo | 80, NS, NS |
| Holdgaard | 30/30 | None | NS | OR/OR | To stoma closure | NS |
| Massick | 50/50 | Bronch | 2/3 | Bedside/bedside | 21 days | 0, 0, 0 |
| Melloni | 25/25 | Bronch | 4/4 | Bedside/15 bedside, 10 OR | 6 mo | NS, 40, 48 |
| Porter | 12/12 | Bronch and PO | NS | Bedside/bedside | NS | NS |
| Raine | 50/50 | NS | NS | Bedside/bedside | 60 days after decannulation | NS, 48, 52 |
| Sustic | 8/8 | US | NS | Bedside/OR | NS | NS |
| Tabaee | 29/14 | Bronch and US | 3/2 | Bedside/bedside | 1 wk | 5, NS, NS |
| Wu | 41/42 | Bronch (12 cases) and PO (all) | 3/NS | Bedside/OR | 2–4 yr | 63, NS, NS |

F/U = follow-up; NS = not specified; PO = pulse oximetry; Bronch = bronchoscopy; US = ultrasound; perc = percutaneous tracheostomy; OR = operating room.

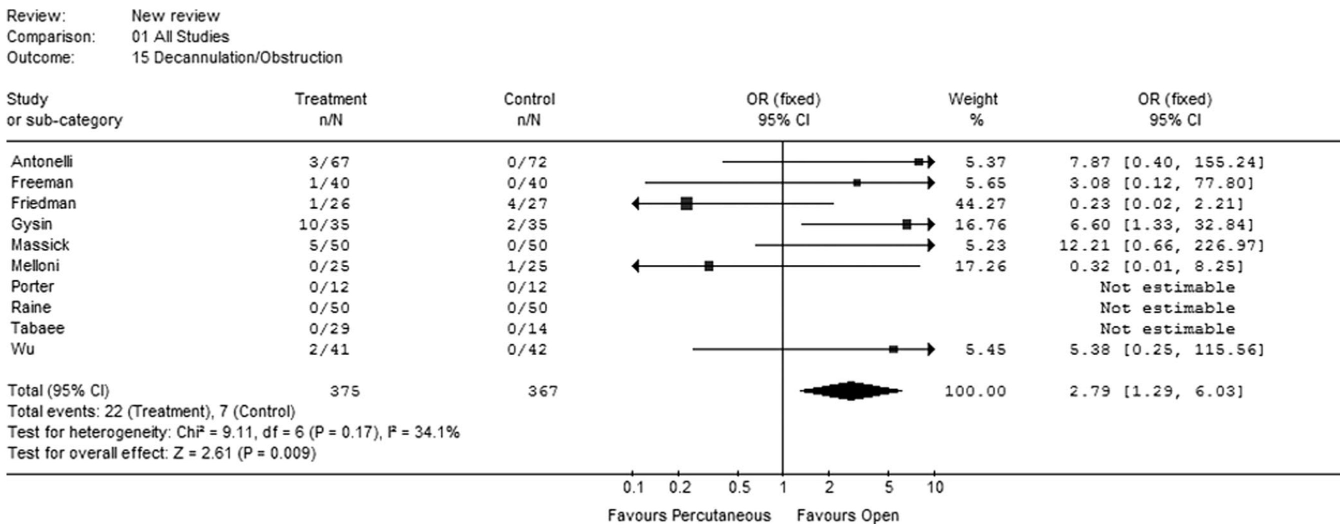


Fig. 1. Comparison for decannulation/obstruction.

sepsis, posterior tracheal wall injury, pneumonia, atelectasis, aspiration, and subcutaneous emphysema.

Of the four studies reporting on the conversion to open technique variable, there were 12 attempted percutaneous tracheotomies of a total 155 (7.7%) that were converted to the open approach. There were no other adverse outcomes reported related to the change in technique. There were only four studies that included any cost-effectiveness estimates. The overall pooled result favored the percutaneous technique by $456.61 USD (Fig. 5). Case length comparison also strongly favors the percutaneous technique by 4.59 minutes (Fig. 6). This comparison was also negatively impacted by heterogeneity.

The planned a priori subgroup analyses continued. A sensitivity analysis based on the dichotomized overall validity scores (studies of highest methodologic quality) did not show any change in the overall effect results. When the operator in the head-to-head comparison was a surgeon in both groups, there was also no significant qualitative difference in complications. When patients were transferred to the operating room for the open technique, the percutaneous technique was better with respect to overall complications ($P$ = .01). However, when both techniques were performed in the same setting (i.e., at the bedside in the ICU), there was a strong qualitative difference favoring the open technique ($P$ = .1) (Figs. 7 and 8). A summary of all results is presented in Table V.

## DISCUSSION

A thorough review of the literature revealed a significant number of prospective-randomized (or quasi-randomized) controlled trials from which to develop the

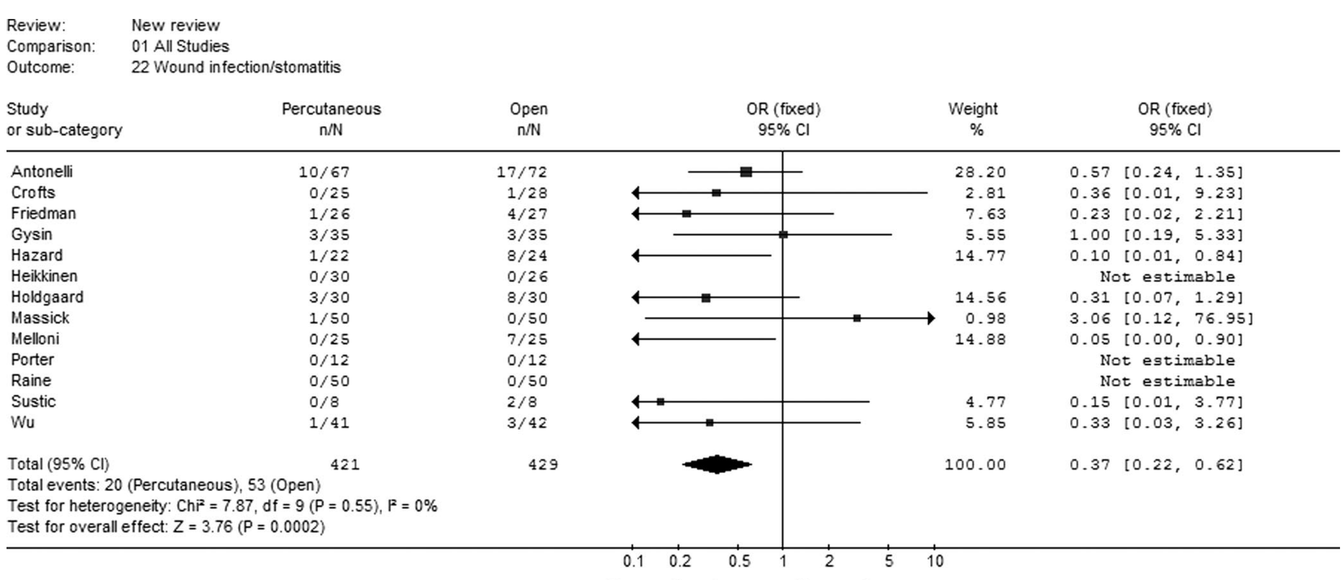


Fig. 2. Comparison for wound infection/stomatitis.

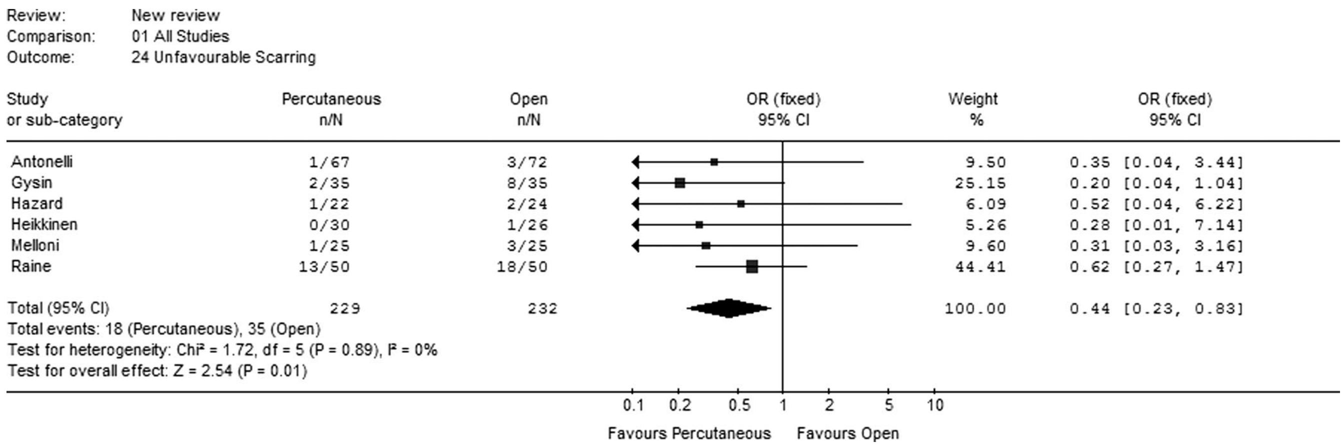


Fig. 3. Comparison for unfavorable scarring.

current meta-analysis. Unfavorable anatomy was identified as a restriction to the percutaneous technique in most studies, which reflects current practice, and the importance of determining anatomic landmarks for this procedure. The lack of palpable midline structures (thyroid cartilage, cricoid cartilage, sternal notch) should direct the operator to perform an open tracheotomy in view of the fact that it would otherwise be a blind, and less safe, procedure. Bronchoscopy was the most common method of monitoring the percutaneous procedure and reflects the best method of visualization of the airway. The open technique was performed in both the operating room and at the bedside in the ICU, which have significantly different resource allocation allotted to each. There was no significant difference with respect to physiologic performance baseline status as measured by Acute Physiology And Chronic Health Evaluation-II and Simplified Acute Physiology Score-2 scales, nor chronologic age between the open and percutaneous group (data not shown). The percutaneous group had 1 less day of endotracheal intubation before procedure initiation (data not shown). The heterogeneity test was also strongly significant in this respect and may reflect differential access to operating room resource and perhaps differential trigger points with respect to securing surgical airway versus continued prolonged endotracheal intubation.

Complications of decannulation/obstruction were significantly more likely to occur in percutaneous tracheostomies and strongly favored the open surgical technique ($P = .009$). This likely relates to the fact that the open technique allows the insertion of a tracheotomy tube with an inner and outer cannula that facilitates nursing. In addition, the larger, more well-defined insertion tract allows for earlier tracheotomy change that also reduces mucous plugging. However, the percutaneous method was significantly better for wound infection/stomatitis ($P =$

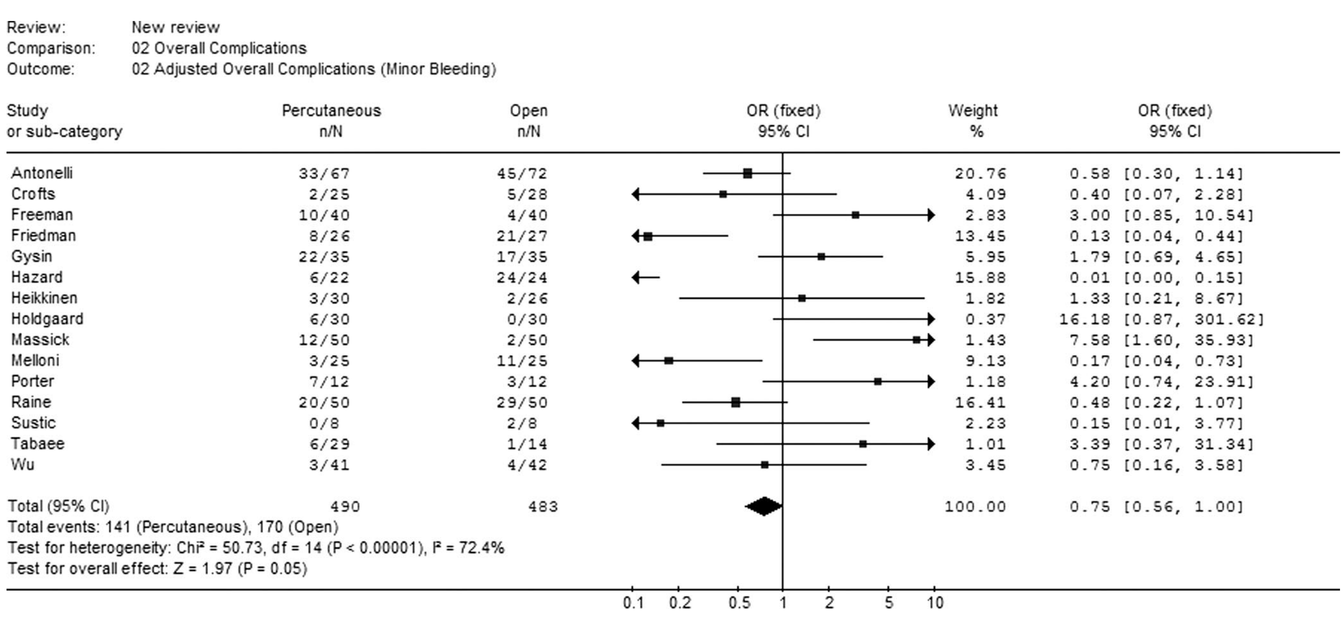


Fig. 4. Comparison for overall complications including adjusted values for minor hemorrhage.

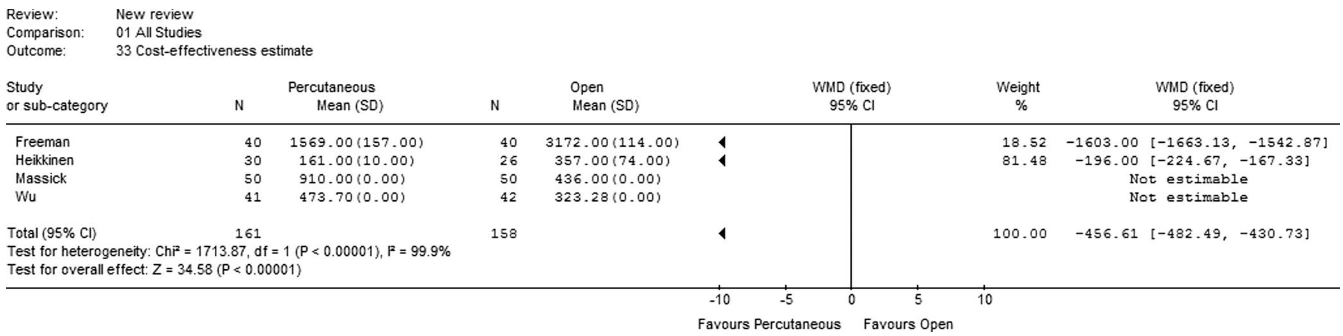


Fig. 5. Cost-effectiveness analysis ($USD).

.0002) and scarring ($P$ = .01). Both of these can be explained by minimal tissue manipulation, reduced tissue trauma, and reduced dead space. False passage trended toward favoring the open technique ($P$ = .08). This relates to the open versus closed nature of the techniques involved. Of significance is the serious, life-threatening nature of decannulation/obstruction and false passage creation, which are more likely to occur in the percutaneous group. Our analysis does not separate life-threatening and non–life-threatening complications, but it should be taken into account that the gravity of all complications are not equal. We did, however, show that there is no significant difference in terms of death between the two groups. Overall complications, however, strongly trended in favor of the percutaneous technique but did not reach statistical significance ($P$ = .05).

Resource allocation in terms of costs, time, and personnel involved for the two techniques all favored the percutaneous method ($456.61 USD less, 4.59 min less, 1 individual less); however, analyses were negatively impacted by heterogeneity. Trainees are more likely to perform open procedures, which may explain the increased amount of time and personnel involved with this technique. Traditionally, surgical trainees learn the anatomy of the airway in the operative setting and then proceed to the percutaneous technique where the airway is less well visualized. Alternatively, the percutaneous technique was often performed by more experienced personnel in these trials. As with any technique, there is a learning curve where, initially, the time required and complications may be higher than after further experience. Subgroup analyses showed that, when the operator in the head-to-head comparison was a surgeon, in both groups, there was a trend toward fewer complications in the open surgical technique, which may reflect the surgeon's comfort level with the open approach. As percutaneous tracheotomies become more commonly performed by surgeons, complication rates may indeed decrease in their hands. However, one of the major advantages of this technique is that nonsurgically trained members of the health care team may perform the tracheotomy using a Seldinger technique, and this person may be more familiar with the percutaneous technique than the respective surgeon.

When patients were transferred to the operating room for the open technique, the percutaneous technique was significantly better with respect to overall complication ($P$ =

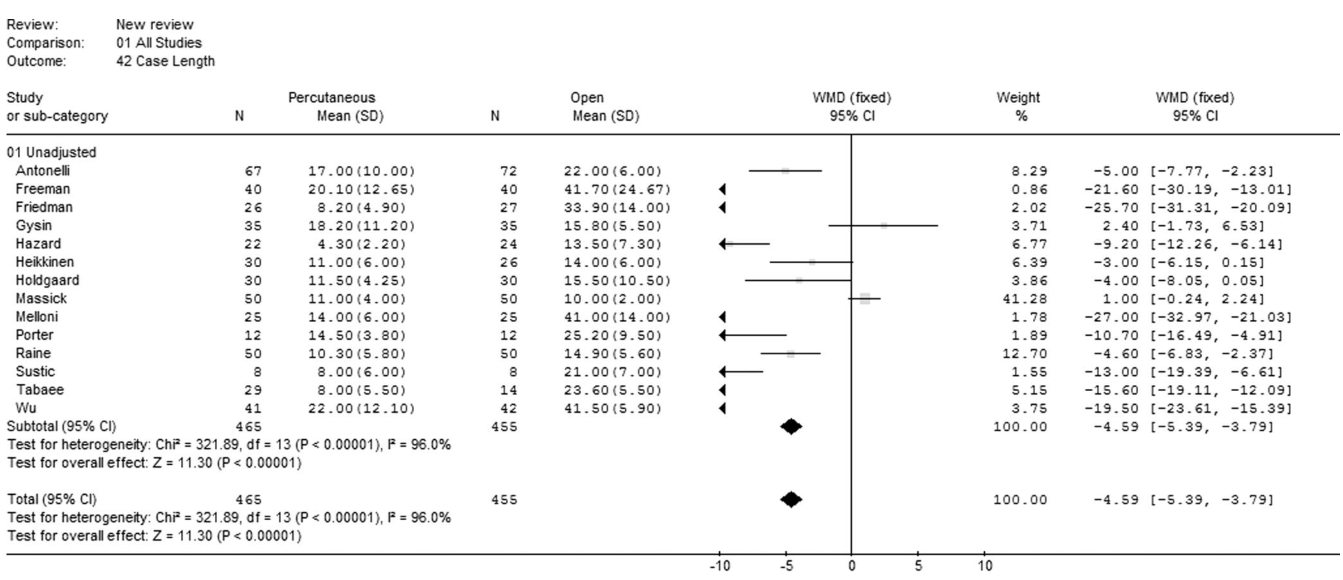


Fig. 6. Case length comparison measured in minutes.

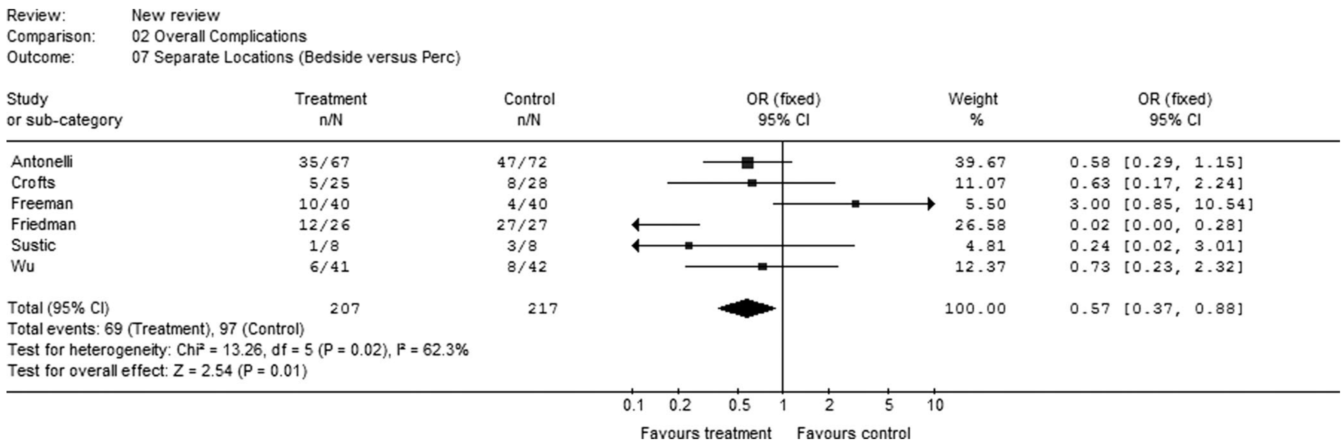


Fig. 7. Subgroup analysis of overall complications in studies where open tracheostomies were performed in operating room and percutaneous tracheostomies at bedside/intensive care unit.

.01). However, when both techniques were performed in the same setting (i.e., at the bedside in the ICU), there was a strong qualitative difference favoring the open technique ($P = .1$). These subgroups may point to the known difficulties/mishaps associated with transport from the ICU, with close to one third of transports sustaining at least one mishap.[24]

There was a visible loss of data represented by the asterisks in the lower left quadrant of the funnel plot, reflecting an absence of small negative or equivocal studies involving the percutaneous tracheotomy technique. Egger's method revealed an intercept of 4.54, $P < .01$, illustrating that there is significant publication bias with regard to differing methods of tracheotomy and overall complications.

Dulguerov et al.[1] analyzed three historical cohorts: percutaneous studies after 1985 and surgical tracheotomy studies divided into two periods: 1960 to 1984 and 1985 to 1996. Comparison of the relevant recent time period 1985 to 1996 revealed perioperative complications more frequent in the percutaneous (10% vs. 3%) group compared with the open technique, whereas postoperative complications are more frequent with the open (10% vs. 7%) technique. There was a higher incidence of perioperative death (0.44 vs. 0.03%) and serious cardiorespiratory events (0.33% vs. 0.06%) in the percutaneous group.

Freeman et al.[2] performed a pooled analysis of 236 patients, showing shorter overall operative times with an absolute difference 9.84 minutes favoring the percutaneous technique. There was no difference with respect to overall operative complications. Percutaneous technique was associated with less perioperative bleeding (pooled OR 0.14), lower overall postoperative complication rate (pooled OR 0.14), and lower incidence of stomal bleeding (pooled OR 0.39) and stomal infection (pooled OR 0.02). There was no difference in terms of days intubated before procedure, death, or overall procedure-related complications.

This study was completed with its own strengths and limitations. This meta-analysis provided a detailed systematic analysis with comprehensive search strategy, auditable relevance testing, and validity assessments with agreement statistics. A thorough pooled quantitative analysis was also undertaken with planned a priori subgroup analyses to be investigated rather than encountered heterogeneity. The study limits were that of loss of allocation concealment and the lack of objective blinded

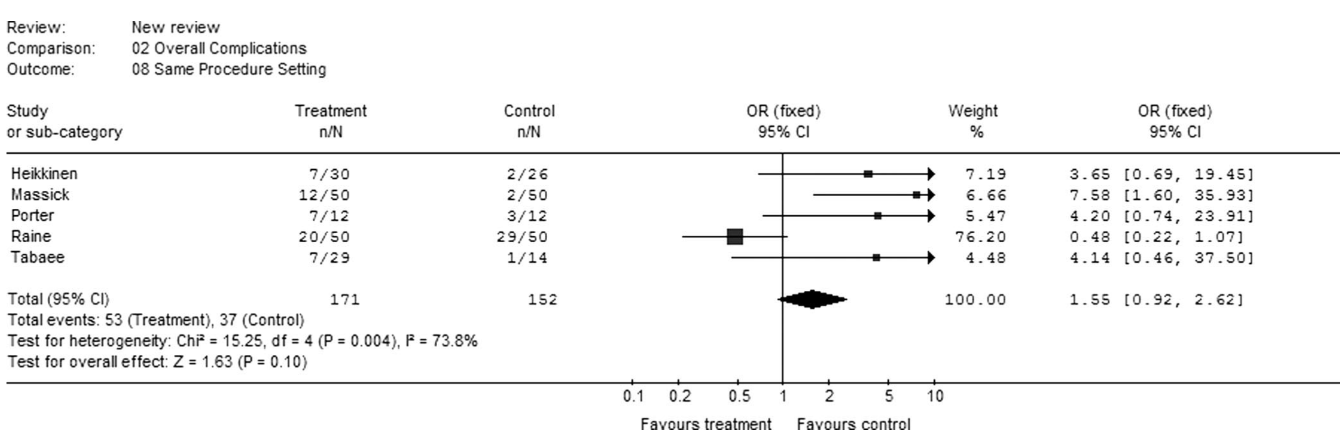


Fig. 8. Subgroup analysis of overall complications in studies where open and percutaneous tracheostomies were performed at the bedside/intensive care unit.

TABLE V.
Summary of Results.

| Favors Percutaneous Technique | Favors Open Technique |
|---|---|
| Wound infection ($P$ = .0002) | Decannulation/obstruction ($P$ = .009) |
| Unfavorable scarring ($P$ = .01) | False passage ($P$ = .08) |
| Cost-effectiveness ($P$ < .0001) | Minor hemorrhage ($P$ = .77) |
| Case length ($P$ < .0001) | |
| Overall complications ($P$ = .05) | |
| Major hemorrhage ($P$ = .17) | |
| Subglottic stenosis ($P$ = .19) | |
| Death ($P$ = .50) | |

observer outcome assessment with the known overestimation of treatment effect in the selected studies. There was an obvious loss to follow-up, which negatively impacts long-term complication analysis, especially as it relates to laryngotracheal sequelae such as subglottic stenosis, tracheomalacia, and posterior glottic stenosis. This unfortunately reflects the survival patterns in most critical care units with patients requiring prolonged ventilation that consequently are considered eligible for surgical airway creation. The study definitions were not entirely uniform, and publication bias was also found to be present. Finally, a major hypothesis surrounds the differential experience level or prerequisite training of the operators involved in the included studies.

## CONCLUSION

This meta-analysis has shown that percutaneous tracheotomies trend toward fewer overall complications than open techniques and appear to be more cost-effective by releasing operating room resources including time and personnel, provide greater feasibility in terms of bedside capability, and allow nonsurgeons to safely perform the procedure. Future directions would include a comparison between open bedside and percutaneous bedside tracheotomy with detailed cost-effectiveness analysis.

### Acknowledgments

The authors thank Mr. Henry Lam, medical librarian, Sunnybrook Health Sciences Centre, Toronto, Ontario, for all his efforts and assistance in the completion of this meta-analysis.

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