

ORIGINAL ARTICLE

Efficacy and airway complications of Parker Flex-Tip tubes and standard endotracheal tubes during airway manipulation

A meta-analysis and trial sequential analysis

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BACKGROUND Despite reported superior intubation outcomes associated with Parker Flex-Tip (PFT) tubes compared with those associated with standard polyvinylchloride tubes, the efficacy and safety of PFT tubes remain uncertain.

OBJECTIVES To compare the intubation outcomes between PFT and conventional standard polyvinylchloride tubes.

DESIGN Meta-analysis of randomised controlled trials.

DATA SOURCES Embase, Medline, Google Scholar, PubMed and the Cochrane controlled trials register from inception until 3 January 2021.

ELIGIBILITY CRITERIA All randomised trials comparing intubation outcomes between PFT (PFT group) and standard polyvinylchloride (standard polyvinylchloride group) tubes.

RESULTS Analysis of the 13 eligible trials showed no significant difference in successful first-attempt intubation rate [risk ratio (RR) 1.20, 95% confidence interval (CI) 0.99 to 1.44] (6 trials, 568 participants), trauma risk (RR 0.83, 95% CI 0.67 to 1.03) (5 trials, 501 participants) as well as the overall risks of epistaxis (RR 0.58, 95% CI 0.26 to 1.31) (3 trials, 262 participants), sore throat (RR 0.90, 95% CI

0.70 to 1.17) (4 trials, 451 participants) and hoarseness (RR 0.71, 95% CI 0.44 to 1.14) (4 trials, 451 participants) between the two groups. However, the intubation time was slightly shorter (weighted mean difference -4.2 s, 95% CI -7.4 to -1.0 s) (8 trials, 759 participants) and the risks of severe epistaxis (RR 0.15, 95% CI 0.03 to 0.84) (3 trials, 262 participants) and overall difficulty in airway manipulation (RR 0.48, 95% CI 0.29 to 0.80) (8 trials, 647 participants) were lower in the PFT group than those in the standard polyvinylchloride group. Trial sequential analysis conclusively confirmed a shorter intubation time with PFT tubes than with standard polyvinylchloride tubes, whereas other intubation outcomes were inconclusive.

CONCLUSION The use of PFT tubes for airway manipulation was associated with a shorter intubation time compared with the standard polyvinylchloride tubes. The results of trial sequential analysis suggest the need for further trials and meta-analysis to compare other intubation outcomes associated with the two devices.

TRIAL REGISTRATION PROSPERO CRD42020197670.

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Introduction

Although tracheal intubation is a common technique for maintaining airway patency in patients requiring general

anaesthesia, mechanical ventilation or airway protection, it is not performed without risk as difficult or failed intubation may be associated with significant morbidity and mortality.¹ Despite recent improvements in

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intubating devices to improve visualisation of the larynx (e.g. the availability of videolaryngoscopes),² successful railroading of the endotracheal tube (ETT) into the trachea remains a key step in successful tracheal intubation. However, difficulty with railroading the ETT at the laryngeal inlet level (i.e. laryngeal impingement) may occur in patients with an incidence of 47.6% to 93%.^{3–5} This difficulty can lead to an increased risk of airway complications and/or intubation failure.⁶ In spite of the self-limiting nature of most airway complications,⁶ repeated tracheal intubation may increase the risk of severe complications, such as hypoxaemia and cardiac arrest in critically ill patients.^{7,8}

Several studies have demonstrated that the design of the ETT tip may influence the success rate, intubation time and airway complications during tracheal intubation.⁹ For instance, despite the already enhanced laryngeal view with the videolaryngoscope,¹⁰ two previous studies reported further improvement in the ease of intubation, decrease in the frequency of ETT impingement and reduction in intubation time when the Parker Flex-Tip (PFT) tube was used for tracheal intubation.^{9,11} Current guidelines for airway management emphasise that repeated tracheal intubations and intubation-associated complications should be avoided.^{12,13} Although the use of sophisticated intubation devices (e.g. videolaryngoscope) is recommended for difficult airway management according to previous guidelines,^{12,13} the impact of ETT selection on intubation outcomes has not been adequately investigated. To address this issue, this meta-analysis aimed to compare the efficacy and airway complications between PFT and standard polyvinylchloride tubes.

Methods

This review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines, and was registered at the PROSPERO international database (CRD42020197670).

We searched the databases of Embase, Medline, Google Scholar, PubMed and the Cochrane controlled trials register for randomised controlled trials (RCTs) comparing the intubation outcomes between PFT and standard polyvinylchloride tubes in patients requiring tracheal intubation using the keywords ‘endotracheal intubation’, ‘Parker Flex-Tip tubes’, ‘standard endotracheal tube’, ‘randomised control trial (RCT)’ and their synonyms, as well as controlled vocabulary from inception to 3 January 2021. Meta-analyses were reviewed for cross-referencing. No publication date or language restriction was applied. The search strategies and syntax for one of these databases (Embase) is shown in Supplemental Table 1, <http://links.lww.com/EJA/A568>.

The inclusion criteria for this meta-analysis were RCTs in which PFT and standard polyvinylchloride tubes were used

in a neutral orientation for participants receiving airway manipulation through the nasal or oral route, and in which intubation outcomes (e.g. intubation time) were available for comparison. Exclusion criteria were studies in which airway manipulation was performed with the standard polyvinylchloride tubes in a nonneutral orientation (e.g. with the bevel in a posterior position), patients with a history of nasal trauma, pharyngeal tumour or concomitant respiratory infections were included, patients with a history of bleeding diathesis or anticoagulant use, or in which information regarding intubation outcomes was unavailable.

After removal of duplicates, the titles and abstracts of the remaining trials were examined by two independent authors (KCH and JYC) who selected studies for inclusion and documented reasons for exclusion of the ineligible studies. In the situation of disagreement, the corresponding authors (HFL or CKS) were also involved. If necessary, the authors of the selected studies were contacted for missing information. If there was still a lack of essential information, the study was excluded. For multiple reports describing data from the same trial, only the report with the largest sample size was selected.

Successful first-attempt intubation rate (SFAIR) was considered to be the primary outcome based on the ETT selected, while the secondary outcomes included the intubation time, difficulty in airway manipulation as well as the risks of airway complications (e.g. sore throat and epistaxis). SFAIR was defined according to the criteria of each study. The overall risk of epistaxis was defined as the occurrence of epistaxis regardless of severity. Similarly, the risk of overall difficulty in airway manipulation was defined as the occurrence of difficulty during airway manipulation regardless of the degree of difficulty. We defined postoperative hoarseness and sore throat as events that occurred in the recovery room or within three postoperative days based on the definitions of individual studies. Whenever this outcome was available at different time points, we chose events that occurred in the recovery room as the main outcome for analysis. For the purpose of this study, laryngoscopy was defined as conventional direct laryngoscopy and videolaryngoscopy, whereas nonlaryngoscopy referred to fibroscopic intubation, laryngeal mask airway-assisted intubation or tracheal intubation through the use of a tube exchanger.

Two authors (MHC and YJC) independently assessed the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions*.¹⁴ We reviewed the original registered protocols of the trials to identify any changes in procedure or data on missing outcomes that may indicate reporting bias. Moreover, the sources of funding and the roles of manufacturers were assessed for the existence of other biases. Additionally, studies in which the authors did not clearly indicate an absence of conflict of interest were considered to have an uncertain risk of other biases. Disagreements were solved

by discussion. The overall risk of bias of all included studies and the risk of bias of individual studies were analysed.

Analysis

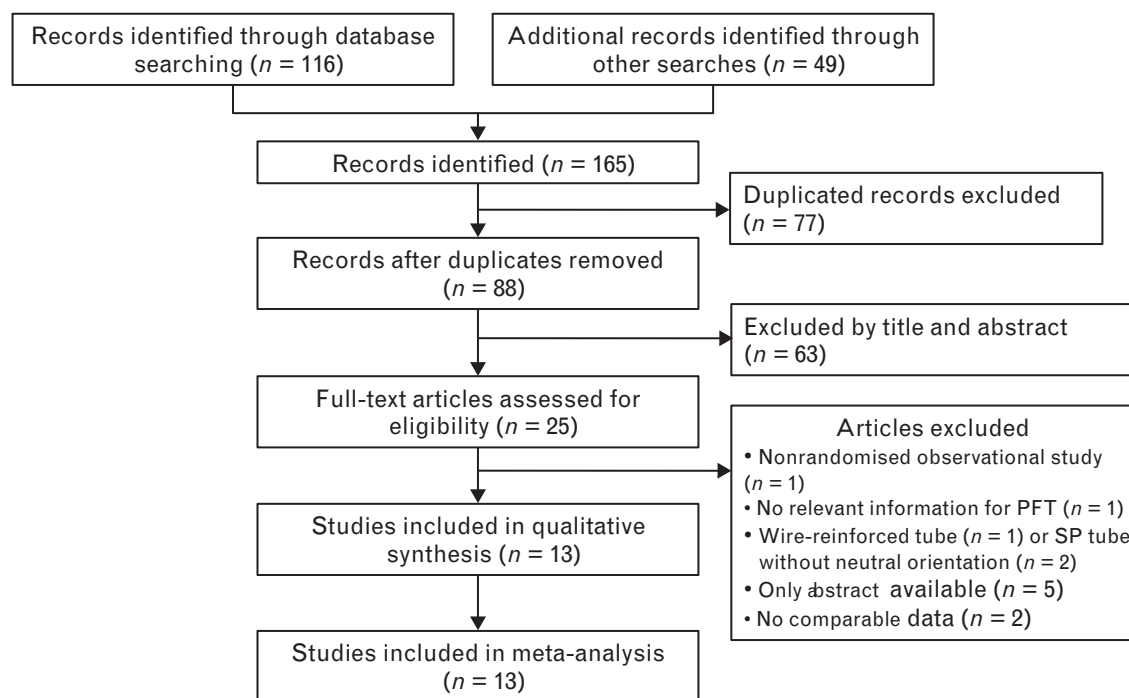
Cochrane Review Manager (RevMan 5.3; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) was used for data synthesis. For dichotomous outcomes, risk ratios (RRs) with 95% confidence intervals (CIs) were calculated by using a random effects model. The Mantel–Haenszel (M-H) method was used to pool dichotomous data and to compute pooled RRs with 95% CIs. Considering the expected heterogeneity across the studies, we decided a priori to use a random-effects model to evaluate outcomes, regardless of the finding of statistical heterogeneity.^{15,16} The heterogeneity among the studies was calculated using τ^2 .¹⁷ Sources of heterogeneity were explored by prespecified subgroup analyses on the airway technique selected (i.e. laryngoscopy or nonlaryngoscopy). The χ^2 test was used to assess for group differences with the cut-off *P* value of the test for group heterogeneity set at 0.05. We performed sensitivity analyses to explore the potential impact of a single trial on the overall results by omitting the trials from the meta-analysis one at a time. We examined the funnel plots when we identified 10 or more studies reporting on a particular outcome¹⁸ to investigate the potential of reporting and publication biases. The significance level was set at 0.05 for all analyses.

The conclusiveness and reliability of the cumulative evidence were scrutinised by trial sequential analysis (TSA) to reduce false-positive or false-negative results from multiple testing and sparse data.^{19,20} TSA was performed with the TSA viewer version 0.9.5.10 Beta (www.ctu.dk/tsa). For all outcomes, we computed the required information size (RIS) and the trial sequential monitoring boundaries. The variance was acquired from the data retrieved from the included studies. Crossing of the cumulative *Z* curve through the TSA boundary signifies a sufficient level of evidence for the anticipated intervention effect and no further studies are needed, while failure of the *Z* curve to cross the TSA boundaries or reach the RIS indicates insufficient evidence to reach a conclusion. We used two-sided tests with a type I error of 5%, a power of 80% and a relative risk reduction of 20% for dichotomous outcomes to calculate the RIS.²¹

Results

We identified 116 potential trials from our database search as well as 49 additional articles during cross-referencing and from the authors' own reference collections. After removal of 77 duplicates, 88 articles underwent title and abstract screening that gave 25 eligible trials for full-text screening. The reasons for exclusion after full-text screening are shown in Fig. 1. Finally, 13 RCTs were included in this analysis for data extraction.

Fig. 1 Meta-analysis flowchart for selecting eligible studies



PFT, Parker Flex-Tip tube; SP, standard polyvinylchloride tube.

Table 1 Characteristics of included studies

Author, year	IT	Device	ETT size (mm)	Patient population	Sample size	Risk of difficult airway	Experience of operators ^c	Main outcomes examined
Chang, 2019 ²⁶	OTI	Fibreoscope	7.0, 8.0	ASA-PS 1 to 3, obese patients ^a	59	Yes ^b	1	Intubation time
Earle, 2017 ²²	NTI	DL	6, 6.5, 7.0	ASA-PS 1 to 2, ≥ 16 years	60	Uncertain	1	Incidence of epistaxis
Kanazi <i>et al.</i> , 2008 ⁵	OTI	ILMA	7	ASA-PS 1 to 2, adult patients	43	Low	1	Success rate
Kristensen, 2003 ²⁷	OTI	Fibreoscope	7.5	ASA-PS 1 to 2, ≥ 18 years	76	Low	1	Ease of insertion
Lal, 2020 ²⁸	OTI	air-Q ILMA	NA	ASA-PS 1 to 2, 18–60 years	96	Low	1	Success rate
Makino, 2003 ³¹	OTI	TE	7.5	ASA-PS 1 to 2, adult patients	92	Uncertain	1	Ease of insertion
Moustafa, 2016 ²³	NTI	DL	NA	ASA-PS 1–2, 4 to 10 years	100	Low	1	Ease of insertion
Radesic, 2012 ⁹	OTI	GS	7, 8	ASA-PS 1 to 3, ≥ 18 years	58	Low	3	Ease of intubation
Sanuki, 2010 ²⁴	NTI	DL	7.0	ASA-PS 1 to 2, ≥ 16 years	102	Low	1	Incidence of nasal trauma
Sugiyama, 2014 ²⁴	NTI	DL	7, 7.5	ASA-PS 1 to 2 adult patients	100	Uncertain	1	Incidence of epistaxis
Suzuki <i>et al.</i> , 2008 ¹¹	OTI	BL	7.5	ASA-PS 1 to 2, adult patients	38	Uncertain	1	Ease of intubation
So, 2006 ²⁹	OTI	DL	7.5, 8.0	ASA-PS 1 to 2, 20 to 75 years	132	Low	2	Ease of intubation
Turkstra, 2011 ³⁰	OTI	DL or GS ^d	7, 7.5, 8, 8.5	ASA-PS 1 to 4	200	Low	2	Incidence of postoperative sore throat

ASA-PS, American Society of Anesthesiologists physical status; BL, Bullard laryngoscope; DL, direct laryngoscope; GS, GlideScope; ILMA, intubating laryngeal mask airway; IT, intubation technique; NTI, nasotracheal intubation; OTI, orotracheal intubation; TE, tube exchanger. ^aObese: BMI at least 30 kg m⁻². ^bThe presence of Mallampati score at least 3 or obesity. ^c1, only anaesthesiologists involved; 2, anaesthesiologists, inexperienced anaesthesiologist and anaesthesia trainees involved; 3, anaesthesiologists, anaesthesia assistant and nurse anaesthetists involved. ^dNinety-three to 95% of patients were intubated with direct laryngoscopy.

Thirteen RCTs, which included 1156 participants, were analysed. Study characteristics are described in Table 1. Four trials^{22–25} included 362 patients receiving nasotracheal intubation with direct laryngoscopy and nine trials^{5,9,11,26–31} enrolled 794 patients receiving oral tracheal intubation with various intubating devices. Twelve studies focused on adult patients, whereas one trial²³ examined the intubation outcomes in the paediatric population. All studies were performed in the anaesthesia setting with the use of a muscle relaxant. Airway manipulation was performed by anaesthesiologists in most studies. Seven studies^{5,9,23,24,27–29} included patients with a low risk of difficult airway, whereas five trials^{11,22,25,30,31} did not specify the presence of a difficult airway and one study²⁶ included patients with obesity.

Risks of bias

The risks of bias of individual studies and the overall risk of bias are summarised in Figs. 2 and 3, respectively. As all of the included studies were found to give sufficient details about randomisation and report a patient dropout rate of less than 15%, the risks of randomisation and attrition biases were considered to be low. However, as most studies were unable to adopt methods to keep both the intubators and the investigators unaware of the type of ETTs, the risks of performance and detection biases were regarded as uncertain or high. In addition, as information about reporting bias (e.g. protocol registers) or other biases (e.g. conflict of interest) were not available in most studies, the risks of these biases were considered to be uncertain or high. Details regarding the assessment of the risks of bias are available in Supplemental Table 2, <http://links.lww.com/EJA/A568>.

Successful first-attempt intubation rate

Six studies with a total of 568 patients (PFT group, $n=285$ vs. standard polyvinylchloride group, $n=283$)

were available for analysis.^{5,11,26,28–30} The criteria for successful first-attempt intubation rate (SFAIR) for both laryngoscopy and nonlaryngoscopy are shown in Supplementary Table 3, <http://links.lww.com/EJA/A568>. Pooled analysis showed no significant difference in SFAIR between the PFT and standard polyvinylchloride groups (RR 1.20, 95% CI 0.99 to 1.44, $P=0.06$; $\tau^2=0.03$, $P<0.001$) (median of RR 1.17, range 0.99 to 2; Fig. 4). Subgroup analysis revealed no significant difference (χ^2 test 3.31, $P=0.07$). Sensitivity analysis demonstrated that this outcome was not significantly impacted by omitting certain trials. TSA showed a failure of the cumulative Z curve to cross the required information size or the futility boundaries, indicating insufficient evidence to reach a firm conclusion (Supplemental Fig. 1, <http://links.lww.com/EJA/A562>).

Intubation time

Eight studies with a total of 759 patients (PFT group, $n=380$ vs. standard polyvinylchloride group, $n=379$) were available for the analysis.^{9,11,23,26–30} The definition of 'intubation time' varied among the included studies (Supplemental Table 4, <http://links.lww.com/EJA/A568>). A forest plot is presented in Fig. 5, which demonstrated a slightly but significantly shorter intubation time in the PFT group than that in the standard polyvinylchloride group [weighted mean difference (WMD) -4.7 s, 95% CI -7.4 to -1.1 , $P=0.009$; $\tau^2 16.95$, $P<0.00001$] (median of WMD -4.6 s, range -11.5 to 2.6) without considering the techniques of airway manipulation. Subgroup analysis based on the airway management techniques selected (laryngoscopy vs. nonlaryngoscopy) (Fig. 5) showed no subgroup difference (χ^2 test 1.29, $P=0.26$). Sensitivity analysis demonstrated no significant impact on outcome by omitting certain trials. Crossing of the cumulative Z -curve through the trial sequential monitoring boundary on TSA indicated

Fig. 2 Risks of bias of individual studies

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Chang 2019	+	+	+	+	+	+	+
Earle 2017	+	+	?	+	+	+	+
Kanazi2008	+	?	-	-	+	?	?
Kristensen 2003	+	+	+	+	+	?	-
Lal2020	+	?	?	?	+	+	+
Makino 2003	+	?	+	+	+	?	?
Moustafa 2016	+	?	-	-	+	?	+
Radesic 2012	+	+	-	+	+	?	-
Sanuki 2010	+	?	+	+	+	?	+
So 2006	+	+	-	-	+	?	?
Sugiyama 2014	+	+	?	+	+	+	+
Suzuki 2008	+	+	-	-	+	?	+
Turkstra 2011	+	+	+	+	+	?	+

sufficient evidence to reach a firm conclusion (Supplemental Fig. 2, <http://links.lww.com/EJA/A563>).

Risk of difficulty in airway manipulation

Of the eight studies with a total of 647 patients (PFT group, $n=326$ vs. standard polyvinylchloride group, $n=321$) that compared the risk of overall difficulty in airway manipulation between the two ETTs,^{5,11,23-25,27,28,31} only three assessed the risk of severe difficulty

in airway manipulation.^{23,27,31} The definition of 'difficulty' varied based on the intubating techniques among the included studies (Supplemental Table 5, <http://links.lww.com/EJA/A568>). Regarding the risk of overall and severe difficulty, the pooled RRs were 0.48 (95% CI 0.29 to 0.80, $P=0.005$; τ^2 0.4, $P<0.00001$) (median of RR 0.41, range 0.1 to 1) (Fig. 6) and 0.59 (95% CI 0.39 to 0.87, $P=0.009$; τ^2 0, $P=0.4$) (median of RR 0.61, range 0.23 to 0.75) (Fig. 7), respectively. The findings suggested that the use of PFT tubes was associated with a lower risk of difficult airway manipulation compared with that associated with the use of standard polyvinylchloride tubes. Subgroup analysis demonstrated no difference (χ^2 test 2.05, $P=0.15$) (Fig. 6). Sensitivity analysis showed no significant impact on this outcome by omitting certain trials. Regarding the risks of overall difficulty (Supplemental Fig. 3, <http://links.lww.com/EJA/A564>) and severe difficulty (Supplemental Fig. 4, <http://links.lww.com/EJA/A565>) in airway manipulation, TSA demonstrated that the cumulative Z curve crossed neither the trial sequential monitoring boundary nor the required information size, implicating insufficient and inconclusive evidence for these two outcomes.

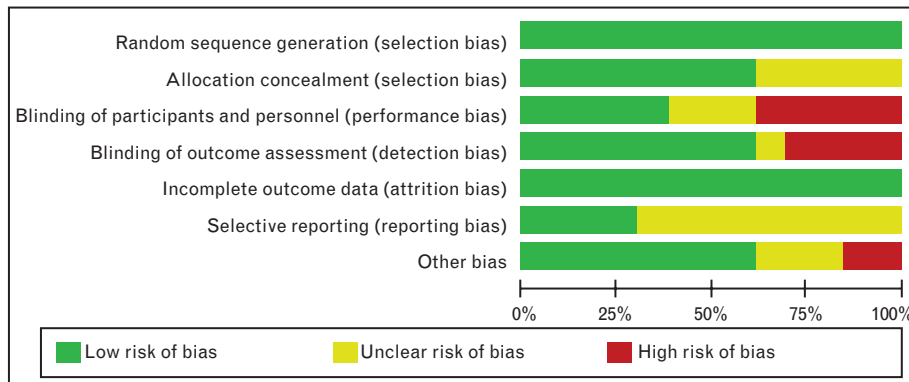
Risk of airway trauma

The pooled RR of the five studies with a total of 501 patients (PFT group, $n=256$ vs. standard polyvinylchloride group, $n=245$) that reported the risk of airway trauma^{22,23,26,28,30} was 0.83 (95% CI 0.67 to 1.03, $P=0.09$; τ^2 0, $P=0.83$) (median of RR 0.85, range 0.52 to 2.9) (Fig. 8), indicating no difference in risk of airway trauma between PFT and standard polyvinylchloride tubes. Subgroup analysis demonstrated no difference (χ^2 test 0.01, $P=0.93$). Sensitivity analysis showed that this outcome was not significantly influenced by omitting certain trials. TSA was not conducted because of insufficient information (data not shown).

Risk of hoarseness and sore throat

Analysis of the four studies with a total of 451 patients (PFT group, $n=231$ vs. standard polyvinylchloride group, $n=220$) that mentioned the incidences of hoarseness and sore throat^{11,28-30} demonstrated a pooled RR of 0.71 (95% CI 0.44 to 1.14, $P=0.15$; τ^2 0, $P=0.45$) (median of RR 0.77, range 0.5 to 1) for hoarseness (Fig. 9) and 0.90 (95% CI 0.70 to 1.17, $P=0.44$; τ^2 0, $P=0.8$) (median of RR 0.83, range 0.59 to 0.99) for sore throat (Fig. 10). The findings suggested no difference in the risk of hoarseness and sore throat between PFT and standard polyvinylchloride tubes. Sensitivity analysis showed no significant effect on this outcome by omitting certain trials. Regarding the risk of hoarseness, TSA was not performed because of insufficient information (data not shown). For the risk of sore throat, failure of the cumulative Z-curve to cross the futility boundary suggested insufficient and inconclusive evidence for this outcome (Supplemental Fig. 5, <http://links.lww.com/EJA/A566>).

Fig. 3 Overall risks of bias of the 13 included studies

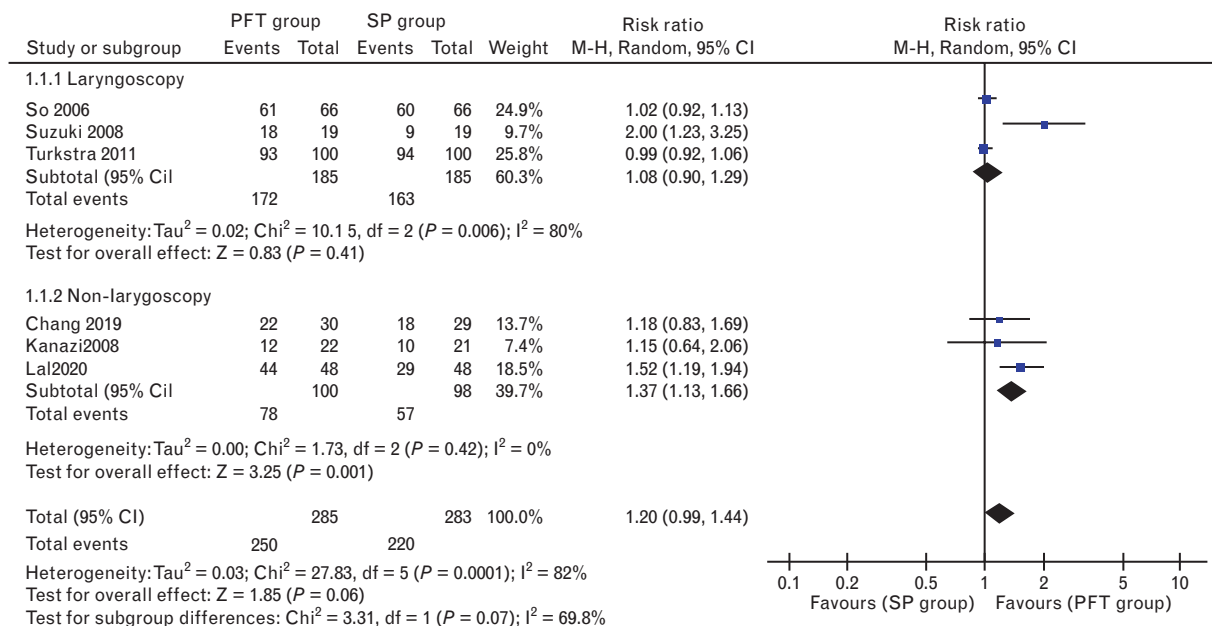


Risk of epistaxis

Three studies with a total of 262 patients (PFT group, $n=131$ vs. standard polyvinylchloride group, $n=131$) reported the risk of overall epistaxis or severe epistaxis.^{22,24,25} All studies classified the severity of epistaxis by assessing the presence of blood on the ETTs or posterior pharyngeal wall with direct laryngoscopy (Supplemental Table 6, <http://links.lww.com/EJA/A568>). The definition of ‘severity’ (Supplemental Table 6, <http://links.lww.com/EJA/A568>), the size of ETTs used (Table 1) and strategies for epistaxis prevention (Supplemental Table 7, <http://links.lww.com/EJA/A568>) varied among the included studies. Regarding the risk of overall or severe epistaxis, the pooled RRs were 0.58 (95% CI 0.26 to 1.31, $P=0.19$; τ^2 0.42,

$P=0.001$) (median of RR 0.48, range 0.33 to 1.05) (Fig. 11) and 0.15 (95% CI 0.03 to 0.84, $P=0.03$; τ^2 0, $P=0.56$) (median of RR 0.22, range 0.11 to 0.33) (Fig. 12), respectively. These findings indicated that although the use of PFT tubes did not decrease the risk of overall epistaxis, the risk of severe epistaxis was reduced significantly compared with that related to the use of standard polyvinylchloride tubes. For the risk of overall epistaxis, failure of the cumulative Z-curve to cross either the trial sequential monitoring or the futility boundary on TSA indicated insufficient and inconclusive evidence for this outcome (Supplemental Fig. 6, <http://links.lww.com/EJA/A567>). There was insufficient information to assess the risk of severe epistaxis with TSA (data not shown).

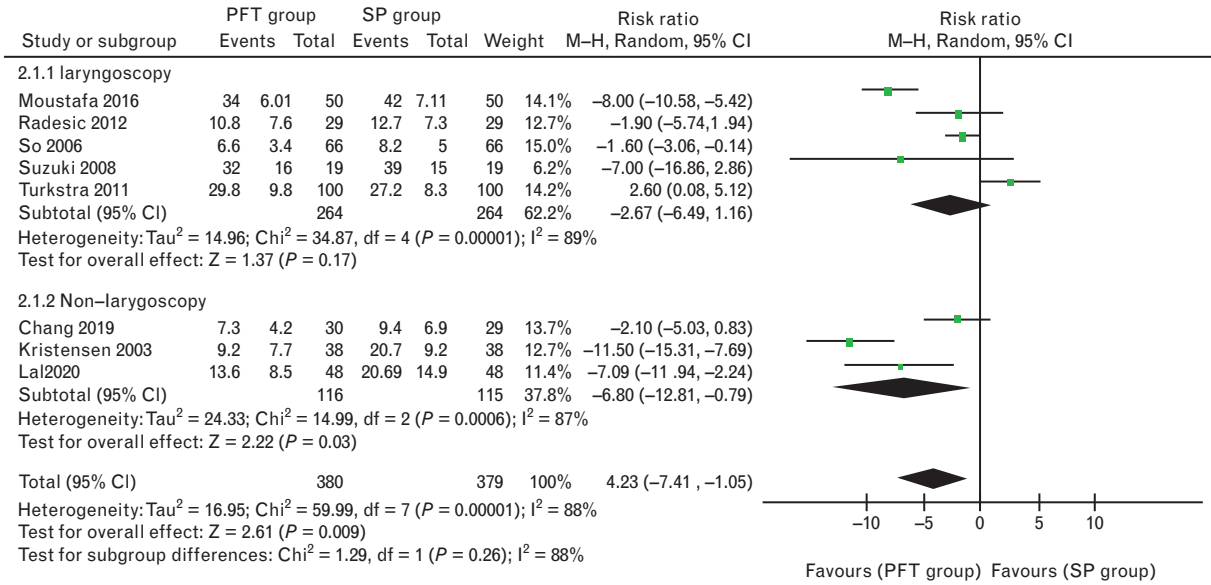
Fig. 4 Forest plot comparing successful first-attempt intubation rate between Parker Flex-Tip and standard polyvinylchloride groups



CI, confidence interval; M-H, Mantel–Haenszel; RR, risk ratio.

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Fig. 5 Forest plot comparing time to successful intubation between Parker Flex-Tip and standard polyvinylchloride groups



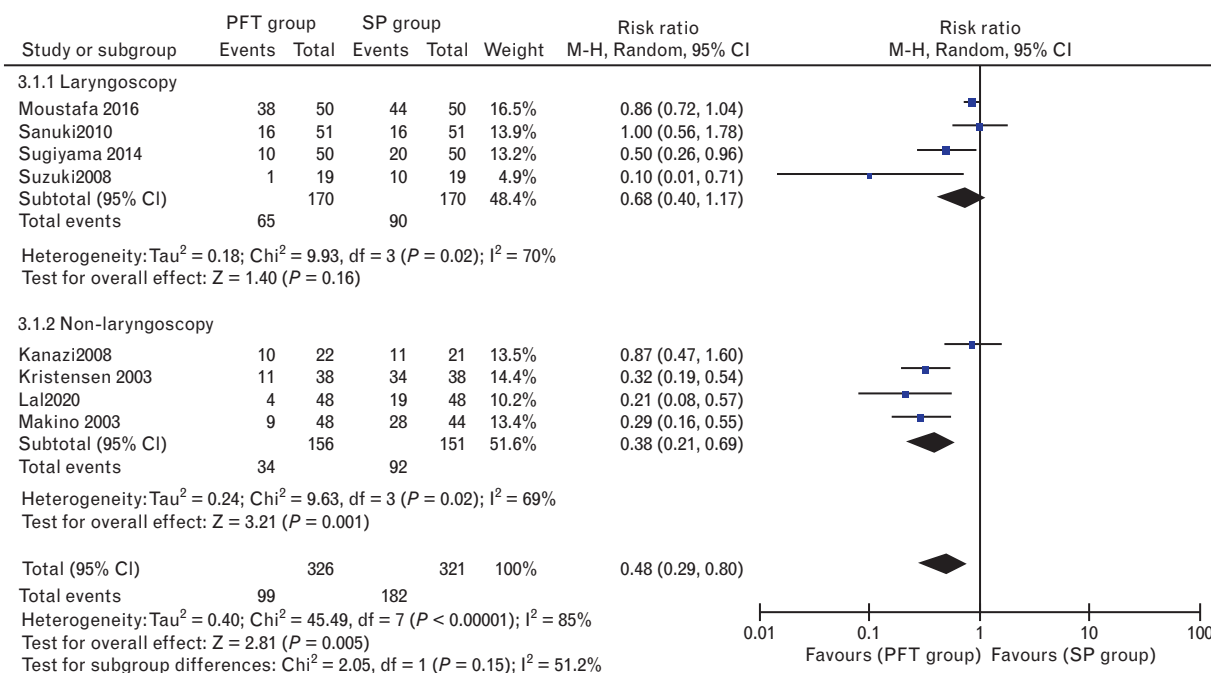
CI, confidence interval; IV, inverse variance; WMD, weighted mean difference.

Discussion

Choosing the suitable instrument under different circumstances to ensure rapid uncomplicated transglottic advancement of ETTs remains the key to successful tracheal intubation, which is a potentially life-saving

procedure. In spite of the emphasis of current guidelines on the use of videolaryngoscopes and supraglottic airway devices for difficult airway management, the impact of tube selection remains poorly addressed. After analysing the benefits of PFT tubes for airway management

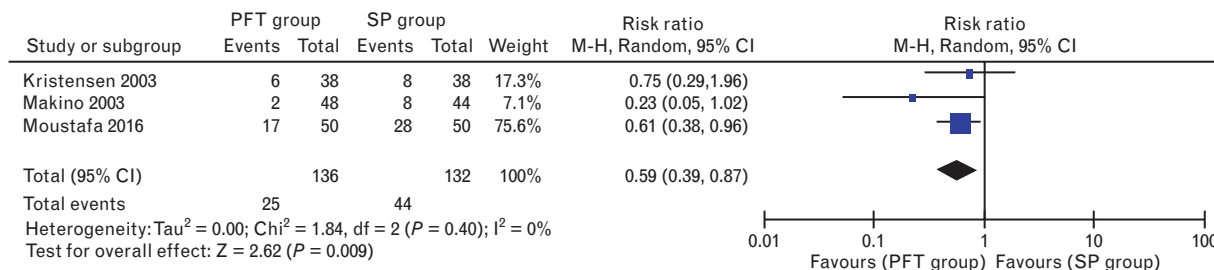
Fig. 6 Forest plot comparing the risk of overall difficulty in airway manipulation between Parker Flex-Tip and standard polyvinylchloride groups



CI, confidence interval; M-H, Mantel-Haenszel; RR, risk ratio.

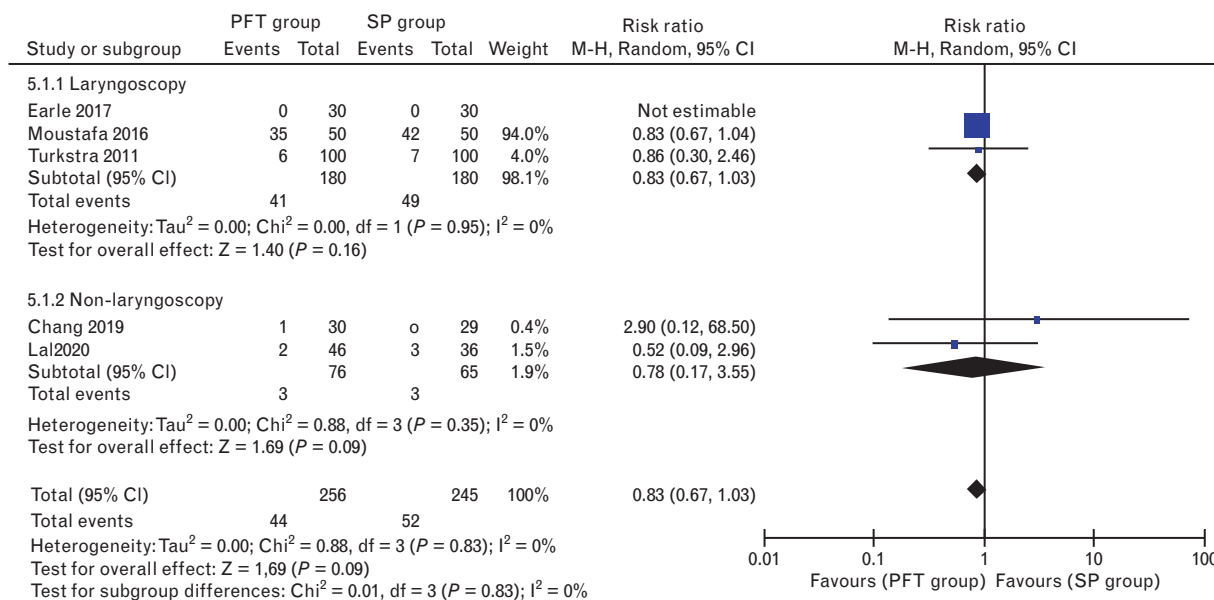
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Fig. 7 Forest plot comparing the risk of severe difficulty in airway manipulation between Parker Flex-Tip and standard polyvinylchloride groups



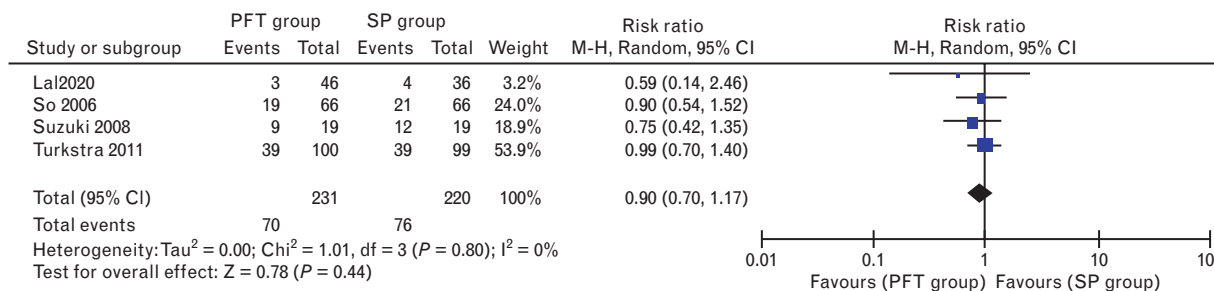
CI, confidence interval; M-H, Mantel–Haenszel; RR, risk ratio.

Fig. 8 Forest plot comparing the risk of trauma between Parker Flex-Tip and standard polyvinylchloride groups



CI, confidence interval; M-H, Mantel–Haenszel; RR, risk ratio.

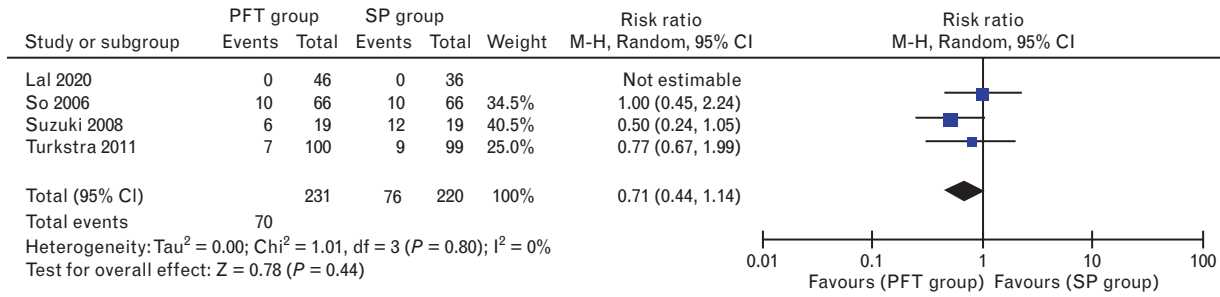
Fig. 9 Forest plot comparing the risk of sore throat between Parker Flex-Tip and standard polyvinylchloride groups



CI, confidence interval; M-H, Mantel–Haenszel; RR, risk ratio.

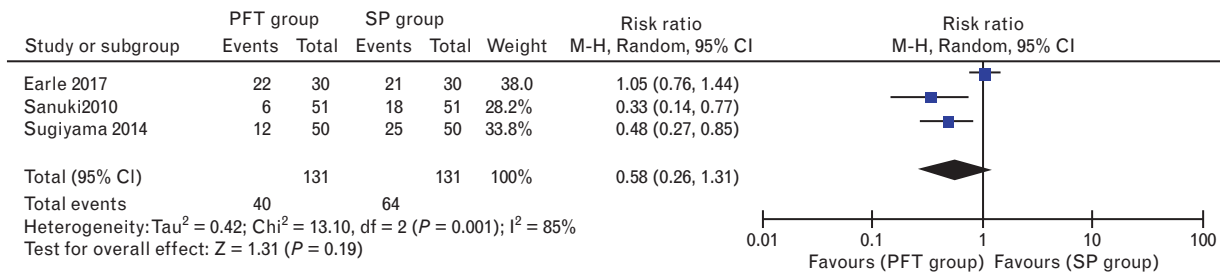
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Fig. 10 Forest plot comparing the risk of hoarseness between Parker Flex-Tip and standard polyvinylchloride groups



CI, confidence interval; M-H, Mantel–Haenszel; RR, risk ratio.

Fig. 11 Forest plot comparing the overall risk of epistaxis between Parker Flex-Tip and standard polyvinylchloride groups



CI, confidence interval; M-H, Mantel–Haenszel; RR, risk ratio.

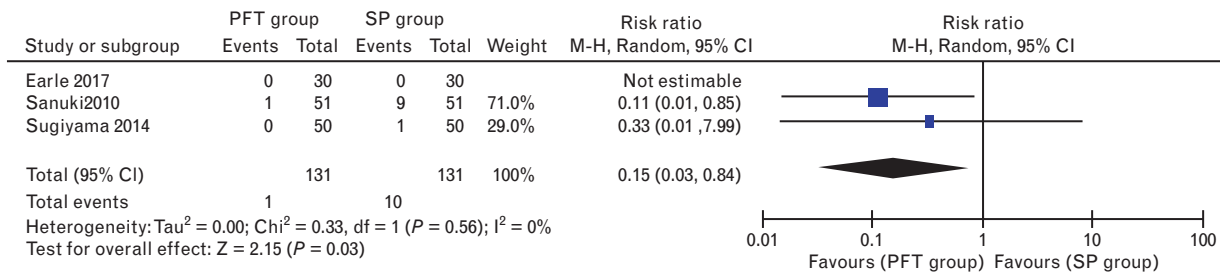
from all the available RCTs, our results demonstrated that the use of PFT tubes affected neither the SFAIR nor the risk of airway complications (airway trauma, hoarseness, sore throat, overall risk of epistaxis) in the hands of anaesthesia providers. However, the use of PFT tubes was associated with a shortened intubation time (−4.2 s) as well as decreased risks of difficult airway manipulation and severe epistaxis compared with those related to the use of conventional standard polyvinylchloride tubes.

The occurrence of laryngeal impingement could delay successful tracheal intubation as well as increase the risks

of intubation failure and apnoea. The sites of laryngeal impingement include arytenoids, epiglottis, interarytenoid tissue and left pyriform fossa.³² With a bevel facing posteriorly at 37° and a flexible and tapered tip, the PFT tube was designed to facilitate transglottic insertion of ETTs and minimise the risk of airway injury during intubation.⁹

The absence of a significant difference in SFAIR between PFT and standard polyvinylchloride tubes in the current meta-analysis may be attributed to some factors related to the clinical setting, patients and intubators. First, compared with the manipulation of the relatively uncommon

Fig. 12 Forest plot comparing the risk of severe epistaxis between Parker Flex-Tip and standard polyvinylchloride groups



CI, confidence interval; M-H, Mantel–Haenszel; RR, risk ratio.

PFT tubes, the operators in the included studies may be more familiar with the use of conventional standard polyvinylchloride tubes, which are routine equipment in the operating room. Second, although PFT tubes have been reported to facilitate tracheal intubation in situations of failed intubation with standard ETTs,^{33,34} most of the included studies did not recruit patients with difficult airways. Third, despite the reported superiority of PFT tubes in the hands of inexperienced operators²⁹ or under suboptimal intubation conditions,⁹ such benefits may be masked by the fact that most intubations in the studies included in the current meta-analysis were performed by anaesthesiologists and all patients were given muscle relaxants, which have been reported to facilitate tube passage through the glottis during tracheal intubation.³⁵ Analysis between laryngoscopy and nonlaryngoscopy subgroups also demonstrated no significant difference. Large-scale studies are needed to support our findings in the nonanaesthesia setting.

The findings of a slight but significant decrease in intubation time (4.2 s) as well as a reduced risk of difficult airway manipulation associated with the use of PFT tubes compared with those associated with the use of standard polyvinylchloride tubes in the present study have several clinical implications. First, the use of PFT tubes may be beneficial for patients with a decreased functional residual capacity (e.g. obese patients) or respiratory distress for whom rapid re-establishment of airway patency may be critical for the prevention of profound hypoxaemia and subsequent complications. Second, taking into account the high morbidities and mortalities associated with multiple tracheal intubations in patients with difficult airways,^{12,13} the relatively low risk of difficulty in airway manipulation when PFT tubes were used may favour their use when the skills of intubators or the intubation conditions are suboptimal.

Postoperative sore throat and hoarseness are common adverse events from airway manipulation. The prevalences of postoperative sore throat and hoarseness are reportedly up to 62 and 49% in patients following tracheal intubation, respectively.^{36,37} Albeit not life-threatening, these complications may persist for several postoperative days and negatively impact a patient's satisfaction with anaesthesia. The proposed mechanisms underlying these laryngeal complications include ETT cuff-associated mucosal erosion, mechanical trauma from intubation and prolonged intubation.^{37–39} Despite the design of PFT tubes for reducing trauma during transglottic ETT placement,³⁰ we did not find significant differences in the risks of airway trauma (Fig. 8) or postoperative sore throat and hoarseness (Figs. 9 and 10) between PFT and standard polyvinylchloride tubes. Plausible explanations may be the multifactorial causes of laryngeal complications and minimisation of the risk of intubation-related trauma in the hands of anaesthesia providers in a well controlled anaesthesia setting.³⁰

Epistaxis is a common complication from nasotracheal intubation with an incidence up to 80% among patients receiving tracheal intubation with standard polyvinylchloride tubes.⁴⁰ Although this complication rarely leads to severe sequelae, excessive nasal bleeding (e.g. a large amount of blood in the pharynx) can impede the laryngoscopic view for intubation⁴¹ and carry the risk of aspiration of blood.⁴² Accordingly, in difficult airway scenarios, avoidance of nasal bleeding is warranted when the nasal route is chosen for tracheal intubation. Although thermosoftening of ETTs⁴³ and the use of topical vasoconstrictors⁴⁴ are effective measures to decrease the risk of epistaxis, the facts that both strategies are time-consuming and are not used without risk⁴⁵ render them impractical in emergency airway management. Our findings of lower risks of both severe epistaxis regardless of the tracheal intubation approach and difficult airway manipulation associated with PFT tube use may further support its application in difficult airway management.

Although systematic reviews and meta-analyses have long been regarded as the gold standard of evidence-based medicine, meta-analyses on trials with small sample sizes often result in false-positive (type 1 error) or false-negative (type 2 error) findings.⁴⁶ TSA is an important statistical tool to verify the results of a meta-analysis and identify the need for any further clinical trials.⁴⁶ On the basis of TSA, our meta-analysis revealed conclusively that airway manipulation with PFT tubes was faster than that with standard polyvinylchloride tubes. However, as current evidence of other intubation outcomes (SFAIR or risk of difficulty in airway manipulation) was still insufficient, future trials and meta-analysis are warranted to compare these outcomes associated with PFT and standard polyvinylchloride tubes.

Several limitations of our study should be addressed. First, as the current study included only trials conducted in an operating room setting, the findings may not be extrapolated to other clinical scenarios. Second, the impact of operator experience on the outcomes needs to be further clarified as most intubations of the included studies were performed by anaesthesiologists. Third, although the intubation success rate for standard polyvinylchloride tubes was reported to improve if the tube was rotated counterclockwise by 90°,²⁷ our studies only compared the intubation outcomes between PFT and standard polyvinylchloride tubes as the latter was passed through the glottis in a neutral position. Fourth, as the diameter of ETTs may impact the successful rate of fiberoptic intubation,⁶ the use of various sizes of ETT in the included studies may bias our results. Fifth, the lack of a significant difference between PFT and standard polyvinylchloride tubes in SFAIR may be attributed partly to the small proportion of studies (only 6 out of the 13) providing the information. Sixth, despite the possible impact of anatomical anomalies on intubation time and complications (e.g. hoarseness), the four studies^{11,23–25}

that mentioned the use of laryngoscopy did not report the level of anatomy-related difficulty (e.g. Cormack–Lehane grade) in assessing the degree of laryngeal view. Finally, the lack of standardised definitions for some of the measured outcomes (e.g. intubation time) may also influence our results.

Conclusion

Through systematically reviewing the current evidence, this meta-analysis demonstrated a shorter intubation time associated with the use of PFT tubes compared with that related to standard polyvinylchloride tubes. Our findings may help in optimising the choice of endotracheal tubes to improve intubation outcomes and minimise the associated complications. On the basis of the results of trial sequence analysis, further trials and meta-analyses are warranted to compare other intubation outcomes (e.g. successful first-attempt intubation rate) associated with the two devices.

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References

- Joffe AM, Aziz MF, Posner KL, et al. Management of difficult tracheal intubation: a closed claims analysis. *Anesthesiology* 2019; **131**:818–829.
- Lewis SR, Butler AR, Parker J, et al. Videolaryngoscopy versus direct laryngoscopy for adult patients requiring tracheal intubation. *Cochrane Database Syst Rev* 2016; **11**:CD011136.
- Jackson AH, Wong P, Orr B. Randomized, controlled trial of the double setup tracheal tube during fiberoptic orotracheal intubation under general anaesthesia. *Br J Anaesth* 2004; **92**:536–540.
- Marfin AG, Iqbal R, Mihm F, et al. Determination of the site of tracheal tube impingement during nasotracheal fiberoptic intubation. *Anaesthesia* 2006; **61**:646–650.
- Kanazi GE, El-Khatib M, Nasr VG, et al. A comparison of a silicone wire-reinforced tube with the Parker and polyvinyl chloride tubes for tracheal intubation through an intubating laryngeal mask airway in patients with normal airways undergoing general anaesthesia. *Anesth Analg* 2008; **107**:994–997.
- Asai T, Shingu K. Difficulty in advancing a tracheal tube over a fiberoptic bronchoscope: incidence, causes and solutions. *Br J Anaesth* 2004; **92**:870–881.
- Natt BS, Malo J, Hypes CD, et al. Strategies to improve first attempt success at intubation in critically ill patients. *Br J Anaesth* 2016; **117** Suppl 1: i60–i68.
- Mort TC. Emergency tracheal intubation: complications associated with repeated laryngoscopic attempts. *Anesth Analg* 2004; **99**:607–613.
- Radesic BP, Winkelman C, Einsporn R, et al. Ease of intubation with the Parker Flex-Tip or a standard Mallinckrodt endotracheal tube using a video laryngoscope (GlideScope). *AANA J* 2012; **80**:363–372.
- Lewis SR, Butler AR, Parker J, et al. Videolaryngoscopy versus direct laryngoscopy for adult patients requiring tracheal intubation: a Cochrane Systematic Review. *Br J Anaesth* 2017; **119**:369–383.
- Suzuki A, Tampo A, Abe N, et al. The Parker Flex-Tip™ tracheal tube makes endotracheal intubation with the Bullard laryngoscope easier and faster. *Eur J Anaesthesiol* 2008; **25**:43–47.
- Higgs A, McGrath BA, Goddard C, et al. Difficult Airway Society, Intensive Care Society, Faculty of Intensive Care Medicine, Royal College of Anaesthetists. Guidelines for the management of tracheal intubation in critically ill adults. *Br J Anaesth* 2018; **120**:323–352.
- Frerck C, Mitchell VS, McNarry AF, et al. Difficult Airway Society intubation guidelines working group. Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. *Br J Anaesth* 2015; **115**:827–848.
- Higgins JP, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011; **343**:d5928.
- DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials* 1986; **7**:177–188.
- Borenstein M, Hedges LV, Higgins JP, et al. A basic introduction to fixed-effect and random-effects models for meta-analysis. *Res Synth Methods* 2010; **1**:97–111.
- Higgins JP. Commentary: heterogeneity in meta-analysis should be expected and appropriately quantified. *Int J Epidemiol* 2008; **37**:1158–1160.
- Abdelgadir IS, Phillips RS, Singh D, et al. Videolaryngoscopy versus direct laryngoscopy for tracheal intubation in children (excluding neonates). *Cochrane Database Syst Rev* 2017; **5**:CD011413.
- Brok J, Thorlund K, Gluud C, et al. Trial sequential analysis reveals insufficient information size and potentially false positive results in many meta-analyses. *J Clin Epidemiol* 2008; **61**:763–769.
- Brok J, Thorlund K, Wetterslev J, et al. Apparently conclusive meta-analyses may be inconclusive – trial sequential analysis adjustment of random error risk due to repetitive testing of accumulating data in apparently conclusive neonatal meta-analyses. *Int J Epidemiol* 2009; **38**:287–298.
- Jiao X-F, Lin X-M, Ni X-F, et al. Volatile anesthetics versus total intravenous anesthesia in patients undergoing coronary artery bypass grafting: an updated meta-analysis and trial sequential analysis of randomized controlled trials. *PLoS One* 2019; **14**:e0224562.
- Earle R, Shanahan E, Vaghadia H, et al. Epistaxis during nasotracheal intubation: a randomized trial of the Parker Flex-Tip™ nasal endotracheal tube with a posterior facing bevel versus a standard nasal RAE endotracheal tube. *Can J Anaesth* 2017; **64**:370–375.
- Moustafa MA, Ossman YM. Nasotracheal intubation with Parker Flex-Tip versus preformed nasal endotracheal tubes for children undergoing adenotonsillectomy. *Middle East J Anaesthesiol* 2016; **23**:625–629.
- Sanuki T, Hirokane M, Matsuda Y, et al. The Parker Flex-Tip™ tube for nasotracheal intubation: the influence on nasal mucosal trauma. *Anaesthesia* 2010; **65**:8–11.
- Sugiyama K, Manabe Y, Kohjitani A. A styletted tracheal tube with a posterior-facing bevel reduces epistaxis during nasal intubation: a randomized trial. *Can J Anaesth* 2014; **61**:417–422.
- Chang LC, Lee SC, Ding AL, et al. Fiberoptic orotracheal intubation of obese patients using Parker Flex-Tip vs. standard endotracheal tube. *Turk J Anaesthesiol Reanim* 2019; **47**:387–391.
- Kristensen MS. The Parker Flex-Tip tube versus a standard tube for fiberoptic orotracheal intubation: a randomized double-blind study. *Anesthesiology* 2003; **98**:354–358.
- Lal J, Bansal T, Dhawan G, et al. Comparison of conventional with Parker flex-tip tracheal tube for intubation through air-Q intubating laryngeal airway. *J Anaesthesiol Clin Pharmacol* 2020; **36**:43–48.
- So M, Sobue K, Arima H, et al. Flexible, tapered-tip tube facilitates conventional orotracheal intubation by novice intubators. *J Anesth* 2006; **20**:344–347.
- Turkstra TP, Smitheram AK, Alabdulhadi O, et al. The Flex-Tip™ tracheal tube does not reduce the incidence of postoperative sore throat: a randomized controlled trial. *Can J Anaesth* 2011; **58**:1090–1096.
- Makino H, Katoh T, Kobayashi S, et al. The effects of tracheal tube tip design and tube thickness on laryngeal pass ability during oral tube exchange with an introducer. *Anesth Analg* 2003; **97**:285–288.
- Jackson AH, Orr B, Yeo C, et al. Multiple sites of impingement of a tracheal tube as it is advanced over a fiberoptic bronchoscope or tracheal tube introducer in anaesthetized, paralysed patients. *Anaesth Intensive Care* 2006; **34**:444–449.
- Ohmura T, Suzuki A, Kurosawa A, et al. Parker Flex-Tip Tube® facilitates intubation when the Pentax-AWS® fails to reach the larynx. *J Anesth* 2010; **24**:974–975.
- Higuera J, Onrubia X, Sánchez de Merás A, et al. Parker Flex-Tip tube for fiberoptic nasotracheal intubation in a case of lingual tonsil hypertrophy. *Can J Anaesth* 2005; **52**:778–779.
- Hattori K, Komazawa N, Kido H, et al. Muscle relaxant effect on tracheal intubation with Pentax-AWS Airwayscope: a prospective randomized controlled trial. *Am J Emerg Med* 2016; **34**:674–675.
- El-Boghdady K, Bailey CR, Wiles MD. Postoperative sore throat: a systematic review. *Anaesthesia* 2016; **71**:706–717.
- Yamanaka H, Hayashi Y, Watanabe Y, et al. Prolonged hoarseness and arytenoid cartilage dislocation after tracheal intubation. *Br J Anaesth* 2009; **103**:452–455.
- Chandler M. Tracheal intubation and sore throat: a mechanical explanation. *Anaesthesia* 2002; **57**:155–161.

- 39 Combes X, Schauliege F, Peyrouset O, *et al.* Intracuff pressure and tracheal morbidity: influence of filling with saline during nitrous oxide anesthesia. *Anesthesiology* 2001; **95**:1120–1124.
- 40 Kihara S, Komatsuzaki T, Brimacombe JR, *et al.* A silicone-based wire-reinforced tracheal tube with a hemispherical bevel reduces nasal morbidity for nasotracheal intubation. *Anesth Analg* 2003; **97**:1488–1491.
- 41 Kim HJ, Kim JT, Kim HS, *et al.* A comparison of GlideScope® videolaryngoscopy and direct laryngoscopy for nasotracheal intubation in children. *Paediatr Anaesth* 2011; **21**:417–421.
- 42 Ryu T, Kim DH, Byun SH. Fiberoptic bronchoscopic treatment of blood aspiration and use of sugammadex in a patient with epistaxis: a case report. *Medicine* 2018; **97**:e0428.
- 43 Kim YC, Lee SH, Noh GJ, *et al.* Thermosoftening treatment of the nasotracheal tube before intubation can reduce epistaxis and nasal damage. *Anesth Analg* 2000; **91**:698–701.
- 44 Katz RI, Hovagim AR, Finkelstein HS, *et al.* A comparison of cocaine, lidocaine with epinephrine, and oxymetazoline for prevention of epistaxis on nasotracheal intubation. *J Clin Anesth* 1990; **2**:16–20.
- 45 Hoshi T, Suzuki T, Somei M, *et al.* Sudden tachycardia due to submucosal migration of an epinephrine-soaked swab during nasal intubation. *Anesth Prog* 2018; **65**:259–260.
- 46 Shah A, Smith AF. Trial sequential analysis: adding a new dimension to meta-analysis. *Anaesthesia* 2020; **75**:15–20.