

Sore throat following routine tracheal intubation with a single-use plastic laryngoscope blade versus a reusable metal laryngoscope blade: A multicenter, prospective, randomized, single-blind controlled study

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Abstract

Background

Reusable metal blade induces throat pain after tracheal intubation in 30% of patients. After the implementation of the Heine[®] single-use plastic blade in our theater, throat pain increased in a magnitude of 10%. However, throat pain induced by plastic blades has not been investigated. We aimed to evaluate the frequency of throat pain induced by this plastic blade in comparison to the Heine[®] reusable metal blade after tracheal intubation.

Methods

This trial was multicenter, prospective, randomized, and single-blind controlled.

We included 693 adult patients scheduled for surgery with tracheal intubation. They did not have any predictive criteria for difficult tracheal intubation. A 60-second step-limit tracheal intubation algorithm was used when performing tracheal intubation using a plastic or reusable blade. The primary endpoint was the frequency of throat pain, without swallowing, 24 hours after tracheal intubation. The first secondary endpoint was the incidence of unexpectedly difficult tracheal intubation (Intubation Difficulty Score ³ 1).

Results

At 24 hours, the throat pain incidence was not significantly higher in the plastic group: 81 (23.1%) vs. 61 (17.8%); difference, 5.3%; 95% Confidence Interval, [– 0.8 - 11.2]; $P = 0.087$; The unexpectedly difficult tracheal intubation incidence was significantly higher in the plastic group: 194 (55.3%) vs. 146 (42.7%); difference, 12.6%; 95% Confidence Interval, [12.3 - 12.8]; $P = 0.0009$.

Conclusions

The plastic blade used in this study exhibited subpar performance in tracheal intubation compared to the reusable metal blade. The protective tracheal intubation algorithm used may explain the low incidence of throat pain in the two groups and the absence of a significant difference. Further studies with other plastic blades are necessary to confirm that their implementation in the operating rooms, especially in the context of video-assisted laryngoscopes and ecological plastic recycling, is not solely dependent on their performance.

Introduction

Pharyngolaryngeal morbidity related to tracheal intubation includes anatomical injuries, dysfunctions, and pharyngolaryngeal symptoms following tracheal intubation (throat pain, dysphagia, dysphonia-hoarseness, and jaw pain).[1] Joffe et al. highlighted the link between difficult tracheal intubation and pharyngolaryngeal injuries.[2] Throat pain and other pharyngolaryngeal symptoms after tracheal

intubation using a reusable metal blade have been widely studied. The overall incidence of sore throat is approximately 30%.[3–7] In our setting, the Heine® single-use plastic blade (Heine XP®, HEINE Optotechnik GmbH & Co. KG, Herrsching, Germany) replaced the reusable metal blade (HEINE Classic+® F.O. Macintosh, HEINE Optotechnik GmbH & Co. KG, Gilching, Germany) to conserve sterilization resources, reduce costs, and avoid cross-infections. A retrospective analysis of the patient satisfaction database showed a 10% increase in throat pain in patients whose trachea was intubated with a plastic blade.

To date, no study has investigated throat pain induced by laryngoscope plastic blades. Therefore, we aimed to evaluate, as the main endpoint, the frequency of sore throat without swallowing 24 hours after tracheal intubation using a plastic blade in patients without any predictive criteria for difficult tracheal intubation, scheduled for surgery under general anesthesia with tracheal intubation. We ensured that the study controlled for the maximum number of identified risk factors for postoperative throat pain including difficult tracheal intubation.[6–7] Additionally, we used a 60-second step-limit tracheal intubation algorithm in accordance with the recommendations of Nolan and Wilson and Latta et al.[8–9] We already used a limit of 120 seconds to switch techniques in a previous study.[10]

Patients and Methods

This was a multicenter, prospective, randomized, single-blind controlled trial. This study was approved by the Ethics Authority Ile-de-France IV of the University Hospital Center of Saint Louis (Paris, France), University's Institutional Review Board 00003888, on 24/09/2009. This study was registered in the Protocol Registration and Results System (ClinicalTrials.gov) under NCT01118533, 06/05/2010. We used the CONSORT reporting guidelines. [11]

The inclusion criteria encompassed adult patients aged 18–70 years with an American Society of Anesthesiology score of I–II, Mallampati score of 1–3, without predictive criteria for difficult tracheal intubation, and scheduled for surgery under general anesthesia with tracheal intubation.

The exclusion criteria included emergency surgery; previous difficult tracheal intubation; limited mouth opening < 35 mm; thyromental distance < 60 mm; a Mallampati score of 4; prominent or fragile teeth; retrognathism; limited cervical mobility; history of radiotherapy or surgery for ear, nose and throat cancer; the presence of pharyngolaryngeal symptoms prior to the surgery; planned postoperative gastric tube; bariatric surgery and withdrawal of gastric banding; pregnancy; language barrier; scheduled thyroid or ear-nose-throat surgery; high-risk criteria for difficult face-mask ventilation (limited jaw mobility, facial dysmorphism, short neck defined as the distance below 6 cm between the clavicle and jaw angle, and thick neck if it extended up to the external mandibular sagittal plane). However, we considered the presence of a beard, lack of teeth, sleep apnea, and age ≥ 55 years as minor risk factors for difficult face-mask ventilation based on our experience. Consequently, these factors were not used as exclusion criteria.

During the anesthesia visit, the anesthesiologists provided clear information to the patients regarding both the purpose and protocol of the study. After several days of reflection, the patients provided written informed consent for the study. Patients were taught to evaluate their throat pain intensity without swallowing using a visual analogue scale. Randomization was performed the day before surgery at the time of patient admission and more often in the operating theater using Clean Web software (Telemedicine Technologies S.A.S., Boulogne-Billancourt, France) just before anesthesia induction. Consequently, informed and non-opposed patients were allocated both a randomization number and the type of blade, plastic or metal (Fig. 1). Patients were unaware of the type of blade used. An independent research assistant at each center, aware of the type of blade used, collected the data in the operating room and 24 hours after tracheal intubation using a visual analogue scale. Outcome data and values were obtained from the Clinical Research Unit of the Hospital Center of Meaux, Meaux, France, and a duplicate database located at the Clinical Research Unit of the Hospital Fernand Widal, Assistance Publique-Hôpitaux de Paris, Paris, France.

1. Anesthesia protocol

Standard monitoring was performed. The depth of neuromuscular blockade required to perform tracheal intubation under optimal conditions was evaluated using a train of four electric stimulations (30 mA) on the ulnar nerve to monitor the contractions of the adductor pollicis. Hypnosis depth was monitored using the bispectral index or entropy, which was expected to be between 30 and 50. The tracheal tube cuff pressure was maintained at 20 cmH₂O. Squared cycles of capnography confirmed that the tube was in the trachea. No nitric oxide was used.

Before anesthesia induction, patients inhaled 100% oxygen until the expired oxygen concentration reached 90%. Anesthesia was intravenously administered using propofol, sufentanil, and atracurium. Cisatracurium or vecuronium as middle-acting neuromuscular blocking drugs or succinylcholine as a short-acting neuromuscular blocking drug were authorized.[12] Neuromuscular blocking drugs were administered if the face-mask ventilation test was positive for chest expansion and cycles of capnography. When the response to the train of four stimulations was zero, laryngoscopy was performed using a plastic or metal blade by an experienced nurse anesthetist or anesthesiologist according to a 60-second step-limit tracheal intubation algorithm (Fig. 2). The tracheal tube sizes were 7.0 mm for women and 7.5 mm for men. No lidocaine gel or spray was applied to the tracheal tube. Patients were randomized and assigned in two groups, each using a specific type of blade: a single-use plastic blade (Heine XP®, HEINE Optotechnik GmbH & Co. KG, Herrsching, Germany) or metal reusable blade (HEINE Classic+® F.O. Macintosh, HEINE Optotechnik GmbH & Co. KG, Gilching, Germany) (Fig. 1). Blade sizes were 3 or 4. The two blades shared the same shape and manufacturer with any potential difference in performance attributed solely to the blade material. For greater accuracy, the laryngeal view was described according to the glottis-arytenoids-epiglottis-tongue (GAET) score, a combination of two validated scores: the Cormack – Lehane score and the percentage of glottic opening (POGO) score.[13–

14] A GAET score diagram was shown to the operator after tracheal intubation to provide the right Cormack – Lehane score. Subsequently, the Intubation Difficulty Score (IDS) was calculated (Fig. 3).

Following tracheal intubation, anesthesia was maintained using inhaled halogenated gas that was moistened. Multimodal postoperative analgesia, including regional analgesia, was provided in the operating room based on the anticipated postoperative pain level. At the end of surgery, the tracheal tube was withdrawn according to the standard procedure recommended by the French Anesthesiology Society. Suctioning of all residual mouth secretions was careful to avoid pharyngolaryngeal injuries. In the post-anesthesia care unit, analgesia was maintained based on specific protocols tailored to each type of surgery (gynecological, urological, abdominal, orthopedic, plastic or peripheral vascular surgeries). Morphine was administered when the pain intensity on the visual analogue scale was $\geq 40/100$. Intraoperatively, postoperative nausea and vomiting were prevented by administering ondansetron. A choice based on the Apfel score, thereby avoiding the use of dexamethasone.

2. Airway management

Under efficient face-mask ventilation, tracheal intubation was performed according to a 60-second step-limit tracheal intubation algorithm, based on the following four points: 1) 100% efficiency under visual control, 2) shortest possible duration, 3) no oxygen desaturation, and 4) no oropharyngolaryngeal injury (Fig. 2). This algorithm was applied only under deep and stable anesthesia, deep neuromuscular blockade, and with oxygen supplied through face-mask ventilation. The operator had 60 seconds to evaluate the difficulty and choose the appropriate technique to fulfill the four specified criteria. Excessive mandibular traction force with the laryngoscope aiming for a grade 1 of Cormack – Lehane score by operators challenging the quick switching to alternative techniques was avoided. Therefore, all the steps of the algorithm could be skipped if required. Furthermore, this algorithm was designed to avoid prolonged tracheal intubation duration and application of excessive backward pressure on the larynx to improve the laryngeal view. Consequently, the algorithm avoided laryngoscopy-induced pharyngolaryngeal injuries and throat pain and ultimately, maximized efficiency. When the first laryngeal view, with a reasonable force of mandibular traction, was poor, leading to unexpectedly difficult tracheal intubation, alternative techniques had to be widely and quickly used.[8–9, 15–16] These alternative techniques were blade switching (plastic to metal), use of an angled-tip tracheal tube introducer (Portex®, Smith Medical, Rungis, France) (gum elastic bougie) and use of an Airtraq™ laryngoscope (Prodol Meditec Limited, Vizcaya, Spain). We previously observed that the Heine® metal blade was more efficient than the Heine® plastic blade in improving a suboptimal laryngeal view. Consequently, the metal blade was not switched to the plastic blade. The angled-tip tracheal tube introducer was inserted under visual guidance while maintaining laryngoscopy. The tube was then carefully inserted into the trachea through the vocal cords and railroaded over the introducer. Additionally, alternative techniques to manage unexpectedly difficult tracheal intubation involved the use of a fiberscope (Olympus, Rungis, France). The fiberscope was used as a visually controlled flexible-tip tracheal tube introducer for railroading in the Airtraq™. The Airtraq™ could be used immediately in cases of grades 3 and 4 of Cormack–Lehane score (GAET 6 and 7) (Fig. 3). All anesthesiologists who participated in this study completed the Airtraq™

learning curve. If the oxygen saturation fell below 92%, face-mask ventilation was initiated. We used a LMA® Fastrach (Laryngeal Mask Company Limited, San Diego, CA) for oxygen supply if oxygenation failure persisted beyond 60 seconds with face-mask ventilation. Tracheal intubation was subsequently attempted using the LMA Fastrach. If oxygenation failure persisted beyond 60 seconds despite the use of the LMA Fastrach, a cricothyrotomy was rapidly performed. Squared cycles of capnography confirmed that the tube was placed in the trachea. Otolaryngology surgeons were available in the two centers to perform emergency surgical tracheostomy in “can’t intubate, can’t oxygenate” situations.

1. Endpoints

3.1 Primary endpoint

The primary endpoint was the frequency of patients presenting with a postoperative throat pain without swallowing 24 hours after the tracheal intubation.

3.2 Secondary endpoints

The secondary endpoints were the frequency of unexpectedly difficult tracheal intubation as evaluated using the IDS, laryngeal view scores (Cormack–Lehane, POGO, and GAET scores), tracheal intubation duration, frequency of blade switching during tracheal intubation, and frequency of tracheal intubation complications (oxygen desaturation, lip and dental injuries, and blood stains on the blade). The duration of tracheal intubation was defined as the time elapsed from the insertion of the blade into the mouth to the passage of the tube through the vocal cords, as determined by the operator. In their study, Adnet et al. defined tracheal intubation as easy (IDS 0), slightly difficult (IDS 1–5) or moderate to very difficult (IDS > 5).[17] In this study, tracheal intubation was considered difficult when the IDS was ≥ 1 .

Additionally, we collected the frequency of using an angled-tip tracheal tube introducer (bougie) and the distribution of each grade of the GAET score.

Moreover, throat pain intensity was evaluated using a visual analogue scale graded from 0 (no pain) to 100 (unbearable pain).

1. Statistical analysis

The sample size was calculated based on a sore throat frequency of 30% using the reusable metal blade as previously reported.[3–7] The observed frequency of sore throat in our operating rooms with single-use plastic blades increase by 10%, which was expected to be confirmed by the study. We then calculated that 356 patients per group (712 patients) would allow the detection of a significant difference using the chi-squared test, with a study power of $1-\beta$ of 0.8, and a two-tailed type I error rate α of 0.05.

Data missing at random were handled with multiple imputation methods for longitudinal data.

All *P* values were two-tailed and $P < 0.05$ indicated statistical significance. Statistical analyses were performed using SAS software, version 9.13 (SAS Institute, Inc., Cary, NC).

Quantitative data were expressed as means (SD).

Qualitative data (frequency) were expressed as numbers (proportions).

A comparison of frequencies was performed using the chi-squared test.

A comparison of means was performed using the Student's t-test.

No outcome data were excluded.

Results

We evaluated the eligibility of 754 patients from both the Hospital Center of Meaux, Meaux, France and the Robert Ballnager Hospital Center, Aulnay sous bois, France, between September 2010 and July 2015. We randomized 730 patients and excluded 37 patients. Finally, 693 patients were included in the final analysis: 351 in the single-use plastic group and 342 in the reusable metal group. A CONSORT flow diagram is shown in Fig. 4.

Patient characteristics of the two groups were not significantly different (Table 1).

Table 1
Baseline characteristics of patients scheduled for surgery with tracheal intubation performed using the Heine® single-use plastic blade or the Heine® reusable metal blade.

	Plastic Blade n = 351	Metal Blade n = 342
Age (years)	48.0 (13.6)	48.8 (13.2)
Sex (male)	103 (29.3)	113 (33.0)
Weight (kg)	74.6 (16.5)	74.2 (15.8)
Height (cm)	166.2 (8.6)	167 (9.7)
Surgery duration (min)	109.3 (60.2)	109.5 (57.0)
Values are mean (SD) or number (proportion).		

1. Primary endpoint

The frequency of sore throat was not significantly different between the plastic and metal blade groups, at 24 hours: 81 (23.1) vs. 61 (17.8); difference, 5.3%; 95% Confidence Interval, [− 0.8–11.2]; $P = 0.087$.

2. Secondary endpoints

Tracheal intubation was significantly more difficult, with an IDS ≥ 1 , in the plastic blade group compared to the metal blade group: 194 (55.3) vs. 146 (42.7); difference, 12.6%; 95% Confidence Interval, [12.3–12.8]; $P = 0.0009$.

Additionally, significantly lower POGO scores, higher Cormack–Lehane scores, higher GAET scores, and a longer duration of tracheal intubation were observed in the single-use plastic blade group compared to the reusable metal blade group (Table 2).

Table 2

Characteristics of routine and scheduled tracheal intubation performed using the Heine® single-use plastic blade or the Heine® reusable metal blade in patients without predictive criteria for difficult tracheal intubation.

Characteristics of Tracheal intubation	Plastic Blade n = 351	Metal Blade n = 342	P
IDS score (mean (SD))	1.4 (1.9)	0.9 (1.4)	0.0001
IDS = 0, n (%)	155 (44.4)	195 (57.2)	0.0007
IDS 1–5	181 (51.6)	139 (40.6)	0.0039
IDS > 5	13 (3.7)	7 (2.0)	0.192
POGO score (mean (SD))	70.8 (32.3)	79.4 (28.3)	0.0002
Cormack – Lehane score (mean (SD))	1.2 (0.6)	1.1 (0.4)	0.0089
GAET score (mean (SD))	2.0 (1.3)	1.7 (1.1)	0.0002
GAET 7, n (%)	3 (0.0)	0 (0.0)	0.086
Tracheal intubation duration (s) (mean (SD))	40.1 (52.6)	29.3 (33.1)	0.0014
Angled-tip tracheal tube introducer, n (%)	34 (9.7)	21 (6.2)	0.0842
IDS, Intubation Difficulty Score; POGO, Percentage Of Glottic Opening; GAET, Glottis – Arytenoid – Epiglottis – Tongue.			
IDS = 0, easy, IDS = 1–5, slightly difficult, IDS > 5, moderate to very difficult. Values are mean (SD) or number, n (proportion, %).			

As an alternative technique, a plastic blade was replaced with a metal blade in 12 patients (3.5) (Table 2). The angle-tip introducer was used at a frequency that was not significantly different between the two groups: 34 (9.7) vs. 21 (6.2); difference, 3.5%; 95% Confidence Interval, [– 0.5–7.6]; $P = 0.0842$.

An Airtraq™ laryngoscope was used in one patient in the single-use plastic blade group. The use of an angle-tip introducer proved to be a suitable choice in this study. The overall frequency of poor laryngeal views (GAET 5–7) was 53 (7.6) whereas angle-tip introducers were used at a frequency of 55 (7.9). Additionally, when we examine the frequency distribution of each grade of the GAET score for the 709 laryngoscopy attempts, spanning from GAET 1 to GAET 7, we observed the following breakdown: 411

(58.0), 117 (16.5), 81 (11.4), 46 (6.5), 43 (6.0), 8 (1.1), and 3 (0.5). Notably, two of the three poor laryngeal views graded as GAET 7 were improved by quickly changing the operator and switching the plastic blade to a metal blade. The third was managed using the Airtraq™.

The throat pain intensity in patients presenting it was not significantly different between the plastic and metal blade groups at 24 hours (mean (SD)): 25.4 (19.9) vs. 25.0 (16.5); difference, 0.4; 95% Confidence Interval, [- 6.05–6.95]; $P = 0.554$.

Additionally, there was no significant difference in the frequency of complications related to tracheal intubation between the two groups. The frequencies of oxygen desaturation, bronchospasm, inhalation, blood stains on the blades, dental trauma and lip wound were, at the anesthesia induction, 13 (3.7) vs. 9 (2.6), 2 (0.5) vs. 0, 0 vs. 0, 11 (3.1) vs. 6 (1.7), 0 vs. 0, 1 (0.3) vs. 2 (0.6), respectively.

Discussion

The present study revealed a notably significantly higher occurrence of unexpectedly difficult tracheal intubation associated with the Heine® single-use plastic blade. This was related to poor laryngeal exposure and consequently, poor performances of the plastic blade. Despite that, there was no significant difference in the frequency of throat pain following tracheal intubation in scheduled patients without predictive factors for difficult tracheal intubation.

Nevertheless, the plastic blades used in this study exhibited poor performances in tracheal intubation despite the random distribution of patients' characteristics and anatomical structures between the two groups. The appropriate choice of tracheal intubation technique and dexterity were guaranteed by the experience of the nurse anesthetists and anesthesiologists. Therefore, the significant difference in intubation difficulty may be attributed to the varying material rigidity of the two blades. The poor performance of the plastic blade in tracheal intubation is consistent with the results of previous studies. Evans et al. demonstrated on a mannequin that the force of mandibular traction during intubation was weaker with a reusable blade than with a plastic blade.[18] Additionally, Galinski et al., found that 10% of difficult tracheal intubation were defined by an IDS > 5 in the Heine® single-use plastic group compared to 3.1% in the Heine® reusable metal group.[19] Similarly, Buleon et al. reported an IDS ≥ 1 in 50.6% of patients in the Heine® single-use plastic group whereas it was 39.1% in the Heine® reusable metal group.[20] Meanwhile, Amour et al. reported poor performances with a different brand of single-use plastic blade, the Lite-blade® (Rush, Kernen, Germany).[21] The performance of various plastic blades has been a subject of investigation in previous studies. Rassam et al. evaluated the Lite-blade® and Heine® plastic blades on a mannequin and ranked them as the best plastic blades.[22] In addition, the Vital View™ plastic blade showed comparable performances to the reusable metal blade when it was used to intubate patients' trachea. Meanwhile, using a Vital View™ single-use plastic blade, Asaï et al. found a frequency of 5% of second attempts of tracheal intubation and Galinski et al., found 5.1% of IDS > 5.[18–23]

Throat pain has been studied previously with a reusable metal blade, and the results are consistent with those of our study, although they mainly evaluated the overall incidence of throat pain. Christensen et al.

reported a sore throat rate of 14.4% between 6 and 24 hours in a sample of 1325 patients, while Higgins et al. reported an incidence of 45.5% in 755 patients.[4–5] In both studies, numerous uncontrolled factors could induce throat pain, including: thyroid surgery, postoperative gastric tube, lidocaine gel, nitric oxide, cuff pressure, dry airway gases, large tracheal tube diameters, airway suctions, and a lack of data on the neuromuscular blockade.[4–5] In contrast, Inoue et al. reported a sore throat incidence of 32% in a large retrospective study involving 10870 patients in whom the risk factors for throat pain were closely controlled.[6]

Interestingly, our study observed a similar frequency of throat pain between the plastic and metal blade groups. This finding may be attributed to the 60-second step-limit tracheal intubation algorithm used in the present study, which may have been airway-protective. Initially, we expected an increase in the frequency of throat pain in the plastic blade group under routine conditions. Surprisingly, the frequency observed in this study was less than that observed in our clinical setting before the study, despite significantly poorer laryngeal views (lower POGO scores, higher Cormack–Lehane scores, and higher GAET scores) and longer durations of tracheal intubation with the plastic blade. Notably, the 60-second step-limit tracheal intubation algorithm has not yet been extensively defined in the literature. However, utilizing a 60-second time limit appears to be a reasonable approach to promptly change techniques and potentially prevent throat pain development or other operators-induced injuries.[24] In a prior study, we have used a 120-second limit to change the technique during tracheal intubation in obese patients.[10] This time-step limit concept was highlighted in a case report on difficult tracheal intubation.[25] Furthermore, the very low incidence of complications related to tracheal intubation, without significant difference between the two groups, could be reasonably attributed to the airway-protective algorithm. In a study by Amour et al., complications were reported in 15% (22/147) of the patients in the plastic group, with the majority consisting in oxygen desaturation (20/147) in emergencies. Similarly, Buleon et al. reported a very low incidence of complications (0.93%), which is consistent with the result of the present study. Both studies also used a 60-second step limit to switch the plastic blade to the metal blade when the first attempt of tracheal intubation failed or exceeded 60 seconds.[19–20] The generalizability of this concept and the implementation of such an airway-protective algorithm in other institutions and clinical settings is worth considering. Numerous alternative techniques are currently available in addition to the tip-angled introducer such as video-assisted laryngoscopes which have demonstrated ease of use, efficiency, harmlessness, and safety. However, further studies are necessary to validate the airway protective effects of the algorithm used in this study.

Nevertheless, it should be noted that the use of a tip-angled introducer (bougie) did not affect the results of this study. Other studies showed that the widespread use of bougies, even on the first attempt, did not induce throat pain or injuries.[26–28] Moreover, Latta et al. and Nolan and Wilson have already highlighted the wide use of a bougie even when the laryngeal view was of grade 1 (the glottis partially exposed), which can reduce the risk of teeth and lip damages associated with efforts to improve the view. [8–9] They also proposed routinely accepting relatively poor views and using a bougie to assist tracheal intubation, thereby avoiding pharyngolaryngeal injuries and oxygen desaturation. Consequently, the authors promoted the concept of airway protection during tracheal intubation, as in the present study.

Considering the complexity of tracheal intubation, throat pain cannot be correctly analyzed without a precise description of tracheal intubation procedure.[29–30] Laryngeal view is one of the characteristics used to describe a tracheal intubation, in addition to tracheal intubation duration, predictive criteria for difficult tracheal intubation, induced injuries, and IDS, which includes assessment of the laryngeal view using the Cormack–Lehane score.[12] To describe the laryngeal view precisely, Guerçi et al. used the POGO and Cormack–Lehane scores, obtained using both disposable and reusable metal blades.[31] The GAET score used in the present study continued in the same vein by combining these two validated scores and aligned GAET 2–3 with Cormack–Lehane 1 (0 point of IDS) and GAET 4 with Cormack–Lehane 2 (1 point of IDS). This allowed for the accurate calculation of the IDS and facilitated a meaningful comparison of the Cormack–Lehane score values with those reported in other studies. Nonetheless, it should be acknowledged that the validation of the GAET score was not conducted prior to the study, thereby representing a limitation of the study. However, the distribution of the GAET score grades was similar to that reported by Yentis and Lee.[32]

This study has some limitations beyond those associated with the GAET score. Firstly, the 60-second step-limit tracheal intubation algorithm has not been well-defined in the literature, has not been widely implemented in operating rooms, nor is it considered standard practice. Secondly, 19 patients were required to reach the intended sample size. However, their absence did not impact the result significantly. This is because the low frequencies of throat pain observed in the study due to the 60-second step-limit tracheal intubation algorithm would have required a larger sample size to detect a significant difference. Additionally, the lack of follow-up after 24 hours is another limitation. It would have been interesting to describe the variations in throat pain intensity over several days after tracheal intubation. Notably, this aspect of follow-up was addressed differently in previous studies. Christensen et al. and Higgins et al. completed the follow-up assessments 24 hours after tracheal intubation.[4–5] Conversely, Inoue et al. extended their follow-up to ten days and demonstrated that the peak frequency of sore throat occurred in the first 24 hours.[6]

Conclusion

The Heine single-use plastic blade used in this study induced a significantly higher incidence of unexpectedly difficult tracheal intubation due to poor laryngeal exposure. However, despite this poor performance, this blade did not induce more throat pain following tracheal intubation in scheduled patients without predictive criteria for difficult tracheal intubation when compared to the Heine® reusable metal blade group. This lower-than-expected increase in throat pain incidence in the plastic blade group could be attributed to the 60-second step-limit tracheal intubation algorithm. Further studies with other single-use plastic blades are necessary to confirm that their implementation in operating rooms, in the context of advancing video-assisted laryngoscopes and ecological plastic recycling, is not dependent on their performance.

Declarations

Ethics approval and consent to participate

Ethics approval obtained at the Ethics Authority Ile-de-France IV of the University Hospital Center of Saint Louis (Paris, France), University's Institutional Review Board 00003888, 24/09/2009.

All the patients were clearly informed, during the anesthesia visit, by the anesthesiologists on both the purpose and protocol of the study. After several days of reflection, the patients provided written informed consent for the study.

All study participants provided informed consent and the study design was approved by the appropriate ethics review board.

Consent for publication

Not applicable

Availability of data and materials

The dataset supporting the conclusions of this article is available in the MENDELEY repository, Licence CC BY 4.0, <http://doi.org/10.17632/26j5zyrwnx.1>.

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There was not any conflict of interests for this research and each author does not have any competing interests to declare.

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Each author does not have any financial interests or connections, direct or indirect, or other situations which may raise the question of bias in the work reported or the conclusions, implications, or opinions stated.

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There have been no involvements that might raise the question of bias in the work reported or in the conclusions, implications, or opinions stated.

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Authors' Contribution

SL: Investigation, Writing - Original draft preparation, Writing - Reviewing and Editing. NF: Investigation, Writing - Original draft, Writing - Reviewing and Editing. MS: Writing - Original draft preparation, Writing - Reviewing and Editing. LB: Investigation. CL: Data curation. EV: Methodology, Validation, Formal analysis, Project administration, Resources, Software, Data curation. SD: Writing - Reviewing and Editing. SKN: Conceptualization, Methodology, Supervision, Validation, Formal analysis, Writing - Original draft, Writing - Reviewing and Editing, Visualization.

References

1. Domino KB, Posner KL, Caplan RA, Cheney FW. Airway injury during anesthesia: a closed claims analysis. *Anesthesiology*. 1999;91(6):1703-11. <https://doi.org/10.1097/00000542-199912000-00023>.
2. Joffe AM, Aziz MF, Posner KL, Duggan LV, Mincer SL, Domino KB. Management of difficult tracheal intubation: A closed claims analysis. *Anesthesiology*. 2019;131(4):818-29. <https://doi.org/10.1097/ALN.0000000000002815>.
3. McHardy FE, Chung F. Postoperative sore throat: cause, prevention and treatment. *Anaesthesia*. 1999;54(5):444-53. <https://doi.org/10.1046/j.1365-2044.1999.00780.x>.
4. Christensen AM, Willemoes-Larsen H, Lundby L, Jakobsen KB. Postoperative throat complaints after tracheal intubation. *Br J Anaesth*. 1994;73(6):786-7. <https://doi.org/10.1093/bja/73.6.786>.

5. Higgins PP, Chung F, Mezei G. Postoperative sore throat after ambulatory surgery. *Br J Anaesth*. 2002;88(4):582-4. <https://doi.org/10.1093/bja/88.4.582>.
6. Inoue S, Abe R, Tanaka Y, Kawaguchi M. Tracheal intubation by trainees does not alter the incidence or duration of postoperative sore throat and hoarseness: a teaching hospital-based propensity score analysis. *Br J Anaesth*. 2015;115(3):463-9. <https://doi.org/10.1093/bja/aev234>.
7. Maruyama K, Sakai H, Miyazawa H, Toda N, Iinuma Y, Mochizuki N, et al. Sore throat and hoarseness after total intravenous anaesthesia. *Br J Anaesth*. 2004;92(4):541-3. <https://doi.org/10.1093/bja/aeh098>.
8. Nolan JP, Wilson ME. An evaluation of the gum elastic bougie. Intubation times and incidence of sore throat. *Anaesthesia*. 1992;47(10):878-81. <https://doi.org/10.1111/j.1365-2044.1992.tb03154.x>.
9. Latta IP, Stacey M, Mecklenburgh J, Vaughan RS. Survey of the use of the gum elastic bougie in clinical practice. *Anaesthesia*. 2002;57(4):379-84. <https://doi.org/10.1046/j.1365-2044.2002.02411.x>.
10. Ndoko SK, Amathieu R, Tual L, Polliand C, Kamoun W, El Housseini L, et al. Tracheal intubation of morbidly obese patients: a randomised trial comparing performance of Macintosh and AirtraqTM laryngoscopes. *Br J Anaesth*. 2008;100(2):263-8. <https://doi.org/10.1093/bja/aem346>.
11. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c332. <http://doi.org/10.1136/bmj.c332>.
12. Mencke T, Knoll H, Schreiber J, Echternach M, Klein S, Noeldge-Schomburg G, et al. Rocuronium is not associated with more vocal cord injuries than succinylcholine after rapid-sequence induction: a randomized, prospective, controlled trial. *Anesth Analg*. 2006;102(3):943-9. <https://doi.org/10.1213/01.ane.0000194509.03916.02>.
13. Cormack RS, Lehane J. Difficult tracheal intubation in obstetrics. *Anaesthesia*. 1984;39(11):1105-11.
14. Levitan RM, Ochroch EA, Kush S, Shofer FS, Hollander JE. Assessment of airway visualization: validation of the percentage of glottic opening (POGO) scale. *Acad Emerg Med*. 1998;5(9):919-23. <https://doi.org/10.1111/j.1553-2712.1998.tb02823.x>.
15. El-Orbany MI, Salem MR, Joseph NJ. The Eschmann Tracheal tube introducer is not gum, elastic, or a bougie. *Anesthesiology*. 2004;101(5):1240. <https://doi.org/10.1097/00000542-200411000-00032>.
16. Driver B, Dodd K, Klein LR, Buckley R, Robinson A, McGill JW, et al. The bougie and first-pass success in the emergency department. *Ann Emerg Med*. 2017;70(4):473-8. <https://doi.org/10.1016/j.annemergmed.2017.04.033>.
17. Adnet F, Borron SW, Racine SX, Clemessy JL, Fournier JL, Plaisance P, et al. The intubation difficulty scale (IDS): proposal and evaluation of a new score characterizing the complexity of endotracheal intubation. *Anesthesiology*. 1997;87(6):1290-7. <https://doi.org/10.1097/00000542-199712000-00005>.
18. Evans A, Vaughan RS, Hall JE, Mecklenburgh J, Wilkes AR. A comparison of the forces exerted during laryngoscopy using disposable and non-disposable laryngoscope blades. *Anaesthesia*. 2003;58(9):869-73. <https://doi.org/10.1046/j.1365-2044.2003.03340.x>.

19. Galinski M, Catineau J, Rayeh F, Muret J, Ciebiera J, Plantevin F, et al. Laryngoscope plastic blades in scheduled general anesthesia patients: a comparative randomized study. *Journal of Clinical Anesthesia*. 2011;23(2):107–112. <https://doi.org/10.1016/j.jclinane.2010.08.005>.
20. Buleon C, Parienti J, Lesage A, Grandin W, Pouliquen E, Flais F, et al. Comparison of plastic and metallic single-use and metallic reusable laryngoscope blades. A randomised controlled trial. *Eur J Anaesthesiol*. 2013;30(4):163–9. <https://doi.org/10.1097/EJA.0b013e32835c1cdb>.
21. Amour J, Marmion F, Birenbaum A, Nicolas-Robin A, Coriat P, Riou B, et al. Comparison of plastic single-use and metal reusable laryngoscope blades for orotracheal intubation during rapid sequence induction of anesthesia. *Anesthesiology*. 2006;104(1):60-4. <https://doi.org/10.1097/00000542-200601000-00011>.
22. Rassam S, Wilkes AR, Hall JE, Mecklenburgh JS. A comparison of 20 laryngoscope blades using an intubating manikin: visual analogue scores and forces exerted during laryngoscopy. *Anaesthesia*. 2005;60(4):384-94. <https://doi.org/10.1111/j.1365-2044.2004.04084.x>.
23. Asai T, Uchiyama Y, Yamamoto K, Johmura S, Shingu K. Evaluation of the disposable Vital View laryngoscope apparatus. *Anaesthesia*. 2001;56(4):342-5. <https://doi.org/10.1046/j.1365-2044.2001.01906.x>.
24. Amour J, Le Manach YL, Borel M, Lenfant F, Nicolas-Robin A, Carillion A, et al. Comparison of single-use and reusable metal laryngoscope blades for orotracheal intubation during rapid sequence induction of anesthesia: a multicenter cluster randomized study. *Anesthesiology*. 2010;112(2):325-32. <https://doi.org/10.1097/ALN.0b013e3181c92111>.
25. Sudrial J, Birlouez C, Guillermin AL, Sebbah JL, Amathieu R, Dhonneur G. Difficult airway management algorithm in emergency medicine: do not struggle against the patient, just skip to next step. *Emerg Med Int*. 2010;2010:826231. <https://doi.org/10.1155/2010/826231>.
26. Driver BE, Semler MW, Self WH, Ginde AA, Trent SA, Gandotra S, et al. Effect of use of a bougie vs endotracheal tube with stylet on successful intubation on the first attempt among critically ill patients undergoing tracheal intubation: A randomized clinical trial. *JAMA*. 2021;326(24):2488-97. <https://doi.org/10.1001/jama.2021.22002>.
27. Oxenham O, Piraudeau C, Moody T, Mendonca C. Standard and flexible tip bougie for tracheal intubation using a non-channelled hyperangulated videolaryngoscope: a randomised comparison. *Anaesthesia*. 2022;77(12):1368-75. <https://doi.org/10.1111/anae.15854>.
28. Hodzovic I, Latta IP, Henderson JJ. Bougie trauma—what trauma? *Anaesthesia*. 2003;58(2):192-3. https://doi.org/10.1046/j.1365-2044.2003.03005_16.x.
29. Levitan RM, Hollander JE, Ochroch EA. A grading system for direct laryngoscopy. *Anaesthesia*. 1999;54(10):1009-10. <https://doi.org/10.1046/j.1365-2044.1999.1133f.x>.
30. Mencke T, Echternach M, Kleinschmidt S, Lux P, Barth V, Plinkert PK, et al. Laryngeal morbidity and quality of tracheal intubation: a randomized controlled trial. *Anesthesiology*. 2003;98(5):1049-56. <https://doi.org/10.1097/00000542-200305000-00005>.

31. Guerçi P, Vial F, Bouaziz H. Single-use and reusable laryngoscope blades: a randomized controlled trial in elective surgery. *Can J Anaesth.* 2012;59(1):114-5. <https://doi.org/10.1007/s12630-011-9603-6>.
32. Yentis SM, Lee DJ. Evaluation of an improved scoring system for the grading of direct laryngoscopy. *Anaesthesia.* 1998;53(11):1041-4. <https://doi.org/10.1046/j.1365-2044.1998.00605.x>.

Figures



Figure 1

Laryngoscope blades used in the study: the single-use plastic blade (Heine XP, HEINE Optotechnik GmbH & Co. KG, Herrsching, Germany) (up), and reusable metal blade (HEINE Classic+® F.O. Macintosh, HEINE Optotechnik GmbH & Co. KG, Gilching, Germany) (down).

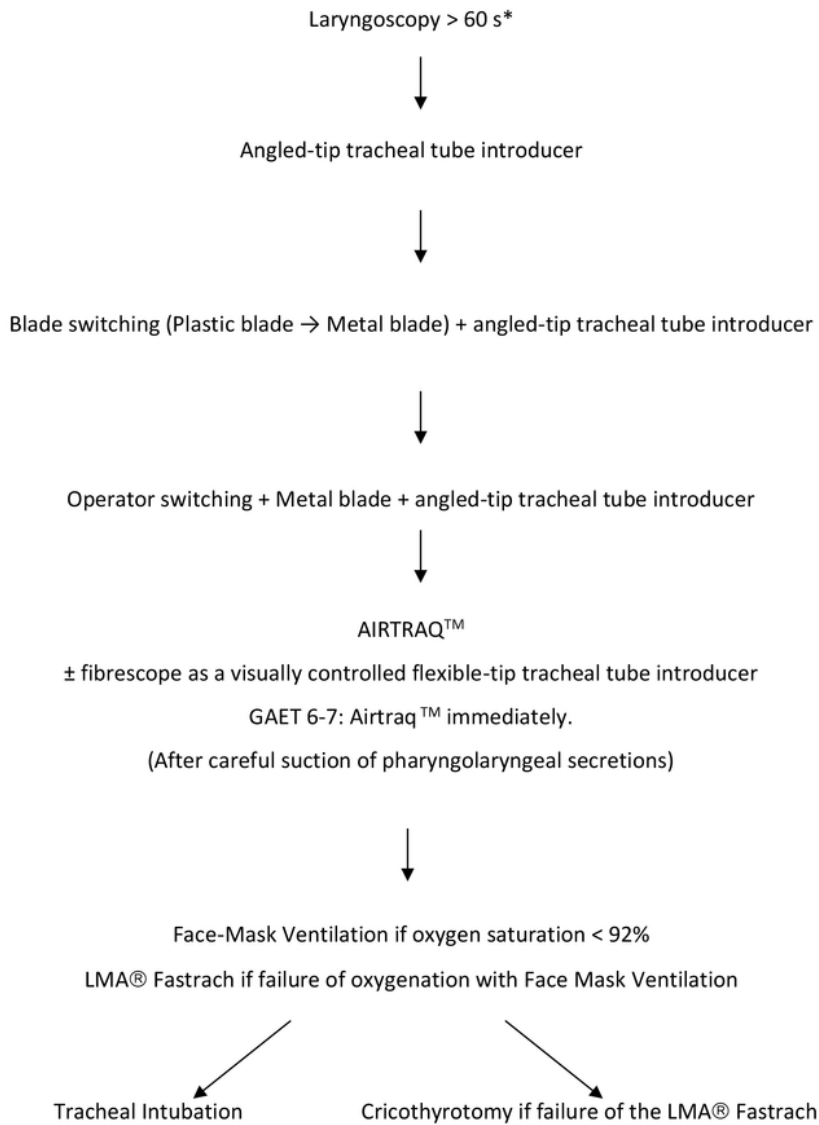


Figure 2

Sixty-second step-limit tracheal intubation algorithm. * The operator could skip steps as necessary to avoid injury and maximize efficiency. Arrow (--->), beyond 60 s, use of an alternative technique.

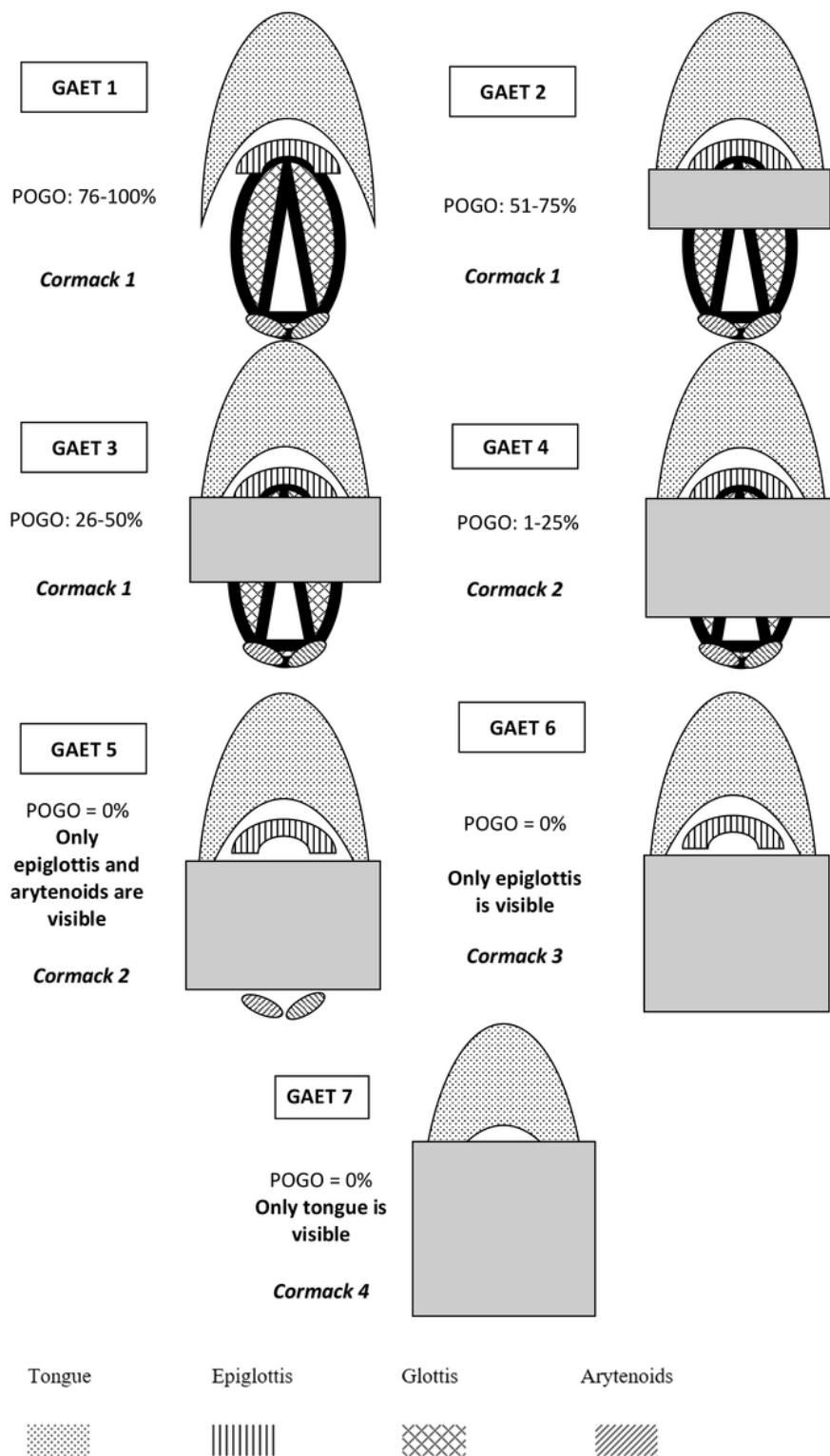


Figure 3

GAET score. A combination of Cormack – Lehane and POGO scores for accurate description of the laryngoscopic view during tracheal intubation and IDS calculation. IDS, Intubation Difficulty Score; POGO, Percentage Of Glottic Opening; GAET, Glottis-Arytenoids-Epiglottis-Tongue.

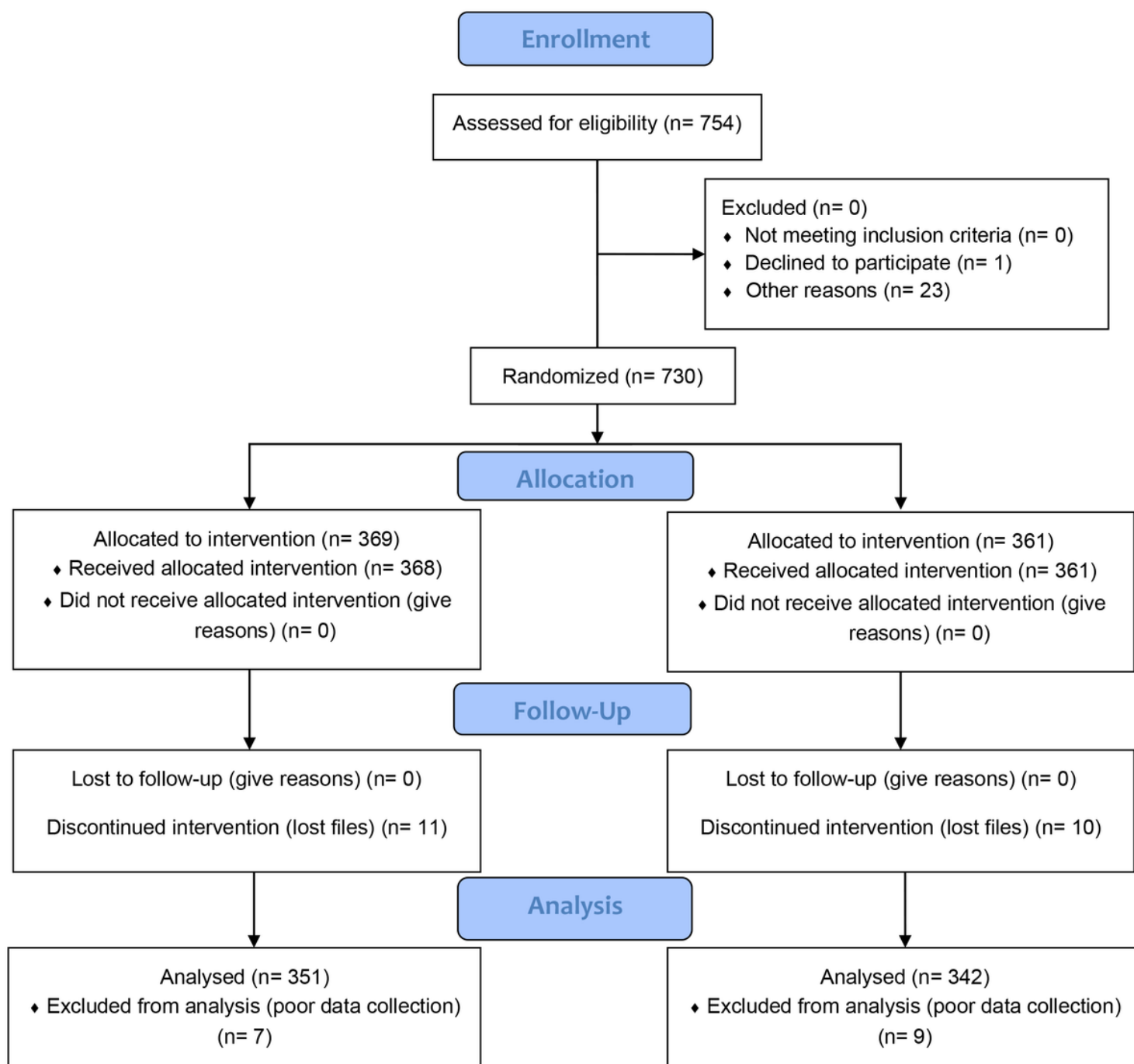


Figure 4

CONSORT flow diagram.