

NEW FLEXIBLE TIP BOUGIE CATHETER FOR DIFFICULT AIRWAY INTUBATION. A RANDOMIZED, CROSSOVER PILOT STUDY

Michael Frass¹, Jacek Smereka², Kurt Ruetzler³, Lukasz Szarpak⁴, Oliver Robak¹

¹Department of Medicine I, Medical University of Vienna, Vienna, Austria

²Department of Emergency Medical Service, Wrocław Medical University, Wrocław, Poland

³Departments of Outcomes Research and General Anesthesiology, Anesthesiology Institute, Cleveland Clinic, Cleveland, Ohio, USA

⁴Lazarski University, Warsaw, Poland

ABSTRACT

INTRODUCTION: The ability to protect the airway is one of the basic skills that medical staff should have, especially those working within the Emergency Medical Service or Emergency Department. Endotracheal intubation under medical emergency conditions based on direct laryngoscopy is not effective enough; this effect is additionally reduced in the case of the difficult airway resulting from reduced visibility of the entrance to the glottis due to tongue or epiglottis oedema, trauma, etc. The aim of the study was to compare the intubation time and its effectiveness using two different stylets for difficult airway intubation.

MATERIAL AND METHODS: The study involved 37 nurses who participated in training on advanced life support procedures. The experiment was designed as a randomized, cross-over simulation study. During the training, participants were instructed to perform endotracheal intubation using the tested intubation methods and had 20 minutes of practical training during which they were able to intubate with the tested stylets under normal airway. In the study, participants performed endotracheal intubation using a laryngoscope with a Macintosh blade and a difficult airway Bougie stylet (ONTEX, Chennai, India), or the Flexible Tip Bougie (MDSS GmbH, Hannover, Germany), which was designed to allow to guide the distal end of the anteriorly and posteriorly to facilitate entry into the larynx.

RESULTS: The effectiveness of the first intubation attempt using a standard Bougie stylet was 37.8%, and that of the new Bougie stylet was 51.4% ($p = 0.037$). The mean intubation time was 55 s (IQR; 34–65) vs. 37 s (IQR; 25–41) (respectively, $p = 0.021$). The median ease of intubation was 7 (IQR; 5–9) points for a standard Bougie stylet and 5 (2.5–7) 2 points for a new Bougie stylet ($p = 0.018$).

CONCLUSIONS: In a simulation study, the use of Flexitip Bougie by nurses compared to a standard Bougie stylet was associated with higher efficacy and shorter intubation times in difficult airway.

KEY WORDS: endotracheal intubation; simulation, catheter, airway management, direct laryngoscopy

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INTRODUCTION

The ability to protect the airway is one of the basic skills that medical staff should have, especially those

working within the Emergency Medical Service or Emergency Department [1, 2]. In pre-hospital settings, each endotracheal intubation is emergency

ADDRESS FOR CORRESPONDENCE:

Lukasz Szarpak, Lazarski University, 43 Swieradowska Str., 02–662 Warsaw, Poland;
e-mail: lukasz.szarpak@gmail.com

procedure so it is impossible to estimate the risk of complications during intubation, so each patient should be treated as a patient with difficult airway and caution should be exercised when securing the airway [3]. Endotracheal intubation under medical emergency conditions based on direct laryngoscopy is not effective enough; this effect is additionally reduced in the case of the difficult airway resulting from reduced visibility of the entrance to the glottis due to the tongue or epiglottis oedema, trauma, etc. [4–6]. It is, therefore, crucial to seek new, more effective endotracheal intubation techniques that both facilitate the intubation process and shorten the whole procedure.

The aim of the study was to compare the intubation time and its effectiveness using two different stylets for difficult airway intubation.

METHODS

The study was designed as a prospective, randomized, cross-over study and was conducted under medical simulation conditions. The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (Approval no: 21.03.2019.IRB). 37 nurses participating in advanced cardiovascular life support courses were included in the study. Voluntary written informed consent was obtained from each participant.

Before the survey was started, all participants attended an airway management training course. During the training, participants were instructed to perform endotracheal intubation using the tested intubation methods and had 20 minutes of practical training during which they were able to intubate with the tested stylets under normal airway.

In the study, participants performed endotracheal intubation using a laryngoscope with a Macintosh blade and a difficult airway Bougie stylet (ONTEX, Chennai, India), or the Flexible Tip Bougie (MDSS GmbH, Hannover, Germany), which was designed to allow to guide the distal end of the anteriorly and posteriorly to facilitate entry into the larynx (Fig. 1).

SimMan 3G simulator (Laerdal, Stavanger, Norway) was used to simulate a patient requiring airway management. Next, the study participants had to perform intubation in difficult airway conditions, which was obtained by inflation of air the tongue until obtaining Cormack-Lehane Grade 3. Both the order of participants and the technique of endotracheal intubation were random (Fig. 2). The study

analyzed the effectiveness of the first intubation attempt as well as the time of the procedure. After intubation, the study participants evaluated the ease of the procedure using a 10-degree audio-visual scale, where '1' was an easy procedure and '10' a difficult procedure. Statistical analysis of the obtained data was performed using Statistica 13.1EN (StatSoft, Tulus, USA).

The Statistica 13.3EN software (TIBCO Inc., Tulsa, OK, USA) was used for statistical analysis. Times needed to archive a sufficient glottic view until insertion of the tracheal tube was compared using the Wilcoxon signed-rank test. To detect possible differences in success rates for endotracheal intubation, the McNemar's test was used. A $p < 0.05$ was considered as statistically significant. All results are shown as median and interquartile range (IQR), mean and standard deviation (SD) or percentages (%).

RESULTS

The study involved 37 nurses, whose mean age was 42 ± 11 years, while the mean work experience was 12 ± 8 years. All persons participating in the study declared their ability to endotracheal intubation based on direct laryngoscopy.

The effectiveness of the first intubation attempt using a standard Bougie stylet was 37.8%, and that of the new Bougie stylet was 51.4% ($p = 0.037$).

The mean intubation time was 55s (IQR; 34–65) vs. 37s (IQR; 25–41) (respectively, $p = 0.021$; Fig. 3).

The median ease of intubation was 7 (IQR; 5–9) points for a standard Bougie stylet and 5 points (2.5–7) 2 points for a new Bougie stylet ($p = 0.018$; Fig. 4).



FIGURE 1. New flexible tip bougie

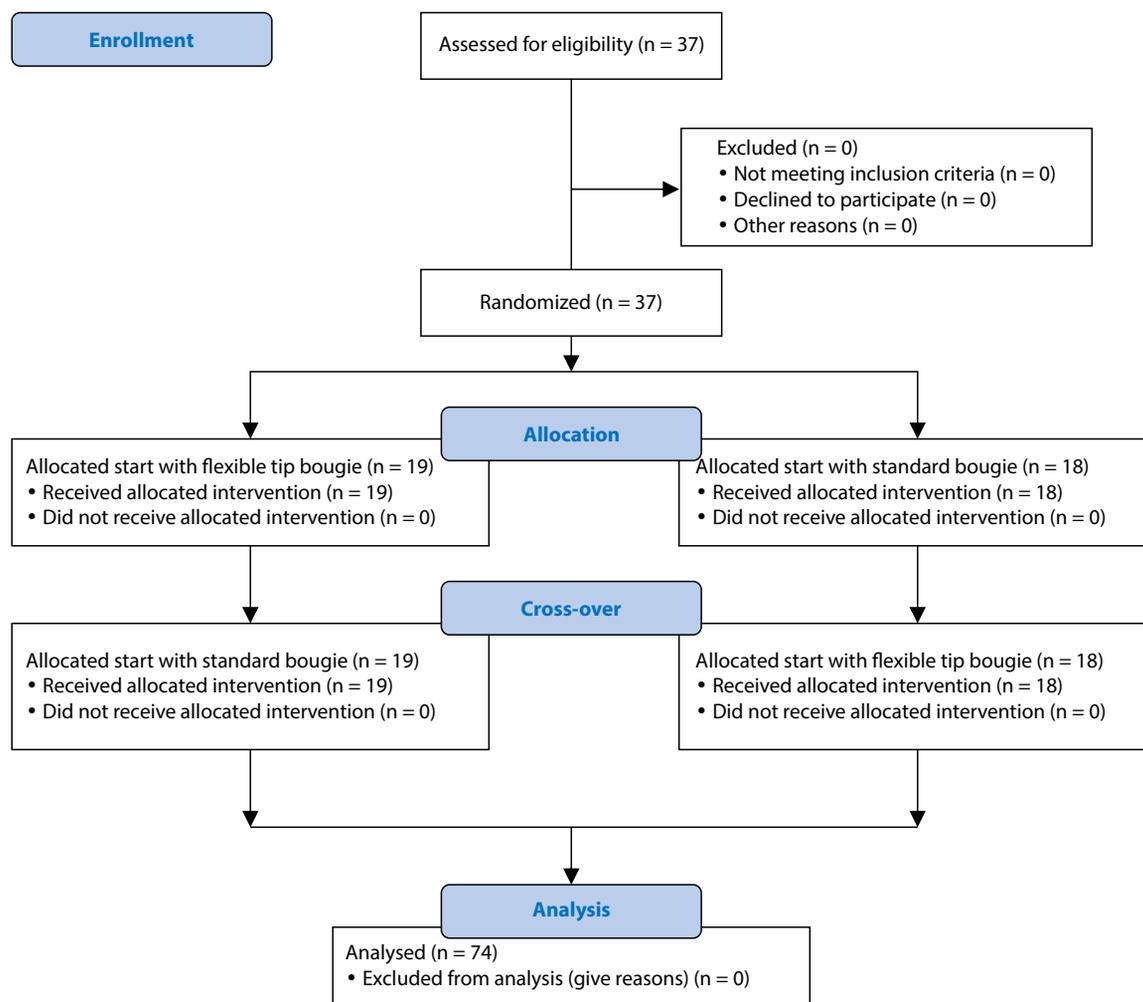


FIGURE 2. Randomization flow chart

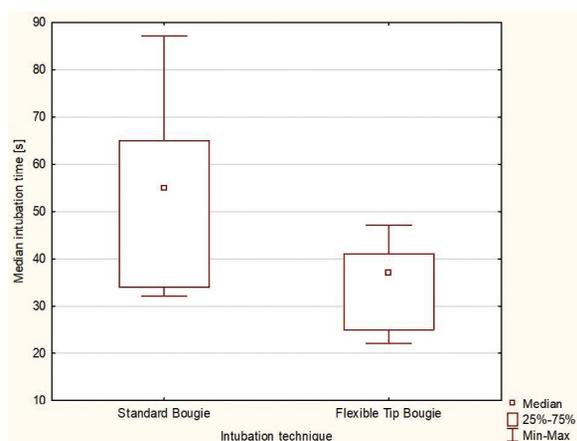


FIGURE 3. Mean intubation time

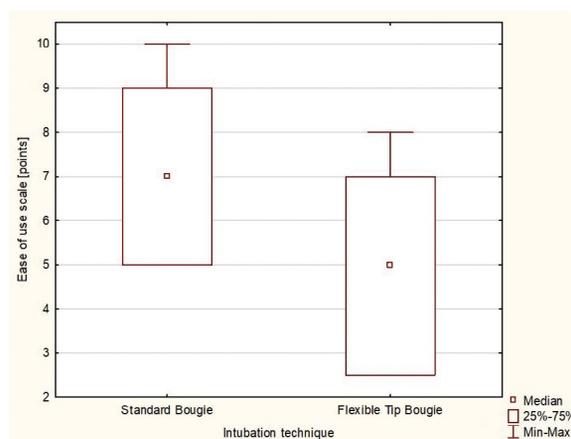


FIGURE 4. Mean ease of intubation

DISCUSSION

The study showed that nurses were able to perform endotracheal intubation with Flexible Tip Bougie with higher efficacy than a standard difficult intubation stylet.

Tracheal intubation in emergency conditions is a challenge for medical personnel [7]. Performed with a Miller or Macintosh blade laryngoscope in many cases can be difficult to perform or completely ineffective. This is particularly the case when intuba-

tion is performed by people without direct laryngoscopy experience [8–11], during cardiopulmonary resuscitation, when continuous chest compression is performed [12–14], in the case of intubation of patients with immobilized cervical spine [15–17], or patients with difficult airways [18–20].

According to research by Bganabhai et al. Flexible -tipped bougie has been helpful during videolaryngoscopic intubation in a patient with a base of tongue tumour [21]. In this study, both the intubation time and the ease of the procedure were in favour of using flexible tip bougies. Due to the fact that flexible tip bougie is a relatively new device on the medical market, there are no scientific reports on the effectiveness of this device, so this study is a pioneering study on the evaluation of flexible tip bougie in simulated difficult airway conditions.

CONCLUSIONS

In a simulation study, nurses were able to intubate a patient with simulated difficult airways in a shorter time and with higher efficiency of the first intubation attempt compared to a standard bougie guide using direct laryngoscopy and a new flexible tip bougie.

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