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GlideScope® Tracheal Intubation with and without Muscle Relaxation: A Prospective, Randomized Clinical Trial

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Abstract: *Purpose:* GlideScope® videolaryngoscope (GVL, Verathon Medical Inc., Bothell, WA, USA) assisted orotracheal intubation is a useful technique for patients who are difficult to intubate, but who can be mask ventilated. The effect of muscle relaxants on the success of GVL intubation has not been evaluated. The authors conducted a prospective, placebo-controlled study to assess the effectiveness and incidence of complications of GVL-assisted tracheal intubation performed during general anesthesia with and without the use of a muscle relaxant in patients with seemingly normal airway anatomy.

Material and Methods: 52 patients who required orotracheal intubation were prospectively included. Anesthesia was induced using midazolam (0.01-0.03 mg/kg), fentanyl (1-3 μg/kg) and propofol (1-3 mg/kg). Patients were randomly assigned to one of two groups to receive rocuronium 0.6 mg/kg (n = 26 for rocuronium group) or saline intravenously (n = 26 for placebo group). GVL-assisted intubation was initiated after 90 s. The number of successful intubations, the number of attempts and their duration were recorded. Events during the procedure, such as airway trauma, blood pressure changes and movements were also recorded.

Results: The success rate of GVL intubation was 100% in the placebo group and 100% in the rocuronium group. Patients in both groups received the same number of intubation attempts and the intubation time were alike (53± 15 *vs.* 55 ± 18 s; *p=0.63*). The Placebo group experienced a greater incidence of events during intubation (81 *vs.* 35%; $P < 0.001$) than patients in the rocuronium group.

Conclusions: Omitting muscle relaxants in patients with apparently normal airways is not associated with a higher failure rate, increased intubation attempts or intubation time when performing GVL assisted orotracheal intubation, but is associated with a higher rate of patient movement.

Keywords: Airway, Airway Management, GlideScope, Muscular Relaxation, Tracheal Intubation, Video Laryngoscope.

INTRODUCTION

The GlideScope® videolaryngoscope (GVL; Verathon Medical Inc., Bothell, WA, USA) uses a high-resolution video camera embedded into a plastic laryngoscope blade. It consistently provides a good glottic view and is a suitable tool for difficult tracheal intubation, such as in patients with restricted cervical spine movements, obesity, difficult direct laryngoscopy or unexpected failed intubation [1-4]. In selected simulated difficult airway scenarios the GVL also improved laryngeal views and intubation conditions, because indirect laryngoscopy enables a 'look-around-the-corner', with a magnified display on the monitor [5-8]. Since the GVL is a fairly new device, GVL tracheal intubation has not been incorporated into the difficult airway algorithm of the American Society of Anesthesiologists (ASA), which was last revised in 2003 [9]. Because difficult intubation and difficult mask ventilation are frequently associated, the guidelines recommend in this situation consideration of anesthetic techniques without muscle relaxation, allowing rapid return to spontaneous ventilation if ventilation becomes inadequate [9,10]. Moreover, in order to establish the place of GVL intubation in the difficult airway management plan, the effects of muscle relaxants on the reliability and safety of GVL tracheal intubation need to be assessed. The feasibility of orotracheal intubation during general anesthesia in patients without muscle relaxation has previously been tested with direct laryngoscopy, Fastrach® (*LMA-Fastrach* ™; LMA North America, Inc., San Diego, CA) and lightwand (Trachlight®; Laerdal Medical Inc., Armonk, NY) techniques [11,14]. So far studies examining GLS tracheal intubation have only been undertaken in anesthetized–paralyzed patients [1,2,15,16]. Based on these previous studies [11-13] and according to our own clinical experience, we hypothesized that the rate of success of the GVL tracheal intubation should be similar between patients with or without muscle relaxation.

MATERIAL AND METHODS

After approval by our institutional research review board (IRB Boston VA Healthcare System) and written informed consent was obtained, we investigated 52 adult patients with

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an ASA physical status I-III, who required general anesthesia with orotracheal intubation for elective surgery.

During the preoperative visit the patient's age, sex, smoking history, weight, height, Mallampati class [17] (evaluated while the patient was in the sitting position, head fully extended, tongue out with phonation), mouth opening, thyromental distance, and neck motion were recorded. Exclusion criteria included: patients with suspected or known difficult airway, requirement of rapid sequence induction, a contraindication to GVL use [18,19], patients undergoing emergency surgery, patients with gastroesophageal reflux disease, unstable patients, patients with severe chronic obstructive lung disease requiring home oxygen therapy, and patients with significant sleep apnea requiring continuous positive airway pressure support. A suspected difficult airway as defined as the presence of a Mallampati class IV, restricted neck motion, retrognathia, or at least two of the following criteria: Mallampati class III, high arched palate, mouth opening less 35mm, or thyromental distance less than 65mm [20].

Intraoperatively, the electronic anesthesia recording system CompuRecord (Philips Medical Systems, Eindhoven, The Netherlands) was used to continuously monitor the electrocardiogram, heart rate, noninvasive arterial blood pressure (every 3 min), pulse oximetry, and capnography. Staff anesthesiologists, certified registered nurse anesthetists (CRNA) and experienced anesthesiology residents were eligible to be GVL operators if they had successfully performed at least 30 GVL intubations prior to participation in this trial and henceforth will be referred to as "the operator".

Patients were randomly allocated into one of two groups by a computer-generated code enclosed within an envelope, which was opened as the patient entered the operating room by the attending anesthesiologist who was not the operator performing the tracheal intubation. The rocuronium group used the standard local practice of GVL intubation: the endotracheal tube (ETT) was loaded onto a GVL stylet and the tracheal intubation followed induction of anesthesia and administration of a muscle relaxant. The placebo group used an ETT loaded onto a GVL stylet and the intubation followed induction of anesthesia without administration of a muscle relaxant.

Before induction the patient's head and neck were placed in the sniffing position, under ambient light conditions. We used an 8-mm-ID ETT for male patients and a 7.0-mm ETT for female patients. Midazolam, 15-30 µg/kg, was administered intravenously 2 min before induction of anesthesia, and patients were preoxygenated with 100% oxygen via a facemask until the oxygen concentration in the expired air reached at least 80%. Anesthesia was induced with 1-2 µg/kg fentanyl intravenously, followed by 1-3 mg/kg propofol intravenously injected within 30 seconds. After verification of adequate mask ventilation, patients received either intravenous rocuronium (0.06 ml/kg of a solution of 10 mg/ml rocuronium, n = 26) or normal saline (n = 26) by the anesthesiologist who opened the envelope. A minimum delay of 90 seconds was utilized for onset of paralysis. The operator performing tracheal intubation was blinded to the entire anesthesia drug administration and was consequently blinded to the muscle relaxants use.

The operator performed GVL laryngoscopy, graded the Cormack & Lehane (C&L) view [21] and noted the position of the vocal cords (open, closed, or intermediate). Operators were permitted to use external laryngeal manipulation in order to improve the glottic view or to facilitate intubation. If the operator removed the GVL blade or ETT from the mouth, this was counted as an additional attempt at intubation. We stopped any attempt that lasted more than 150 seconds or an attempt that was associated with cough, patient movements, peripheral oxygen saturation less than 94%, or esophageal intubation. In any such case, oxygenation with 100% oxygen and supplemental doses of propofol were given before the next attempt. If the intubation attempt took longer than 150 sec or three attempts, it was deemed a failure and the airway was then managed using any technique deemed appropriate by the attending anesthesiologist. Anesthesia was then maintained with desflurane.

Successful tracheal intubation, time to intubate (TTI), ease of intubation (as scored by the operator immediately after laryngoscopy on a 10-cm visual analogue scale [VAS]), number of intubation attempts, number of failures, C&L grades, use of external laryngeal manipulation and other events were recorded. The following other events were recorded during the procedure: cough, patient movements, bronchospasm or laryngeal stridor, mucosal or dental trauma, hemodynamic events, esophageal intubation, and peripheral oxygen saturation less than 94%. Postoperatively, bronchospasm, laryngospasm or stridor and need for bronchodilators were recorded in the recovery room.

The time to intubate (TTI) was defined as the time elapsed between inserting the tip of the GVL into the mouth and visualization of three consecutive end-tidal CO_2 waveforms on the capnograph. The TTI was not revealed to the operator until after the data collection had been completed.

Mucosal or dental trauma was defined as the presence of blood on the tip of the GVL, oropharyngeal bleeding, or dental extraction. The occurrence of bronchospasm, stridor, or mucosal or dental trauma was an indication for stopping the attempt. Hemodynamic events were defined as any deviation of heart rate or mean arterial blood pressure of more than 30% from baseline values. The data collection sheet also included a blank "comments" box where operators could add comments.

STATISTICAL ANALYSIS

The primary outcome variables were the rate of successful intubation and the TTI. Pre-specified secondary outcomes for each group included: The number of attempts made, ease of intubation, C&L grade, and whether external laryngeal manipulation was used.

Data are presented as mean ± standard deviation (SD) and number of patients (%). For normally distributed values, between- and within-group comparisons were performed using unpaired and paired Student's t-test, respectively. The Fischer exact method was used for comparison of two proportions. The TTI and the ease of intubation VAS were compared using the Mann-Whitney U test. Kaplan-Meier plots were constructed to graphically represent the temporal component of intubation.

For sample size calculation, we defined the difference of ten seconds in TTI to be considered clinically significant. The TTI and SD were estimated from two previous human studies [3, 22]. Results were considered statistically significant when $P < 0.05$.

RESULTS

There was no significant difference in the two groups in regards to age, sex, height, weight, body mass index, mouth opening, thyromental distance, presence of teeth, neck motility, smoking history, and Mallampati class 1 and II distribution (Table **1**). There were more patients with a Mallampati classification grade III in the placebo group compared with the rocuronium group (P<0.001).

The main results are summarized in Table **2**. The success rate of GVL tracheal intubation was 100% in the placebo and in the rocuronium group. The failure rate of intubation on the first attempt was 8% in both groups (not significant [NS]). The number of intubation attempts, need for laryngeal manipulation, the C&L view and the TTI (53±15s vs.55±18s [p=0.63]) were equal in both groups (Fig. **1**). The mean VAS

Table 1. Characteristics of the Patient and their Airway Classification

	Placebo (n=26)	Rocuronium (n=26)	P Value
Age, yr	65±13	66±14	0.68
Weight, kg	88±19	87±19	0.82
Height, cm	173±7	177±8	0.11
Body mass index, kg/m^2	28±6	27±5	0.42
Male	24	24	1
Female	2	2	1
Mallampati class			
I	9 (35%)	10 (39%)	0.2
II	12 (46%)	17 (61%)	0.09
III	5 (19%)	0 (0%)	<0.001
Thyromental distance, cm	6.7±1	6.6±1	0.87
Mouth opening, cm	4.9±0.9	4.9±1	0.93
Free neck flexion	21 (81%)	21 (81%)	1
Resricted neck flexion	5 (19%)	5 (19%)	1
Teeth present	13 (50%)	12 (46%)	0.9

Values are mean ± standard deviation or number of patients (%). Because of rounding, adding percentages may not provide a sum of 100%. Results were considered statistically significant when $P < 0.05$.

Table 2. Comparison of GlideScope® Tracheal Intubation between Patients With and Without Muscular Relaxation

	Placebo (n=26)	Rocuronium (n=26)	P Value
Successful Intubation	26 (100%)	26 (100%)	1
Time to intubate, s	53±15	55±18	0.63
Number of attempts			
1	24 (92%)	24 (92%)	1
2	2 (8%)	2 (8%)	1
Dose of Propofol, mg	197±37	129±36	<0.05
Dose of fentanyl, µg	138±60	129±36	0.63
Vocal cords open during entire intubation	17 (65%)	26 (100%)	<0.001
Laryngeal manipulation	4 (15%)	4 (15%)	1

Values are mean ± standard deviation or number of patients (%). Because of rounding, adding percentages may not provide a sum of 100%. Results were considered statistically significant when $P < 0.05$.

for ease of intubation between both groups was likewise similar in both groups (1.7± 0.7cm vs. 1.8± 1cm [p=0.63]) (Fig. **2**). The vocal cords were open in 100% of patients in both groups upon insertion of the GVL. Brief partial vocal cord closure after introduction of the ETT into the hypopharynx was seen in 35% of patients in the placebo group compared with 0% in the rocuronium group (P<0.001). Interestingly, the operators were able to successfully pass the ETT smoothly and without force through the vocal cords in all the patients, so that the TTI was not prolonged in these patients compared to the rocuronium group (p=054).

There was no significant difference in TTI between patients with a Mallampati oropharyngeal view I, II or III (54±20s vs. 56±17s vs. 46±10s [p=0.42]). There also was no significant difference in the TTI in patients with teeth compared to patients who were edentureless (50±12s vs. 55±17s [p=058]). Furthermore, there was no difference in the TTI in obese patients (BMI >30kg/m^2) and non obese patients (BMI < 30kg/m^2) in both groups and in the groups combined (54s±16 vs. 54±19s [p=0.95]).

Of the 52 patients only four patients weren't intubated on the first attempt (two in each group). In two patients of the

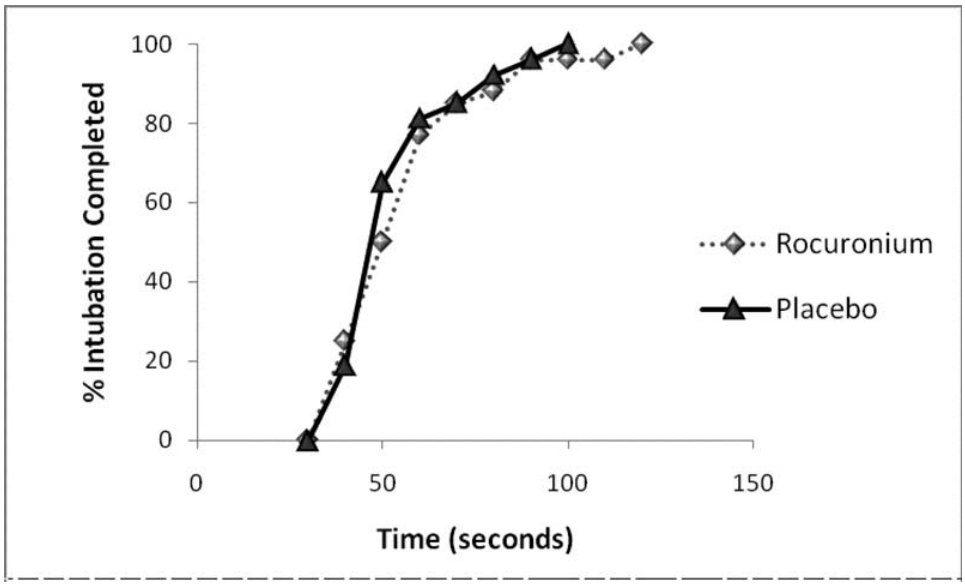

Fig. (1). Kaplan-Meier plots comparing the time to successful completion of tracheal intubation with the GlideScope® with and without muscular relaxation. There was no statistical difference between the groups.

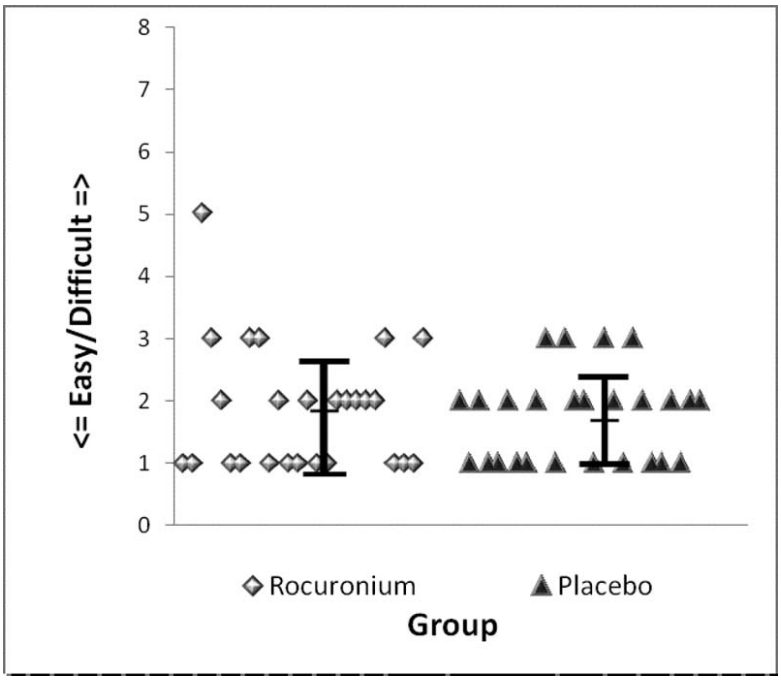

Fig. (2). Ease of intubation operators as measured on a 10-cm visual analogue scale (VAS) by GlideScope®. The VAS score was marked "easy" at 0 cm and "most difficult" at 10 cm. The Bars indicate median and 25th and 75th percentiles. There was no statistical difference between the groups.

placebo group and one patient of the rocuronium group a C&L grade I view was achieved but the ETT was withdrawn and reinserted to achieve a more favorable alignment of the ETT with the glottis opening. In one case of the rocuronium group the GVL had to be adjusted to improve a C&L grade 3 view to a C&L grade 2 view so that tracheal intubation became achievable.

Since the amount of induction agent was not a standardized number, but the anesthesiologist administering the anesthesia medications could choose between a range of drug per kilogram, we examined the total dose and the per kilogram dose of midazolam, fentanyl and propofol in both groups. There was no difference in total dose and dose per kilogram of midazolam and fentanyl, but the placebo group received significantly more propofol than the rocuronium group (198±38mg vs. 129±36mg; 2.4±0.6 mg/kg vs.1.5±0.3mg/kg [$p<0.05$]).

Events during the intubation attempts occurred more frequently in the placebo group (Table **3**). The total percentage of events was 81% in the placebo group and 35% in the rocuronium group ($p<0.001$). Patients in the placebo group were more likely to move or cough during the attempt than in the rocuronium group (58% vs. 8% [$p<0.001$]). Interestingly, none of these patients moved or coughed before the ETT actually passed the vocal cords and was inserted into the trachea. The incidence of hemodynamic disturbance was not significantly different between the groups (23% vs. 26% [$p=0.23$]). Moreover, there were no apparent cases of mucosal, dental or other airway trauma, desaturation, esophageal intubation or bronchospasm in either group.

Postoperatively all the patients were woken up in the operating room, extubated and transported to the recovery area. None of the patients in recovery demonstrated laryngeal stridor or bronchospasm, needed bronchodilators or needed to be reintubated.

DISCUSSION

The main finding of our study is that omitting muscle relaxants during the induction of anesthesia does not affect the success rate of tracheal intubation when the GVL is used in patients with presumed normal airway anatomy. This finding is important, since it confirms that a normal airway can be managed effectively and successfully without the paralyzing effects of muscle relaxants when a GVL is used. Moreover, the results indicate that intubating conditions for GVL laryngoscopy were not negatively affected by non-relaxation of the oropharyngeal and laryngeal muscles. In fact, the C&L view and the need for laryngeal manipulation did not differ between the 2 groups demonstrating that GVL laryngoscopy enables the operator to consistently achieve an excellent view of the glottis opening regardless of muscular relaxation. These findings are comparable to the results of Cooper *et al.* [1] who found a C&L grade I view in 92% of 728 paralyzed patients examined.

In addition, the TTI and number of intubation attempts also did not differ between both groups. The TTI in our study is comparable to the TTI in previous reports [2, 16, 23] with the small differences possibly being explainable with mildly modified definitions of TTI. These results emphasize that the lack of oropharyngeal and laryngeal paralysis does not lead to poorer intubation conditions after the induction of general anesthesia with the GVL. However, it remains unclear whether induction of anesthesia itself created a degree of muscular relaxation that led to similar intubating conditions compared to the relaxed patients. According to the study design a range of 1-3 mg/kg propofol was administered by the attending anesthesiologist who knew the randomization during the induction of anesthesia. The exact dose was chosen by the attending anesthesiologist to provide an adequate depth of anesthesia for tracheal intubation without creating cardiovascular side effects. Patients without muscle relaxants received significantly higher doses of propofol. This higher dose of propofol has likely contributed to the equal success rate of tracheal intubation and TTI in both groups by relaxing the oropharyngeal and laryngeal muscles enough to perform laryngoscopy and to pass the ETT. This is consistent with a previous study that indicates that increasing doses of propofol improve intubating conditions [12]. Furthermore, the vocal cords were open in all patients in both groups upon initial GVL laryngoscopy. The vocal cords tensed into a partially closed position in 9 out of 26 patients (35%) in the placebo group when the ETT touched the supraglottic laryngeal structures. The operators recorded that the vocal cords opened with gentle advancement of the ETT in all 9 patients and that the trachea was intubated smoothly and without force. This observation indicates that the induc-

Table 3. Events During GlideScope® Tracheal Intubation

	Placebo (n=26)	Rocuronium (n=26)	P Value
Coughing/moving	15 (58%)	2(7%)	<0.001
Hemodynamic changes	6 (23%)	7 (27%)	0.23
Esophageal intubation	0 (0%)	0 (0%)	1
Airway trauma	0(0%)	0 (0%)	1
Peripheral oxygen satutation < 94%	0 (0%)	0 (0%)	1
Bronchospasm	0 (0%)	0 (0%)	1
Total events	21 (81%)	9 (35%)	<0.001

Values are number of patients (%). Because of rounding, adding percentages may not provide a sum of 100%. Results were considered statistically significant when $P < 0.05$.

tion of anesthesia relaxed the laryngeal muscles to the degree that tracheal intubation was possible, but did not immobilize them.

Cardiovascular side effects were not significantly different in the two groups despite the difference in the dose of propofol. There was no difference in heart rate, arterial blood pressure and peripheral oxygen saturation between the two groups. These findings indicate that the range of induction agent used in both groups was appropriate.

Furthermore in our study, obese patients were equally distributed and the TTI and the intubation attempts were not different when compared with the non-obese patients. This is an important finding considering a previous study has demonstrated that difficult intubation had an incidence of 15.5% in morbidly obese patients [22]. Our TTI are similar to previous reports of videolaryngoscopy in obese patients [23]. Likewise we did not find a difference in TTI between patients with and without teeth and in patients who had a Mallampati class I, II and III airway in the placebo group compared to the rocuronium group. Since we had only 5 patients with a Mallampati class III and no patients with a Mallampati IV airway more studies are necessary to evaluate the effect of muscular relaxation on GVL intubation in these patients. Likewise, we only studied patients with apparently non-difficult airway anatomy. In a recent study, GVL use significantly improved the glottis view in paralyzed patients with an anticipated difficult airway [24]. Further clinical studies under controlled settings will be necessary to evaluate if the GVL success rate and TTI are similar in patients with difficult airway anatomy with and without muscular relaxation.

There are some limitations in our study, and the major one is that it could not be double-blinded. In an attempt to perform an operator blinded study, we tried to keep the study group a secret for the operator. Unfortunately, it became evident that all patients with body or vocal cord movements were in the placebo group.

Since previous studies looking at intubation times with airway devices have suggested a learning curve for the operators at the start of the study [25], we analyzed the data from patients and found no significant changes in the TTI in the operators with increasing number of intubations.

AUTHORS CONTRIBUTION

Kay B. Leissner helped design the study, conduct the study, analyze the data, and write the manuscript. He has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files

Sascha Beutler helped conduct the study and write the manuscript. He has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Luca Bigatello helped write the manuscript. He has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Venkatesh Srinivasa helped conduct the study and write the manuscript. He has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

CONCLUSION

In conclusion, the rate of success and the TTI of GVL assisted orotracheal intubation are similar in patients with apparently normal airway anatomy with or without muscle relaxation. Omitting muscle relaxants is associated with a higher rate of events such as patient movement.

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