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S-Guide® : Comparaison du S-Guide avec le Gliderite®, dans l'intubation au vidéolaryngoscope chez des patients aux voies aériennes difficiles simulées

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UNIVERSITE DE LAUSANNE - FACULTE DE BIOLOGIE ET DE MEDECINE

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Service d'Anesthésiologie

**S-Guide® : Comparaison du S-Guide avec le Gliderite®, dans l'intubation
au vidéolaryngoscope chez des patients aux voies aériennes difficiles
simulées**

THESE

préparée sous la direction du Professeur Patrick Schoettker

et présentée à la Faculté de biologie et de médecine de
l'Université de Lausanne pour l'obtention du grade de

DOCTEUR EN MEDECINE

par

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***Comparing S-Guide® and Gliderite™ times to assist
videolaryngoscopic intubation in patients with simulated
difficult airways. A single blinded randomized prospective study***

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*pour Le Doyen
de la Faculté de Biologie et de Médecine*


*Monsieur le Professeur John Prior
Vice-Directeur de l'Ecole doctorale*

Full title: Comparing S-Guide® and Gliderite™ times to assist videolaryngoscopic intubation in patients with simulated difficult airways. A single blinded randomized prospective study.

C.Nkoulou, T.Maibach, I. Bathoray, N. Fournier, P. Schoettker

Short title: **Comparing S-Guide® and Gliderite® for videolaryngoscopy**

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ABSTRACT

Objective: Gliderite™, one of the first stylets designed specifically to assist tracheal intubation with non-channelled curved blades videolaryngoscopes, can cause injury. The S-Guide® is a new, malleable, intubating guide allowing oxygenation. Its soft tip is designed to prevent trauma. We aimed to compare the duration of tracheal intubation with S-Guide compared to Gliderite using a C-MAC® D-Blade® videolaryngoscope in patients with simulated difficult airways.

Methods: We performed a single blinded prospective randomised study, with 50 adult patients requiring orotracheal intubation under general anaesthesia in Lausanne University Hospital. A cervical collar was fitted around patient's neck to simulate difficult intubation conditions. Exclusion criteria were ASA>3, BMI > 35 kg/m², known or at risk of difficult intubation and risk of aspiration of gastric content. We recorded T1: Time to identification of the glottis; T2: time to inflate the cuff and T3: total intubation time (capnography curve appearance). Secondary outcomes were the presence of arytenoid contact during intubation and post-operative airway discomfort

Results: There were no significant differences between T1 and T2 (sec) while using the S-Guide or Gliderite respectively: 14.6 [9.6–18.6] vs 16.5 [11.0–20.6]; $P=0.368$ and 43.3 [33.2–49.3] vs 46.3 [35.6–61.5], $P=0.308$. T3 (sec) was shorter in the S-Guide group: 58.1 [50.2–61.8] vs 65.3 [57.6–78.7], $P=0.044$. Fewer arytenoid contact occurred during intubation using the S-Guide ($P=0.032$), without difference in post-operative airway discomfort.

Conclusion: S-Guide assisted tracheal intubation, with a C-MAC D-Blade in simulated difficult airways, allows successful and faster intubation than with the Gliderite Stylet.

KEY WORDS: videolaryngoscopic intubation, difficult airways, intubation trauma, stylet

Main Points:

The S Guide is a new malleable, intubating stylet, with a soft coloured tip, designed to prevent trauma and allowing oxygenation through its hollow lumen.

In a single blinded prospective randomised study including 50 adults, the S-Guide assisted tracheal intubation with a C-MAC D-Blade, in simulated difficult airways, allowed successful and faster intubation.

The comprehensive uses of the newly designed S-Guide for intubation will need further investigation.

Introduction

Tracheal tube introducers (TTI or bougie) and stylets are essential tools in difficult airway management (1,2) with reported success rates from 78%–100% (3–7). Various complications related to their extended use range from mild sore throat to mucosal bleeding and bronchial or palatopharyngeal perforation (8,9).

First described in 1949 by Sir Robert Macintosh, while using a urethral catheter (hence the popular term of Gum Elastic Bougie or GEB), improvements in manufacturing, technology and understanding airways have resulted in numerous modifications of the original device (10). TTI and stylets have proven useful with newer airway management techniques, such as indirect or video-laryngoscopy (VLS), which allow intubation without a direct view of the glottic opening (6,11–15). To increase success rates, videolaryngoscope manufacturers and experts have advocated tube guidance with the help of a dedicated stylet or bougie (6,11–15) to assist intubation with unchanneled VLS. Questions remain about optimal angulations, length, structure, stiffness and the type of extremity which should be used for these intubation aids (14,16,17).

The manufacturer of the Glidescope® has specifically designed a reusable stylet for VLS (18). The Gliderite® Rigid Stylet (33) is reusable and more rigid than standard malleable stylets. Its length of 266 mm and outer diameter allows railroading a tube size 6 and greater. The distal curvature approaches 90° and its radius of curvature is approximately 6 cm. It does not allow oxygenation (19) (Verathon Medical Inc. BWU: GlideScope video intubation system-operator and service manual). The potential for injury has however been highlighted, despite its specific design (20–23).

The 15 French (Fr) S-Guide® is a new single use, flexible, multifunctional intubating guide (24) (VBM Medizintechnik GmbH, Einsteinstrasse 1, D-72172 Sulz a.N.). Its colour-coded soft tip (24) is designed to prevent trauma during intubation (see Image 1 and image 2). Its metallic core allows malleability with shape-retention (25) and oxygenation is possible through its hollow lumen (24). Recent developments have allowed two new sizes to be produced (11 Fr and 8 Fr), allowing railroading of tubes sized respectively 4.5 and 3.0.

To the best of our knowledge, there is no available evidence comparing the performance of the 15 Fr size intubating guide with an established intubation stylet to assist VLS intubation.

We hypothesised that, in a simulated difficult airway setting, the total time for intubation using a C-MAC D-Blade would be significantly shorter if the intubation procedure was assisted with the S-Guide stylet instead of the Gliderite. Through observation of the intubation technique, we also took an interest in post-operative throat discomfort, and tried to see if there was any correlation with arytenoid contact.

We aimed to conduct a single blinded randomised controlled trial to compare the S-Guide intubating guide with the specifically designed Gliderite® stylet to assist C-MAC® D-blade® videolaryngoscopic tracheal intubation for patients with simulated difficult airways.

Methods

All procedures performed in this study involving human participants were in accordance with the ethical standards of the Human Research Ethics Committee of the Canton Vaud (July, 7th 2015, protocol 267/15, Chairperson Prof. Patrick Francioli) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all subjects participating in the study. The study was registered prior to patient enrolment at www.clinicaltrials.gov (NCT02519647, Principal investigator: Schoettker Patrick, Date of registration: August, 11th 2015). This prospective, patient-blinded, randomised controlled trial was designed to compare time necessary to intubate, success rates, ease of intubation and post-operative complications due to tracheal intubation assisted by the S-Guide or the Gliderite using the C-MAC D-blade in patients with a difficult airway simulated by a cervical collar (11,26). We included 50 adult patients, with ASA physical status 1 to 3, scheduled for elective surgery at Lausanne University Hospital and requiring orotracheal intubation under general anaesthesia (Fig. 1). Exclusion criteria were patients with a BMI > 35 kg/m², known difficult intubation, an interdental distance (IDD) < 3.5 cm, a thyromental distance (TMD) < 6 cm or at risk of aspiration of gastric content. Patient recruitment and follow up took place from August 1, 2015 until June 2, 2016.

The anaesthesia protocol has been published previously (26,27). A cervical collar was fitted around patients' necks before intubation in order to reduce mouth opening and limit cervical movement in order to simulate a difficult airway, as already published in a previous study (26). Patients were randomly assigned to the Gliderite or S-Guide group using a computer-generated randomisation list (www.randomization.com). The disclosure of the intubating device was done by the supervisor just before the beginning of each procedure. Thus the patients stayed blinded while at that point the operator wasn't anymore. Gliderite and S-Guide were available as part of our department's equipment and were bought at market price.

All tracheal intubations were performed using a standard 6.5 mm cuffed tube for women patients and a 7.5 mm tube for men (Mallinckrodt® Hi-Contour Oral Tracheal Tube Cuffed; Covidien llc, 15 Hampshire Street, Mansfield, MA, USA). The Gliderite and S-Guide were lubricated with silicon spray before insertion into the tube and used according to manufacturers' instructions.

The timer was started on contact with the C-MAC (T0). Time to identification of the glottis was recorded as T1 (expressed as median seconds [25th;75th]), and time to blocking the cuff was recorded as T2. Time to ventilation was defined as the time needed to see the end-expiratory CO₂ curve on capnography and also represented the total intubation time T3 (time to CO₂) as defined in our previous protocol (26)

Success and the number of attempts necessary were recorded. Tracheal intubation was considered as failed if it could not be accomplished within 3 minutes or in the event of a desaturation ($\text{SpO}_2 < 92\%$).

All patients' tracheas were intubated, under the first author's supervision, by trainee anaesthetists to avoid a potential bias towards any specific equipment that senior anaesthetists could have. All had at least one year's experience in anaesthesia and had used the C-MAC D-blade more than five times previously in a clinical setting. Both the intubating doctor and the supervisor assessed the subjective ease of the intubation procedure on a scale from 1 (very easy) to 5 (very difficult). Ease of insertion of the D-blade, ease of glottis identification and ease of insertion of the tracheal tube through the tracheal inlet were also assessed. The supervisor also recorded whether there was contact with the arytenoid during the intubation process.

Post-operative discomfort was assessed 24 h after intubation, identifying presence of a sore throat (pain score from 1–5), hoarseness, dry throat or dysphagia.

The primary outcome was the total intubation time. Secondary endpoints included successful intubation and number of attempts necessary, the times for glottis identification, inflating the cuff and apparition of end-expiratory CO_2 , as well as the subjective ease of intubation and post-operative discomfort.

Sixteen different anaesthetists took part in the study, each performing from 1–8 tracheal intubations, reflecting the clinical setting of a teaching hospital center. At the end of the study, the anaesthetists involved were asked to rate the devices they had used and give one positive and/or one negative comment about the device of their choosing.

Statistical analysis

Based on a reference established by Bathory et al. (26), in a similar model of difficult intubation, we identified a 20% shorter intubation time for the S-Guide group to be clinically relevant.

Sample size calculation yielded a required sample size of $n = 25$ per group to detect statistically significant group differences with an α error of 0.05 and a power of 80%.

All statistical analyses were performed using Stata software (v. 14.2, StataCorp, College Station, TX, USA). Categorical data are presented as raw frequencies and relative percentages. Distribution differences in the categorical data between two or more independent groups were assessed using the Chi-squared test, or Fisher's exact test in cases of insufficient sample size. Distributions of continuous data were first evaluated using Normal QQ-plots. Gaussian distributed data were summarised as mean, standard deviation (SD) and range, whereas non-Gaussian distributed data were summarised as median, interquartile range (IQR) and range. Differences in means between two independent groups of Gaussian distributed data were assessed using Student's t-test; for non-Gaussian distributed data, the non-parametric Mann-Whitney-Wilcoxon rank-sum test was used. A P -value < 0.05 was considered statistically significant. The presence of statistically significant differences of co-founding factors between the two groups in terms of ASA status, weight, height, and factors predictive of difficult intubation, were tested also tested through student's t-tests and Mann-Whitney-Wilcoxon tests.

Results

Fifty patients were randomly attributed to two groups without any statistically significant differences noted in terms of sex, ASA status, weight, height, and factors predictive of difficult intubation (Table 1).

All the patients' trachea were intubated successfully except for one patient in the Gliderite group. For this particular individual, tracheal intubation was eventually successful using the S-Guide as a rescue tool. None underwent desaturation.

No significant differences were measured in times for glottis identification T1 (sec): 14.6 [9.6–18.6] vs 16.5 [11.0–20.6]; $P = 0.368$, or cuff blocking T2 (sec) 43.3 [33.2–49.3] vs 46.3 [35.6–61.5]; $P = 0.308$, for the S-Guide and Gliderite groups respectively (Fig. 2). The total intubation time (time to CO₂), T3 (sec) was significantly shorter in the S-Guide group: 58.1 [50.2–61.8] vs 65.3 [57.6–78.7]; $P = 0.044$.

Concerning our secondary endpoints, the trainee anaesthetists and supervisor subjectively considered the tracheal intubation to be significantly easier with the S-Guide (Table 2). There were no differences between the two groups with regards to D-blade insertion difficulty or glottis identification.

Significantly less contact with the arytenoids was observed with the S-Guide (13 vs 20; $P = 0.032$). Postoperatively, S-Guide group patients experienced overall less discomfort yet not significantly, as no significant correlation was established (Table 3).

Decreased trends for each individual variable assessed were reported (Table 4).

Overall, anaesthetists favoured usage of the S-Guide (nine rated the S-Guide higher than or at least equal to the Gliderite; six only used one of the devices and could therefore not compare; one rated the Gliderite higher).

Negative comments concerning the S-Guide included the potential need for a “three-handed intubation procedure”, with the third hand mainly needed to withdraw the S-Guide to allow for tube movement (two negative comments). Two anaesthetists made negative comments about the soft-tipped curved end and two complained about an involuntary rotation movement of the S-Guide within the tube.

Negative comments about the Gliderite mainly concerned difficulties in positioning the tube between the vocal cords, and the need to sometimes forcefully withdrawal the device after tracheal intubation.

Discussion

Recent studies highlighted that differences in tracheal intubation times were dependent on devices and operators (11), especially when using VLS technology instead of Macintosh intubation.

This randomised controlled trial shows that the success of tracheal intubation performed with a C-MAC D-Blade in patients with a simulated difficult airway was not significantly different between the use of a 15 Fr S-guide and a Gliderite. Although, tracheal intubation times were significantly shorter in the S-guide group, we did not demonstrate the 20% time reduction of the total time of intubation (T3), initially expected while designing the present study.

Tracheal intubation for VLS requires tube handling and positioning to allow delivery through the tracheal inlet. While anatomical visualisation using unchannelled VLS can generally be described as good, the success rate of tracheal intubation increases with the usage of a stylet or bougie (13). Various authors have described specific distal curvatures, ranging from 60° to 90° (28), but no specific curve has shown overall superiority. The S-Guide was used according to the manufacturer's instructions and bent by the user into a hockey stick shape (24), which is slightly less angulated than the Gliderite.

Subjectively, the colour-coded soft tip of the S-Guide allowed anaesthetists easier positioning in front of the tracheal inlet, better aim and positioning between the vocal cords, streamlining the process of tracheal intubation. A similar technique could not be achieved with the Gliderite, which could furthermore lead to potential airway trauma, due to its rigidity and hard tip.

Stylet assisted tracheal intubation for VLS has been described as responsible for airway trauma (8,9). Our study revealed no significant differences in post-operative airway discomfort with regards to sore throat, throat pain score, hoarse voice or dysphagia. However, every single item showed a diminished incidence in the S-Guide group. Less arytenoid contact was described in the use of the S-Guide, whereas no significant correlation could be established between arytenoid contact and post-operative discomfort. A soft-tipped bougie and associated lower arytenoid contact might be independent characteristics contributing to a decrease in post-operative airway discomfort, although this has variable origins, ranging from mucosal lacerations to arytenoid dislocation. The present study documented no clinically relevant injuries, and all tracheal intubations were performed safely.

The present study has some limitations. First, our study simulated difficult airway management by using a semi-rigid collar, limiting mouth opening and neck extension. It did not assess the S-Guide's performance in comparison with the Gliderite in a variety of difficult intubation scenarios. In cases involving airway malignancies or disrupted anatomy, the performances of both devices might differ from our results, and this needs further assessment.

Second, although we were able to show a statistically significant time reduction in the S-Guide group, a difference of 7 seconds might not be clinically relevant. We however believe that a reduction of more than 10% of the total intubation time contributes to better airway management in patients with simulated difficult airways.

Third, no significant differences in post-operative airway discomfort were revealed in this study. Yet, our study wasn't powered to assess potential outcome on throat injury and the sample size was relatively small. New studies should be carried out in different clinical cohorts, especially with the newly sized paediatric 11 Fr and neonatal 8 Fr. S-Guide have been made available on the market (24). Follow-up multi-center study is necessary to generalise the conclusion of this study

Furthermore, even though oxygenation is possible through its hollow lumen, no patient presented episodes of desaturation in any group. Further investigations are necessary to assess the clinical significance of this option.

Fourth, the Gliderite stylet was originally designed to assist intubation using the GlideScope® VLS. Yet, in our study, we used a single videolaryngoscope model which was the C-Mac with D-Blade. This might be seen as a potential bias as the curvature differs between the two set-ups(29).

Finally, although every effort was taken to minimise any conflicts of interest, the present study's senior author was part of the S-Guide's design team. This might have influenced results in terms of a bias in the intubating anaesthetists' responses. However all procedures were performed by trainee anaesthetists, thus reducing the risk of any consolidated preference for any specific intubation system. In addition, the senior anaesthetist was neither present in the operating theatre when intubation was performed, nor was he involved in data collection.

Conclusion:

The use of the newly designed S-Guide compared to the Gliderite for successful intubation will need further investigation. The S-Guide stylet can be seen as a new helpful tool in the management of the difficult airway available to the anaesthetist, intensivist or the emergency physician. Its single use profile can be seen as an advantage in pandemic situation(30).

Recent case reports have shown the S-Guide utility either in a out-of-hospital emergency settings (31) or in a situation of subglottic stenosis (32). Its colour coded soft tip is considered as an advantage to ease its precise positioning between the vocal cords without fearing of hurting them and its malleability might help to overcome anatomic barriers in the oropharyngeal tract.

This study did not assess the possibility of oxygen delivery through the S-Guide. While this option is a promising tool for patients with low oxygen reserve, its usefulness is also expected in situations where the intubation procedure is feared to be time consuming.

These clinically relevant advantages represent an opportunity for further research.

Based on the present findings, our department has added the S-Guide to its range of primary learning tools for dealing with difficult airway, especially for young trainees less experienced.

Emphasis on understanding, teaching and training has further been implemented.

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Conflicts of interest: The present study's senior author was part of the S-Guide's design team. However, he did not participate in any intubations or data collection himself.

Clinical trial number and registry URL: NCT02519647 www.clinicaltrials.gov

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33. Gliderite [Internet] Verathon Inc. 20001 North Creek Parkway Bothell, WA 98011©2021. Disponible sur <https://www.verathon.com/gliderite-rigid-stylet/>

Table 1. Characteristics of patients randomly assigned to Gliderite or S-Guide. Data are shown as number (percentage), mean value, median, standard deviation (SD) and IQR [range]. Abbreviations: TMD=thyromental distance, IDD=interdental distance

	Gliderite (n=25)	S-Guide (n=25)	p value
Sex			
Female	11 (44.0)	9 (36.0)	
Male	14 (56.0)	16 (64.0)	0.564
Weight in kg			
	72, 75.3	74, 73.7	
	(16.8) 65–82	(14.3) 62–85	
(median, mean, (SD), IQR, [range])	[50–128]	[48–99]	0.961
Height in cm			
	172, 170.9	170, 169.1	
	(9.6) 164–178	(9.7) 165–175	
(median, mean, (SD), IQR, [range])	[154–186]	[148–185]	0.586
BMI, in kg/m²			
	24.7, 25.7	24.5, 25.7	
	(5.0) 22.0–27.5	(4.9) 21.8–29.4	
(median, mean, (SD), IQR, [range])	[19.8–39.1]	[19.3–36.2]	0.977
Age in years			
	55, 55.3	61, 58.2	
	(15.1) 46–66	(15.8) 49–66	
(median, mean, (SD), IQR, [range])	[23–92]	[28–91]	0.610
ASA status			
I	1 (4.0)	0 (0.0)	
II	19 (76.0)	20 (80.0)	
III	5 (20.0)	5 (20.0)	1.000
Mallampati score			
1	9 (36.0)	7 (28.0)	
2	14 (56.0)	15 (60.0)	
3	3 (8.0)	2 (8.0)	
4	0 (0.0)	1 (4.0)	0.905
TMD in cm			
	7.5, 7.6	7.5, 7.4	
	(0.6) 7.0–8.0	(0.5) 7.0–8.0	
(median, mean, (SD), IQR, [range])	[6.5–9.0]	[6.5–8.5]	0.466
IDD in cm			
	4.2, 4.0	4.2, 4.2	
	(0.7) 3.5–4.5	(0.6) 3.9–4.5	
(median, mean, (SD), IQR, [range])	[2.4–5.8]	[2.8–5.6]	0.315

Table 2. Intubation characteristics data are shown as number and percentage ()

	Gliderite (n=24)	S-Guide (n=25)	p value
Insertion difficulty scale			
[intubator]			
1	7 (29.2)	9 (36.0)	
2	8 (33.3)	8 (32.0)	
3	5 (20.8)	4 (16.0)	
4	4 (16.7)	4 (16.0)	0.977
Visualisation difficulty scale			
[intubator]			
1	9 (37.5)	8 (32.0)	
2	10 (41.7)	12 (48.0)	
3	5 (20.8)	4 (16.0)	
4	0 (0.0)	1 (4.0)	0.897
Passage difficulty scale			
[intubator]			
1	3 (12.5)	10 (40.0)	
2	12 (50.0)	5 (20.0)	
3	4 (16.7)	4 (16.0)	
4	5 (20.8)	6 (24.0)	0.081
Insertion difficulty scale			
[supervisor]			
1	9 (37.5)	8 (32.0)	
2	7 (29.2)	6 (24.0)	
3	3 (12.5)	6 (24.0)	
4	5 (20.8)	5 (20.0)	0.835
Visualisation difficulty scale			
[supervisor]			
1	9 (37.5)	8 (32.0)	
2	6 (25.0)	6 (24.0)	
3	7 (29.2)	9 (36.0)	
4	2 (8.3)	2 (8.0)	0.973
Passage difficulty scale			
[supervisor]			
1	7 (29.2)	10 (40.0)	
2	4 (16.7)	5 (20.0)	
3	9 (37.5)	6 (24.0)	
4	4 (16.7)	4 (16.0)	0.774

Table 3. Throat soreness post-intubation related to arytenoid contact. Data are shown as number (percentage) or median, IQR [range].

	No arytenoid contact	Arytenoid contact	<i>p</i> value
Sore throat (post-intubation)			
(at day 1)			
No	11 (68.8)	18 (54.6)	
Yes	5 (31.3)	15 (45.4)	0.343
Sore throat pain score (if any)	4.0, 2.0–5.0	2.0, 1.0–3.0	
(median, IQR, [range])	[2.0–6.0]	[1.0–4.0]	0.069

Table 4. Post-intubation results. Data are shown as number (percentage) or median, IQR [range]			
	Gliderite (n = 24*)	S-Guide (n = 25)	p value
Sore throat (post-intubation)			
No	12 (50.0)	17 (68.0)	
Yes	12 (50.0)	8 (32.0)	0.200
Sore throat pain score (if any)			
(median, IQR, [range])	2.0, 1.5–3.5 [1.0–6.0]	2.0, 2.0–4.0 [1.0–5.0]	0.760
Hoarse voice			
No	19 (82.6)	21 (84.0)	
Yes	4 (17.4)	4 (16.0)	0.897
Dry throat			
No	8 (33.3)	11 (44.0)	
Yes	16 (66.7)	14 (56.0)	0.444
Expectorations			
No	22 (91.7)	25 (100.0)	
Yes	2 (8.3)	0 (0.0)	0.235
Dysphagia			
No	19 (79.2)	23 (92.0)	
Yes	5 (20.8)	2 (8.0)	0.247
Any of the above complications			
No	5 (20.8)	8 (32.0)	
Yes	19 (79.2)	17 (68.0)	0.376
Arytenoid contact			
No	4 (16.7)	12 (48.0)	
Yes	20 (83.3)	13 (52.0)	0.032

Figure 1. Consort Flow Diagram

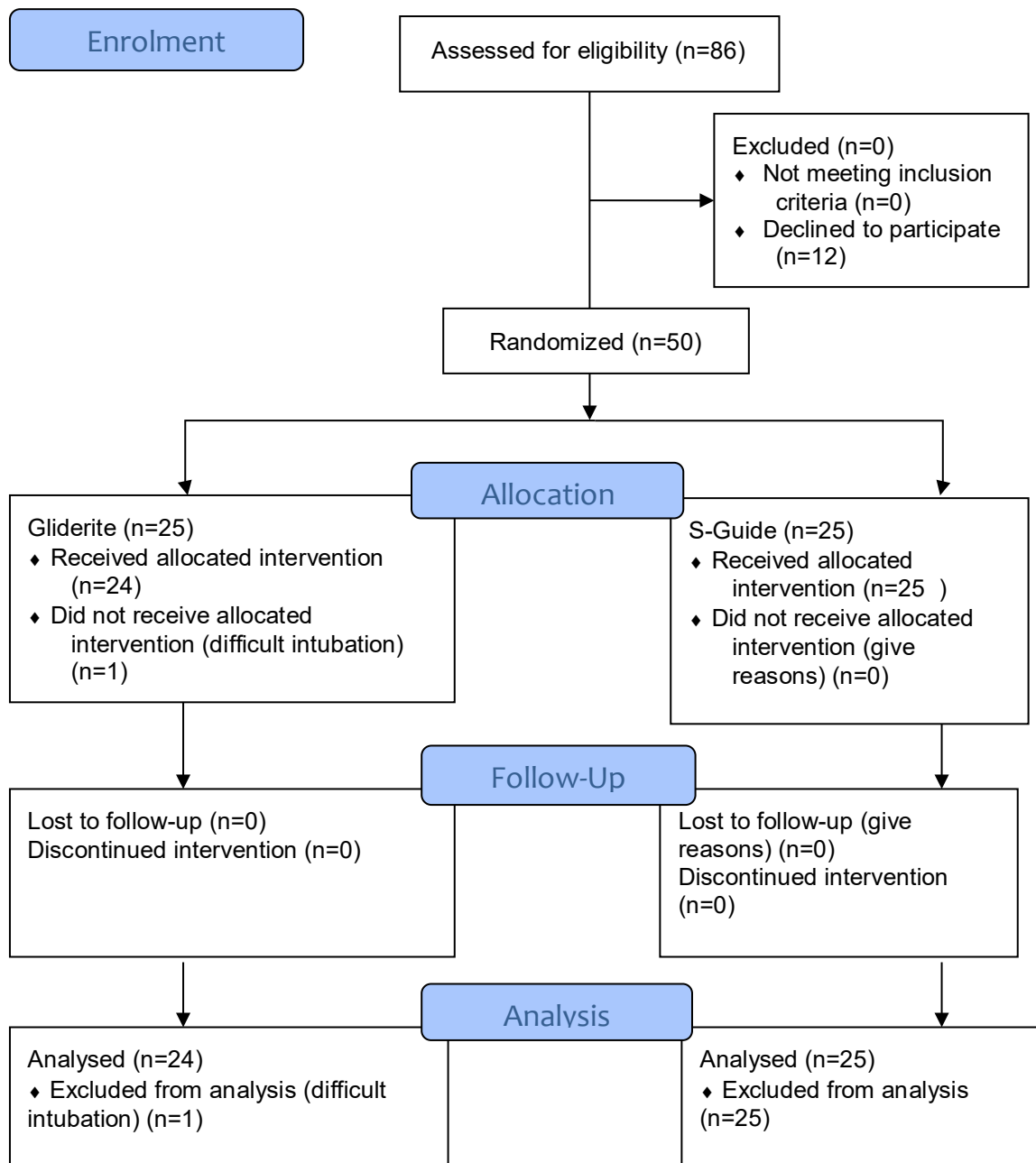
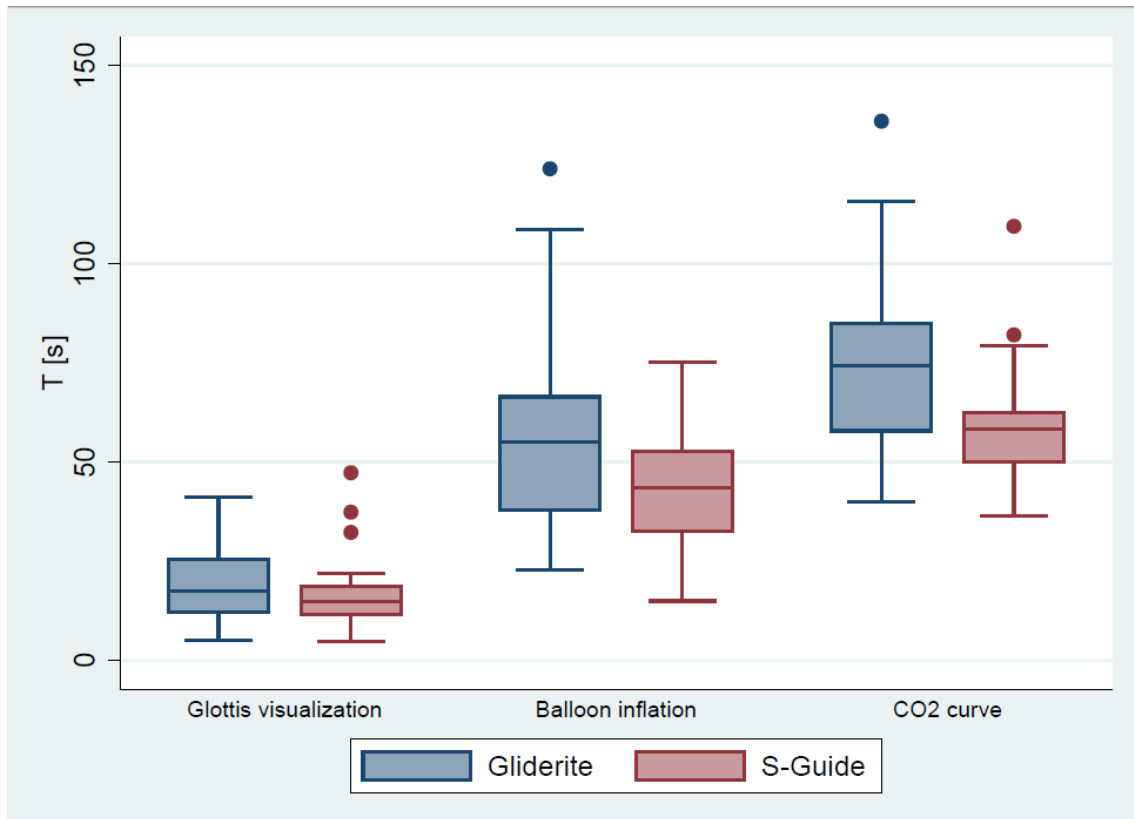


Figure 2. Times to Glottis identification, balloon inflation and CO2 curve



Images 1 and 2 : S-Guide® sized-color-coded soft tip with oxygen flow openings (24)

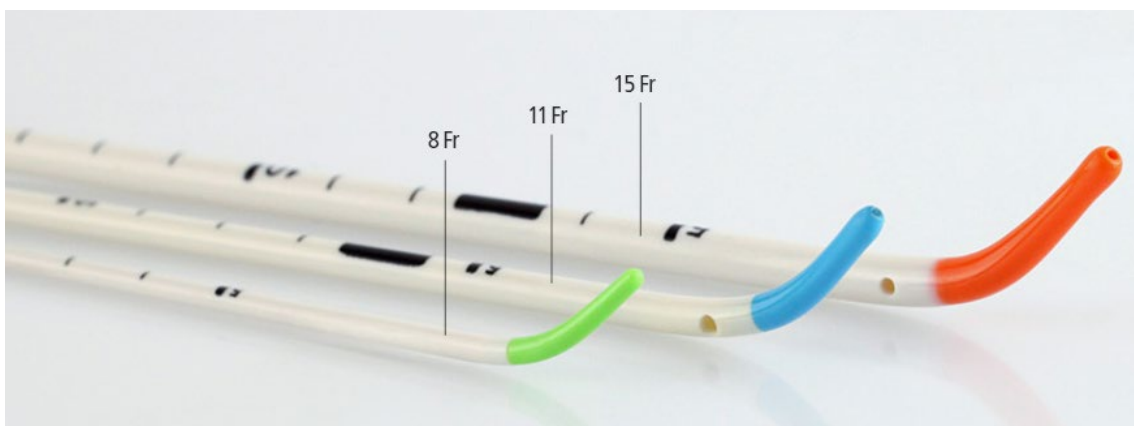


Image 3: Gliderite™(33)

