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► To cite this version:

Corinne Lejus-Bourdeau, Nicolas Grillot, Ségolène Dupont, Vincent Robert-Edan, Olivier Bazin, et al.. Randomised comparison of Enk™ and Manujet™ for emergency tracheal oxygenation with a high-fidelity full-scale simulation. *Anaesthesia Critical Care & Pain Medicine*, 2020, 39, pp.807 - 812. 10.1016/j.accpm.2020.01.011 . hal-03493188

HAL Id: hal-03493188

<https://hal.science/hal-03493188>

Submitted on 15 Dec 2022

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Randomised comparison of Enk™ and Manujet™ for emergency tracheal oxygenation with a high-fidelity full-scale simulation

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Financial Disclosures: None

Conflicts of interest: None

Clinical trial number and registry URL: not applicable

Abbreviated Title (running head): Enk™ or Manujet™ for emergency tracheal oxygenation

Authors' contribution to the manuscript:

CLB designed the study, wrote the research protocol, contributed to the data collection, conducted the statistical analysis and wrote the manuscript.

NG participated in the interpretation of the results and the proof-reading of the manuscript.

SD participated in the data analysis and writing of the article.

VRE assisted in the writing of the research project and in the data collection.

OB and SV participated in the data collection.

VP participated in the design of the study, project writing, data collection, interpretation of the results and manuscript review.

Acknowledgement to Dr Didier Péan, M.D., Service d'Anesthésie Réanimation Chirurgicale, Hôtel Dieu, CHU Nantes, co-founder of LE SiMU de Nantes, who prematurely died.

Abstract

Background: We aimed to compare time and difficulties of emergency tracheal oxygenation with Enk™ or Manujet™ by anaesthesiologists or intensivists, in a full-scale cannot ventilate and intubate scenario on a SimMan3G™ high-fidelity patient simulator.

Methods: After ethical committee approval and written informed consent, teams (two to three learners with at least one physician senior) participating at a difficult airway training with a massive sublingual haematoma scenario, were randomised in Enk™ (E) group (29 teams, 76 learners) and Manujet™ (M) group (31 teams, 84 learners) according to device at disposal. Main criterion was time between taking device in hand and first insufflation delay. Data were medians [25 - 75%].

Results: The handling-insufflation time was shorter with Enk™ than with Manujet™ (74 [54 - 87] s *versus* 95 [73 - 123] seconds (s), $P = 0.0112$). The team number performing insufflation within one minute after device handling was higher in the E group (8, 27.6 %) than in the M group (6.4, %) ($P = 0.0392$) as well as the team number performing insufflation within 90 s in the E group (22, 75.09%) than in the M group (12, 38.7%) ($P = 0.0047$). In E group, 75% of learners reported no difficulty *versus* 58.8% in M group ($P = 0.0443$). Insufflation frequency was high in both groups and higher than 12/minute in 51.7% of the teams.

Conclusion: In a simulation context, Enk™ use is faster and easier. A high insufflation rate was also in favor of Enk™ that generates lower airway pressures.

Keywords: anaesthesia; difficult airway; intubation; safety, high-fidelity simulation

Introduction

Major progress has been made over the last decade in the management of difficult adult airways. The “cannot intubate cannot ventilate” situation has become rare with paradoxically thereby decrease of the experience of practitioners [1]. In this situation, if supraglottic airway ventilation is unsuccessful, difficult intubation algorithms advocate emergency airway access including surgical [2] or percutaneous tracheotomy cricothyroidotomy, or jet ventilation [3-4]. The latter technique involves blowing oxygen under pressure through a 13 or 15 gauge catheter introduced through a needle, after puncture of the cricothyroid membrane while waiting for a surgical tracheotomy [5]. The use of hand-held devices expose to severe complications and justifies the use of a specific device such as the Manujet™ (VBM, Vitrolles, France) or the oxygen flow modulator Enk™ (Cook, Charenton, France) [6]. Given the critical emergency context in which they are used, the only data available on these two devices result from animal studies [7-8] or lung simulator [9-11]. Their effectiveness on the pig is equivalent [7,12]. In an artificial lung model, the pressures generated by the gas trapping by the two devices increase with the frequency and duration of the insufflation, but the risk of barotrauma is lower with the Enk™ [10]. This single use device is compact and requires only connection to an oxygen flow meter. We hypothesise that in a life-threatening critical situation, the Enk™ ergonomics allow oxygen insufflation to be faster than with the more complex Manujet™. Because of the rarity and severity of this situation, this assumption is impossible to verify in clinical practice. The main objective of this prospective randomised study was therefore to determine the faster transtracheal

oxygenation technique (Enk™ or Manujet™) in a full-scale high-fidelity simulation using a standardised scenario of a massive sublingual haematoma. Secondary objectives were to identify the difficulties observed and felt by professionals in the use of each of the devices.

Materials and methods

This monocentric randomised open study was performed in our University high-fidelity simulation centre, after approval of our Institutional Ethic Committee (Group of Ethics in the field of Health, 27th of March 2013).

The health professionals included in the study were participants in two continuing education programs. The first education program (Formation de référents aux techniques d'intubation difficile or FRTID), a three-day course in January 2013 and 2014 previously described in Brisard et al.'s paper [13] was exclusively dedicated to train anaesthesiologists, emergency physicians or intensivists in difficult air way management and include conferences, workshops, adult and paediatric training on inert manikins before participation to high-fidelity training. The second program took place between January and December 2017. These one-day courses consisted of high fidelity-full-scale simulation training in crisis operative theatre management for anaesthesiologists, graduates or end of course residents, and nurse anaesthetists. The participants to this course received eLearning consisting of a slide show on trans-tracheal oxygenation techniques and devices, the week before the training. Both courses included full-scale high simulation training with a standardised “cannot ventilate cannot intubate” scenario. The participation to the study was proposed

before the training to all health care professionals who participated to this scenario. Inclusion was made after informed written consent. Exclusion criteria were refusal to participate in the study. In this case, the learner participated in the simulation but his/her data was not analysed.

Training process

Each workshop was preceded by the presentation of the simulation environment and the patient simulator, the study and information about educational objectives, audio-video recording and modalities of debriefing. Learners were asked not to broadcast the content of the scenarios and verbalise aloud their decisions and actions. The team participating in the scenario included two to three learners, with at least one senior emergency physician, anaesthesiologist or intensivist. One of the investigators played the role of a nurse. A debriefing on technical and non-technical skills took place at the end of each scenario.

High-fidelity patient simulator and environment

The study was conducted on a SimMan3G™ patient simulator (Laerdal Medical, Stavanger, Norway). Briefly, airway configuration, pulmonary and cardiac auscultation, chest movements could be modified to simulate labial or pharyngeal oedema, intubation difficulties, vocal cord closure, laryngospasm, bronchospasm, or respiratory distress. It was possible to mobilise the head in extension and rotation, to sublunate the mandible, to introduce a gastric tube and to use all the airway management devices. Perioral cyanosis occurred when oxygen percutaneous saturation (SpO₂) was below 85%. A microphone built

into the simulator allowed the audition of pre-recorded sounds. The evolution of haemodynamic (electrocardiogram, blood pressure) and ventilatory parameters (respiratory rate, SpO₂, capnogram, inspiratory and expiratory oxygen concentrations) were displayed on a monitoring screen.

Scenario

The scenario took place in the recovery room and began with the call for help from the nurse, in front of an acute respiratory distress, after extubation in a 24-year-old woman who had undergone general anaesthesia for surgical placement of dental implants. Airway distress was due to the rapid formation of a sublingual massive haematoma, allowing neither face mask ventilation nor the introduction of a laryngoscope. The haematoma was simulated by a ball of red and blue modeling clay wrapped in a plastic film and inserted into the mouth. The picture of a patient with a sublingual haematoma was shown on a screen to emphasise the lack of possibility of ventilation and intubation by the usual techniques. The expected reactions of the learners were the awareness of the life-threatening prognosis situation and implementation of trans-tracheal oxygenation. The participants had to ask for the difficult intubation trolley, puncture the cricothyroid membrane, prepare the trans-tracheal oxygenation device and start tracheal oxygen insufflation. The evolution of the simulator was programmed, so as to be strictly comparable in all tests. At the entrance of the participants in the recovery room, the SpO₂ was at 92%, the heart rate at 100 and the blood pressure at 140/80 mmHg. Then desaturation continued with initial tachycardia and then extreme bradycardia when SpO₂ was less than 60%.

Material under study

Learners were assigned with a balanced computer randomisation by block of four to the Manujet™ (M) group or Enk™ (E) group according the device available in the difficult intubation trolley (Figure 1).

The Manujet™ (VBM Vitrolles, France), presented in a suitcase, has an inlet tube for connection to a 4-bar oxygen source (wall outlet or cylinder), a pressure regulator, a handle and a connection tube to the ventilation jet catheter. An integrated manometer allows to adjust the working pressure between 0 and 3.5 bars. The device is manually activated using a trigger on the handle. According to the manufacturer, a pressure of 1 s delivers 350 milliliters (ml) of oxygen when the working pressure is set between 2.5 and 3 bars.

The Enk™ Oxygen Flow Modulator (Cook, Charenton, France), presented in sterile disposable packaging, is a tube with 5 holes located on both sides of the duct. Both ends are connected respectively to the oxygen supply connection and the tracheal catheter. The flow of oxygen must be between 15 and 30 liters/min. Oxygen is delivered to the patient by covering the holes with thumb and index fingers. A pressure of 1 second theoretically delivers 250 ml of oxygen.

A cognitive aid describing the functioning and the modalities of insufflation (frequency, duration of insufflation) accompanied each of the devices. The puncture needle (Cook, Charenton, France) was the same in both cases.

Evaluation

The primary endpoint was time between handling of the bag or the suitcase containing respectively the Enk™ and the Manujet™, and the first effective insufflation that was observed and verbalised aloud by the nurse. The secondary evaluation criteria were time between decision-making and handling, handling and puncture, puncture and insufflation and decision-making and insufflation, the frequency of difficulties of use and non-compliance with the recommendations felt by the learners and observed by the investigator. The scenario data was collected on live by one of the investigators. An audio-video recording was also made for the control and prevention of data loss. In addition, at the end of the scenario, each participant fulfilled a questionnaire specifying his demographic data, the nature of his previous learning before the present course and experience of the two devices under study, their role and the difficulties encountered during the simulation training.

Statistical analysis

The statistical analysis was performed using the Statview® 5 (Abacus Concept, Inc. Berkzley CA) software. Data were medians (percentiles 25-75%) and number (proportion, %) of participants or team according data. The number of team or participants to include in this study was determined using the primary endpoint. The mean value of the time handling – first insufflation with the Manujet™, was 180 ± 50 s in adult difficult airway previous workshops with the same scenario (unpublished personal data, 2012). Fifteen teams were needed by group to objective a 30% difference (i.e. 60 s) with a 5% α risk, a β risk of 10% and

a two-tailed test. However, as the program and context of the three-day and one-day trainings were different, we choose to include 30 teams in each group with a stratification of the course. Comparative analysis between E and M group was made with U Mann and Whitney test, Qui₂ or contingency table as appropriate. $P < 0.05$ was considered as significant.

Results

Finally, the study included 161 participants, i.e. 76 in the E group (29 teams) and 85 in the M group (31 teams). Demographic data of the participants (table 1) were similar in both groups. The majority of participants (55.3%) were graduate anaesthetist physicians with a median duration of experience of 12 (5 – 25) years. In each group, eleven teams participated to a three-day course and the others (18 in the E group and 20 in the M group) to a one-day course. Half of the participants, i.e. 36 (50.7%) in the E group and 39 (51.3%) in the M group ($P > 0.9999$), had already followed a training with a high-fidelity patient simulator. Most participants (93.7%) had available in their structure a difficult intubation trolley, but 76 (47.5%) participants had no available tracheal oxygenation device. The Manujet™ was more often available (45.6%) than the Enk™ (6.8%). Previous theoretical training for both devices before the study was not different between groups. The only difference was the shorter time since last Manujet™ theoretical training ($P = 0.0378$) in the E group (12 (6.2 – 24) months) than in the M group (24 (12 – 60) months).

The participants reported essentially Manujet™ (45.6%) and Enk™ (15.5%) theoretical training. Practical training was described mainly for Manujet™ on inert manikins (21.2%) or on high-fidelity simulation (10.6%). Only 2.5% of the participants experienced training on cadavers. Among graded physicians ($n = 114$), only 22.8% previously benefited from a theoretical and practical training on at least one transtracheal oxygenation device; 49.1% of them received neither theoretical nor practical training before the present course. Previous

experience with Enk™ and Manujet™ was not different between groups. Respectively, 8.7% and 31.0% of the participants, and 8.7% and 30% of the participants had already used the Enk™ and the Manujet™ on a patient, with a delay of 18 (9 – 24) and 42 (24 -133) months.

In six cases (2 in the E group and 4 in the M group), video recording could not be completed due to a technical problem. The median difference between direct and video time measures (i.e. decision-handling, handling-puncture, and puncture-insufflation) was 0 (-5, 6) s and was not different between M and E groups. Also, the 6 cases were kept in intention to treat with the direct observation data. The data used for all other cases were those of the video recording.

The handling-insufflation time (main criteria) and decision-insufflation time were shorter in the E group because of a shorter handling-puncture time than in the M group (table 2). Decision-handling and puncture-insufflation times were not different. The team number performing insufflation within one minute after device handling was higher in the E group (8, 27.6 %) than in the M group (6.4, %) ($P = 0.0392$), as well as the team number performing insufflation within 90 seconds in the E group (22, 75.09%) than in the M group (12, 38.7%) ($P = 0.0047$).

Manikin and scenario realisms were equally and highly graded by participants of both groups (Table 3). Just over half of the participants in each group considered that they had respected the recommendations of cognitive help. Deviation to recommendations was essentially a too high insufflation rate. The usability score was higher for the Enk™ than the

Manujet™ as well the number of users who judged they had not encountered any difficulty with the device use.

Incidence of difficulties observed by the investigators was not different between both groups (Table 4). Main problems were a too high insufflation rate and rotation upside down when the participants tried to Manujet™ pressure.

Discussion

The main message of this study is that a better ergonomics of Enk™ allows a faster emergency transtracheal oxygenation than Manujet™ when compared during a full-scale high-fidelity simulation of “cannot intubate cannot ventilate”. A twenty-second benefit may seem low, but the use of Enk™ has practically doubled the number of teams able to achieve insufflation in less than 90 s. The average time to intercricothyroid membrane puncture on fresh cadavers by novice residents is about 20 s after the 4th attempt [14]. The later puncture observed with Manujet™ seemed probably due to a longer focus of the entire team on the preparation of the device. Only the most expert teams were able to simultaneously prepare the device and puncture the membrane.

The main difficulty with the Manujet™ was the adjustment of the manometer pressure, which requires a pull on the adjustment button followed by its rotation and locking. The pressure recommended by the manufacturer for adults (2 -2.5 bar) is indicated on the pressure gauge by a green zone. This is already very high and a lower level (1.5 bar) is recommended to limit barotrauma [10]. Misuse of this adjustment results in excessive pressure being applied or makes the device unusable if the ball-bearing compartment is accidentally opened by improper rotation. Another difficulty was the oxygen supply. Connecting the Enk™ to a simple flow meter is easier than connecting the Manujet™ to an oxygen bottle connector.

The insufflation frequency recommended by the manufacturer of Manujet™ is 60 per minute. But on an artificial lung model, when airway is partially occluded, lung pressure

increases with insufflation rate with both devices while they are higher with the Manujet™. In case of total obstruction, mean airway pressure dramatically increases even with Enk™ with a rate of twelve insufflations per minute [10]. A frequency of about four insufflations per minute limits the pressure rise.

Despite cognitive help recommending one-second breaths with a frequency between 4 and 8 per minute, insufflation rate was excessive in at least half of the cases. This observation highlights the potential dangerousness of the technique, which may lead to a preference for cricothyroidotomy [15]. The superiority of jet ventilation or cricothyroidotomy has not been demonstrated [6, 16-19]. Nevertheless, high-pressure oxygenation is only a temporary solution before the arrival of a pickling surgeon to perform a surgical tracheotomy. In pre-hospital situation, cricothyroidotomy is preferred as it is more adapted to a transfer of the patient.

One strong point of this evaluation is the realisation of the test in team, in full-scale simulation, by a large number of professionals, with varied previous experiences and training, which is in favour of the generalisation of our results. Inclusion of participants was not limited to anaesthesiologists insofar as “cannot intubate, cannot ventilate” could occur in pre-hospital critical situations or in intensive care unit [20].

Very few comparative data are available at Enk™ and Manujet™. Emergency transtracheal oxygenation training is usually conducted on inert low fidelity simulator and cadaver. But these educational methods ignore the emotional component and the stress generated by a vital distress, which are better integrated by a full scale simulation on a high-

fidelity patient simulator [21-22]. A single simulation training session improves resident's compliance with difficult airway management guidelines with a retention period of at least one year [22]. In one study, Enk™ is compared with three other emergency airway accesses on the METI high-fidelity human patient simulator in a "cannot intubate cannot ventilate" scenario by ten anaesthesiologists without any previous training, with a median time of around 100 s to achieve a patent airway [23]. But each anaesthetist repeats 4 times the trial with the same scenario, which removes any element of surprise to the learners.

The oral floor haematoma scenario, which caused the upper airway partial obstruction, was considered realistic by all participants. Although this is a rare event, it is a classic complication of endobuccal procedures eventually promoted by prior anticoagulation [23] and a scenario that can easily be repeated in simulation.

High-fidelity simulation training has developed considerably in intensive medicine as evidenced by previous training for one out of two participants. While keeping in mind that a clinical study on patients is impossible, we must remain cautious about extrapolating our results to real clinical situations. In particular, the cricothyroid membrane of SimMan3G™ is easily identifiable, which is not always the case in "cannot ventilate cannot intubate" situations, such as angioedema. Severe complications are favoured by catheter malposition, which justifies the Anglo-Saxon recommendations to recommend a direct tracheal approach [3,20,24]. Indeed, an aspiration test through the needle and catheter, recalled in the cognitive aid, was not systematically carried out.

This work also highlights the insufficient training in rescue oxygenation despite recommendations. The Enk™, a recent relative device, was still rarely present in the participants' intubation trolleys. On the other hand, almost half of the participants had a Manujet™ available in their structure. As expected, few practitioners already had the opportunity to use it. On the other hand, the proportion of professionals who had already received training was surprisingly low, despite the inclusion in the study of a majority of anaesthetists who had graduated more than 10 years earlier. The need for repeated training should be emphasised when the use of equipment is both rare and indicated in life-threatening situations [25, 14].

Conclusion

In conclusion, in a full-scale high-fidelity simulated situation, the Enk™ transtracheal oxygenation device is easier to use than the Manujet™. The direct consequence observed in high-fidelity simulation is a faster implementation of transtracheal oxygenation. The misuse observed with Enk™ as with Manujet™, and potential source of severe complications questions us about the benefit risk ratio of trans-tracheal technical oxygenation that could be evaluated through a comparative study in the same condition with the insertion of a cannula via cricothyroidotomy allowing conventional ventilation.

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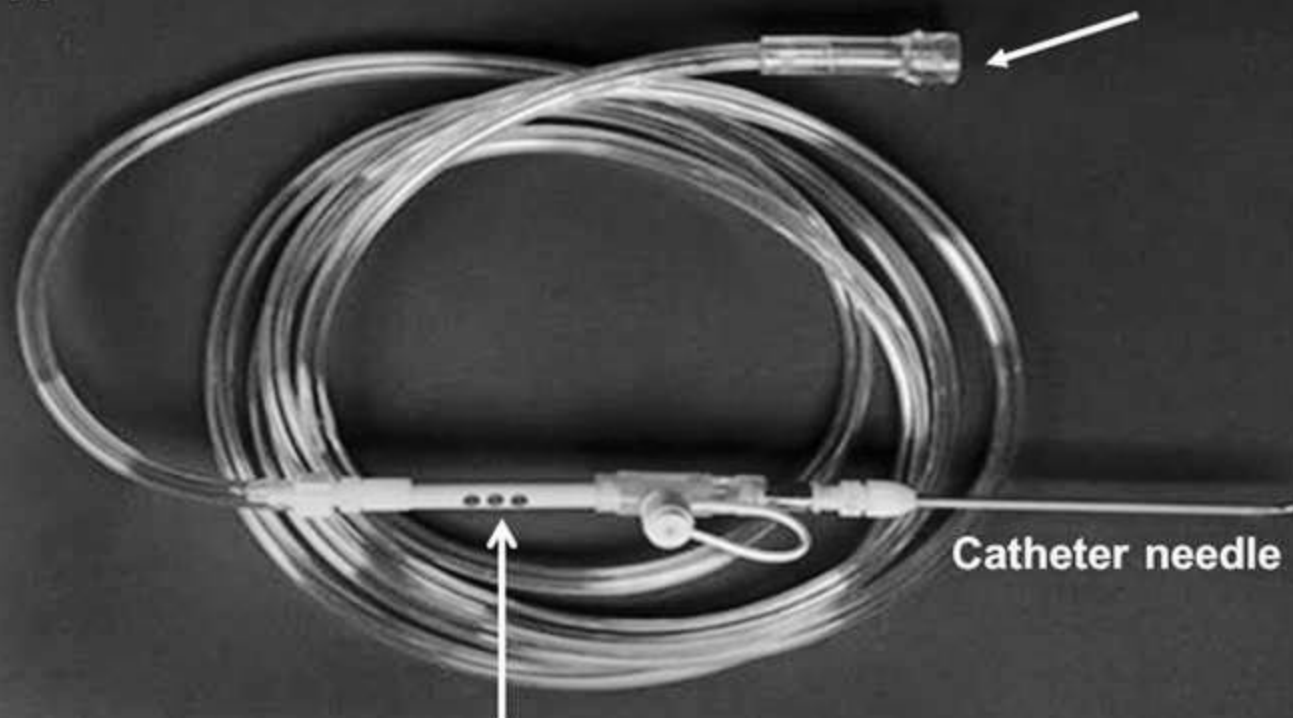
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Figure 1: Transtracheal oxygenation devices: A. Enk™, B. Manujet™

A

Oxygen connecting tube



5 holes to be plugged, to insufflate

B

Manometer

Pressure setting

Oxygen delivery trigger

Patient

Oxygen supply

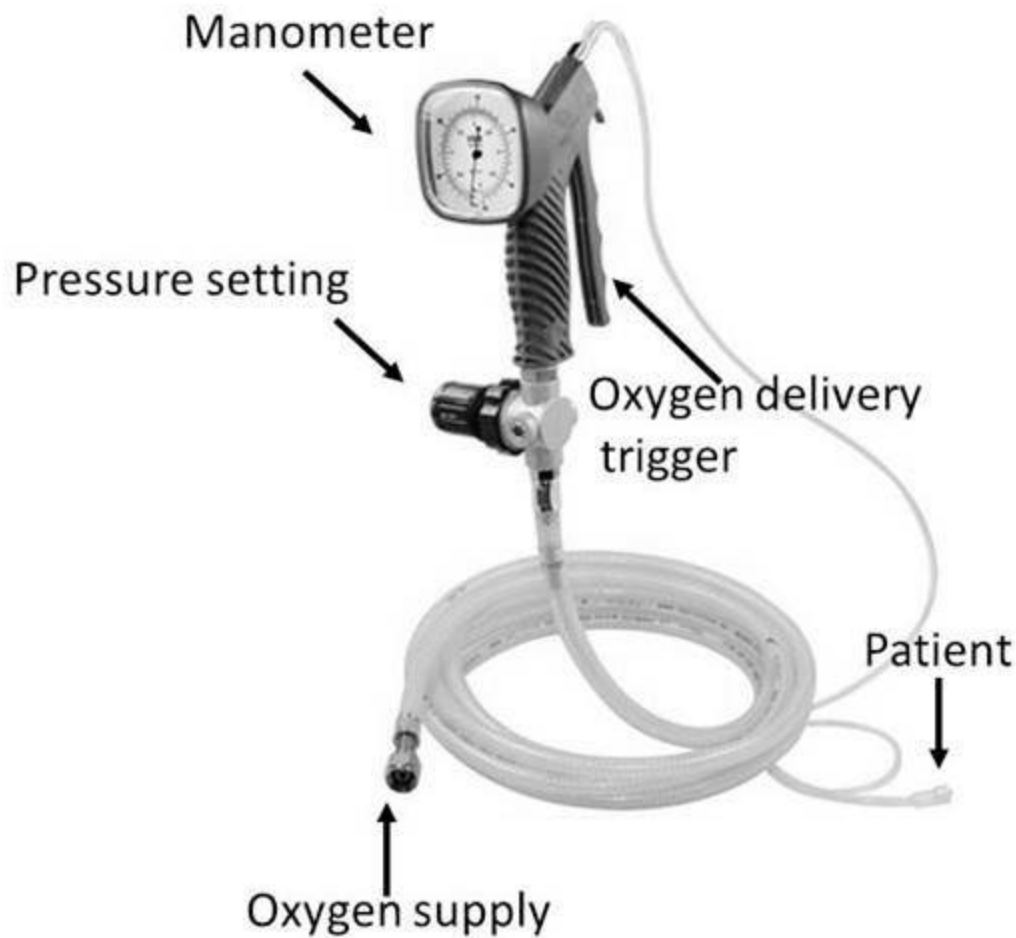


Table 1. Demographic data of participants to the study

Group	Enk™ (E) (n = 76)	Manujet™ (M) (n = 85)	P
Sex, n (%)			0.5229
Female	30 (39.5)	38 (45.3)	
Male	46 (60.5)	46 (54.7)	
Age (years)	38.5 (32-46)	39 (32.2-51)	0.3611
Profession, n (%)			
Anaesthesiologist	42 (55.3)	47 (55.3)	0.8984
Resident in anaesthesiology	9 (11.8)	12 (14.1)	
Intensivist	5 (6.6)	3 (3.5)	
Emergency Physicians	9 (11.8)	9 (10.6)	
Anaesthesiologist nurse	11 (14.5)	14 (16.5)	
Experience (years)*	14 (3.7-21.2)	12 (5-26)	0.8493
Resident semester, n	7.5 (4.5-9)	3.5 (3-6)	0.0625
Participants by team, n (%)			
Two	13 (44.8)	11 (35.5)	0.7403
Three	14 (48.2)	18 (58.1)	
Four	2 (6.9)	2 (6.4)	
Presence of a difficult airway trolley in their structure, n (%)	72 (96.0)	78 (94.0)	0.7224
Transtracheal oxygenation device in the structure, n (%)			0.7945
Enk™	5 (6.6)	5 (5.9)	
Manujet™	36 (47.4)	38 (44.7)	
Enk™ and Manujet™	0 (0)	1 (1.2)	
None	35 (46.0)	41 (48.2)	

Data are medians (25%-75%) or number (percentage) of participants

Comparison Enk *versus* Manujet groups by Mann-Whitney U test.

$P < 0.05$ was significant; *except for resident.

Table 2. Times (s) of transtracheal oxygenation with Enk™ or Manujet™ devices

	Enk™ (E)	Manujet™ (M)	P
Team (n)	(n = 29)	(n = 31)	
Decision-handling	21 (14-34)	17 (8-40)	0.6359
Handling-puncture	42 (32-62)	60 (53-98)	0.0077
Puncture-insufflation	21 (11-31)	21 (13-51)	0.2513
Decision – insufflation	88 (71-120)	130 (103-161)	0.0014
Handling-insufflation	74 (54 – 87)	95(74 – 123)	0.0042

Data are expressed by medians and percentile 25%-75%. Comparison Enk *versus* Manujet groups by Mann-Whitney U test. $P < 0.05$ was considered as significant.

Table 3. Individual response of the participants to the questionnaire

Group	Enk™ (E) (n = 76)	Manujet™ (M) (n = 85)	P
Easy use	8 (7-9)	7 (5-8)	<0.0001
Manikin realism	8 (7-9)	8 (7-9)	0.2940
Scenario realism	9 (8-10)	9 (8-10)	0.6433
Recommendation respect, n (%)	37 (54.4)	41 (56.2)	0.8666
Deviation to recommendations, n (%)			
None	31 (56.4)	35 (54.8)	0.4346
Insufflation frequency too high	18 (23.7)	16 (18.8)	0.5623
Insufflation too long	4 (5.3)	0 (0)	0.0476
Puncture without aspiration	3 (3.9)	0 (0)	0.1030
Inadequate insufflation pressure	-	2 (6.45)	-
Inadequate oxygen flow	1 (3.4)	-	-
Difficulties experienced by users, n (%)			
None	57 (75)	50 (58.8)	0.0443
Insufflation rate respect	7 (9.2)	11 (12.9)	0.6175
Insufflation duration respect	1 (1.3)	3 (3.5)	0.6227
Pressure adjustment	-	16 (18.8)	-
Inappropriate gesture	-	1 (1.2)	-
Occlusion holes	2 (6.89)	-	-
Catheter plicature	1 (1.3)	1 (1.2)	1
Difficult puncture	1 (1.3)	4 (4.7)	0.3711

Data are expressed by medians and percentile 25%-75% or number (percentage) of participants. Comparison Enk *versus* Manujet groups by Mann-Whitney U test. $P < 0.05$ was considered as significant.

Table 4. Enk™ and Manujet™ modalities and difficulties use observed by investigators during transtracheal oxygenation

All teams	Enk™ (E) (n = 29)	Manujet (n = 31)	P
Minimal insufflation rate, min ⁻¹	10 (4-21)	4 (4-15)	0.0890
Maximal insufflation rate, min ⁻¹	20 (9-32)	13 (5-28)	0.2397
Fréquence la plus importante, /min	120	200	-
Insufflation rate > 12/min, n (%)	17 (60.7)	14 (50.0)	0.5913
Work pressure > 1.5 bars, n (%)	-	13 (46.4)	-
Oxygen flow 8 liter/min, n (%)	-	1 (3.7)	-
12 liters/min	-	11 (40.7)	-
15 liters/min	-	15 (55.6)	-
Catheter connection difficulty, n (%)	1 (3.5)	3 (10.3)	0.6115
Oxygen connection difficulty, n (%)	1 (3.5)	6 (20.7)	0.1020
Overall connection difficulty, n (%)	5 (17.2)	8 (27.6)	0.5301
Rotation upside down, n (%)	-	9 (31.0)	-
Device use difficulty, n (%)	6 (20.7)	14 (45.2)	0.0579
Too long insufflation trop, n (%)	3 (10.3)	2 (6.5)	0.6658
Pressure adjustment difficulty, n (%)	-	4 (12.9)	-
No catheter retention, n (%)	4 (13.8)	4 (12.9)	>0.9999
No catheter control, n (%)	2 (6.9)	2 (6.4)	0.6990
Difficulty occlusion holes, n (%)	2 (6.9)	-	

Data are expressed by medians and percentile 25%-75% or number (percentage) of teams.

Comparison Enk™ versus Manujet™ groups by Mann-Whitney U test. $P < 0.05$ was considered as significant.