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A new option in airway management: evaluation of the TotalTrack® video laryngeal mask

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Background: The TotalTrack® Video Laryngeal Mask (VLM) is a novel airway management device consisting of a disposable laryngeal mask paired with a reusable video display. Prior to the commencement of this study, there was no published literature on the performance of the TotalTrack®.

Methods: The device was evaluated in sixty patients without predictors for difficult airway under general anaesthesia with neuromuscular blockade. Primary outcomes were laryngeal mask seal pressures and success of tracheal intubation through the device.

Results: Insertion and ventilation was successful in 98.3% of cases. Median static leak and maximal inflation pressures of the laryngeal mask component were 32 and 40 cmH₂O respectively. Tracheal intubation through the device was successful in 95% of cases, with a mean intubation time of 9.5 s. No gastric insufflation occurred. Haemodynamic variability was found to be clinically insignificant. No significant side-effects were reported.

Conclusions: In this initial study, the TotalTrack® VLM was found to be effective as a laryngeal mask airway, exhibiting good sealing pressures. It facilitated predictable, easy intubating conditions under video guidance, with minimal interruption of ventilation.

Keywords: airway management, intubation, laryngeal masks, laryngoscopes

Introduction

The TotalTrack® Video Laryngeal Mask (VLM; Medcom Flow, Spain) is a new airway management system which is designed to combine a second generation supraglottic airway with video capabilities, which allows tracheal intubation under vision. It has been proposed for use in routine airway management, for predicted difficult airways, as a rescue airway device for the unanticipated difficult airway, and for video documentation of airway management.

The TotalTrack® VLM consists of a disposable laryngeal mask in a rigid introducer. The laryngeal mask component has a supraglottic suction port, and a conduit for a nasogastric tube. A preloaded tracheal tube allows ventilation when functioning as a laryngeal mask. A reusable camera and video display (Videotrack®) is connected before each use, protected from contact with the patient by an isolated channel and clear lens. Power is provided to the Videotrack® from a battery pack in the disposable portion when the Videotrack® is inserted.¹ (Figure 1)

Although the device has been in limited clinical use with anecdotal reports of efficacy, there were no prior published case series on the use of the device prior to 2015. In order to ascertain the basic performance of the device, this study assessed the TotalTrack® in a single device descriptive trial, as suggested by publications on device testing.^{2–4} Representation of such data regarding a new device, in patients with no obvious airway pathology, allows clinicians to assess device efficacy and safety in the general population before further studies are conducted to ascertain use in difficult airway scenarios. Very recently, a series of 100 cases in Spain was published, where further trials in anticipated difficult airways are registered.⁵ Later randomised

controlled trials with comparison of the device against the gold standard in its class may be warranted if the initial trials are promising.

Materials and methods

Departmental and institutional ethics approval were granted by the University of Cape Town Human Research Ethics Committee. Three investigators with more than 5 years' experience in anaesthesia received training in the use of the TotalTrack®.



Figure 1: TotalTrack VLM® and Videotrack (left), and device ready for use (right).

Sixty patients were invited to participate, and written informed consent was obtained. This sample size was selected to balance risks of assessment of a new device against obtaining sufficient measurements for statistical analysis. Patients recruited were ASA class I or II, over the age of 18 years, with a lean body mass of 50 to 80 kg (suitable for a size 4 supraglottic airway). They had no indicators of a difficult airway or predictors of delayed gastric emptying. The elective procedure had to be of an estimated duration of 30 min to 2 h, and necessitate tracheal intubation.

Patients excluded from recruitment were those who were unable or unwilling to provide informed consent, those who were morbidly obese ($\text{BMI} \geq 35 \text{ kg.m}^{-2}$), had overt airway or neck pathology, and those with an indication for a rapid sequence induction of anaesthesia.

A standardised anaesthetic technique was used. After application of routine monitoring, haemodynamic parameters were measured and documented at 2.5 min intervals. Midazolam 1 mg was followed by induction with fentanyl $1 \mu\text{g.kg}^{-1}$ and propofol 1.5 - 2.5 mg.kg^{-1} , titrated until an adequate depth of anaesthesia was attained. Rocuronium 0.6 mg.kg^{-1} was then administered to establish neuromuscular blockade.

After TotalTrack® insertion, adequacy of ventilation was assessed by evidence of adequate bilateral chest expansion, expired tidal volumes of $\geq 6 \text{ ml.kg}^{-1}$, adequate oxygenation ($\text{SpO}_2 \geq 95\%$), and end-tidal carbon dioxide partial pressures of 4 - 6 kPa, with a normal capnograph waveform. The time period from first handling the device until adequate ventilation was achieved, was recorded.

As safety measures within the protocol, insertion and intubation processes were limited to two attempts. Failing this, the study was abandoned and standard airway management ensued.

After placement of the device, seal pressures were tested using manometric stabilisation techniques.⁶ This involved measuring the pressure at which an audible leak was heard at the mouth with fresh gas flow at 5 l.min^{-1} , and measuring maximum inflation pressure generated when using a slow manual inspiration over 1.5 to 2 s, with the adjustable pressure-limiting valve closed and fresh gas flow at 2 l.min^{-1} . If no leak was generated by $40 \text{ cmH}_2\text{O}$, testing was deemed adequate and seal pressure was documented as $40 \text{ cmH}_2\text{O}$. Readings were taken using the aneroid pressure gauge on the circle absorber system. The quality of the laryngeal mask seal was assessed in 4 different head positions: flexion, extension and 30° rotation from midline to either side, and was documented as positive or negative for the presence of a leak.^{7,8}

The presence of gastric insufflation was also assessed by auscultation over the epigastrium during manually generated pressures of up to $35 \text{ cmH}_2\text{O}$.⁹

Using the Videotrack®, the view of the glottis was graded by consensus between the two investigators present at the time, using the Cormack-Lehane scale and percentage of glottic opening (POGO) score.^{10,11} (Figure 2)

Once optimal view of the glottis was obtained, the pre-loaded tracheal tube (standard Mallinkrodt or Rüsch tracheal tube, internal diameter 7.0 to 8.0 mm, as supplied by the hospital) was advanced through the glottis. Time for intubation was measured from time of optimisation of glottic view on the Videotrack® to



Figure 2: Laryngeal view with totaltrack *in situ*.

the time of tracheal tube cuff re-inflation and confirmation of adequate ventilation. The need for any assistive device or external laryngeal manipulation to aid with tracheal intubation was documented. Video recordings of the intubation process were made. Only two attempts were allowed, and if these were unsuccessful, the device was removed and standard airway management ensued. On confirmation of placement, positive pressure ventilation was continued throughout the procedure.

A 12 French gauge nasogastric tube was then inserted through the specific conduit in the device. Insertion was graded as easy, difficult or impossible. Placement was confirmed by aspiration of gastric contents and/or auscultation over the epigastrium whilst 5 ml of air was insufflated through the nasogastric tube. Once testing was complete, the nasogastric tube was removed unless the surgical procedure required it to be left in place. At this time, the Videotrack® and rigid introducer were removed, the TotalTrack® cuff was deflated and the device was left *in situ* to enable post-procedure observations.

Towards the end of surgery, the Videotrack® was re-attached to the device and the LMA cuff was re-inflated. If secretions were present at the glottis, the supraglottic suction port of the device was tested. On return of spontaneous respiration, with the patient still anaesthetised, the tracheal tube was withdrawn through the LMA before reversal of residual neuromuscular blockade. Vocal cord function was assessed and video recordings were made.

On completion of surgery, once the patient had adequately regained consciousness, the laryngeal mask was removed. Any soiling, whether by secretions, gastric contents or blood, was documented.

Patients were followed up on the day of-, and the day following surgery. Patient-reported side-effects (including sore throat, dysphagia and hoarseness) were sought. These were graded as mild, moderate or severe. Thereafter, the patients were discharged from the study.

Statistica® (Version 12, Statsoft, Tulsa, OK, USA) was used for statistical analysis. Means and standard deviations were used to describe parametric data; medians and interquartile ranges were used to describe non-parametric data; and rates and percentages were used for success rates and nominal data. Haemodynamic

changes were analysed using repeated measures analysis of variance.

Results

Patient characteristics are represented in Tables 1 and 2. Of note, only one patient had a thyromental distance of less than 6 cm.

Haemodynamic parameters were documented pre- and post-insertion of the device as well as pre- and post-intubation, to assess for significant changes in mean arterial pressures and heart rate with insertion and/or tracheal intubation. Mean arterial pressure changes in relation to insertion of the TotalTrack® and tracheal intubation varied over a range of 90 to 99 mm Hg, while changes in heart rate varied over a range of 83 to 95 beats per minute (Figures 3 and 4).

Insertion and ventilation was successful in 59/60 cases (98.3%), and mean time to adequate ventilation was 16.8 s (range 4.0 – 52.0, SD 10.8). One case was abandoned due to difficult placement of the LMA. One patient had an episode of desaturation to 92% during insertion. No other patient desaturated to < 94% at any stage during testing. Median static leak and maximal inflation pressures of the laryngeal mask component were 32 cmH₂O (range 10.0 to 40.0 cmH₂O) and 40 cmH₂O (range 16.0 to 40 cmH₂O) respectively. Presence of leak was assessed in different head positions: flexion, extension and 30° left and right of midline. Leak was positive in 12.2% (29/236 positions in total) with the majority occurring with flexion of the head.

The view of the glottis was reported in 59/60 cases, using Cormack-Lehane grade and POGO score (Table 3).

Tracheal intubation was successful in 57/60 cases (95%), with a first attempt success rate of 86% (51/60) and mean time for intubation of 9.5 s (95% CI 14.0 – 19.7, SD 10.8). Two cases were

abandoned, since tracheal intubation could not be achieved within the two allotted attempts. In 25% (15/60) of cases the device had to be repositioned (without removal) to obtain an adequate laryngeal view.

Total apnoea time was calculated as the sum of LMA insertion and tracheal intubation times (mean 25.6 s [95% CI 20.4 – 30.9, SD 19.9]). These times were combined to allow for the fact that, although ventilation could be continued during tracheal intubation, a leak was present due to tracheal tube cuff deflation, resulting in a brief reduction in adequate ventilation.

Gastric tube insertion was successful in 91% (52/57) of cases, of which 25 had residual gastric content present. Placement was regarded as successful if auscultation over the epigastrium identified typical sounds during air insufflation via the gastric tube.

Supraglottic secretions were present in 79% of cases, and the supraglottic suction port was found to be effective in 91%. Tracheal tube withdrawal was graded as easy in 92% and effective in all cases. The glottic opening was viewed successfully in 75% (43/57) of cases post extubation. Failure to view the vocal cords was mainly due to excessive secretions which obscured the Videotrack® lens. The device was easily removed in all cases and there was no soiling of the device in 77% (44/59) of patients.

On the day of procedure, 35% (21/60) reported various grades of sore throat, 15% (9/60) reported dysphagia and 8.3% (5/60) reported hoarseness.

The 24 h follow-up report showed that 21% (13/60) still experienced sore throat, 8.3% (5/60) had dysphagia and 11.6% (7/60) were hoarse.

Discussion

The TotalTrack® VLM is a novel airway device, whose components allow for supraglottic ventilation, video-assisted laryngoscopy and intubation, placement of a nasogastric tube and supraglottic suctioning. The testing of the TotalTrack® VLM has shown that the device functions well purely as a laryngeal mask, with seal pressures comparable to that published in studies of the ProSeal™ LMA. The use of the laryngeal mask allows continuous ventilation while optimising the view for tracheal intubation. The Videotrack® provides a good quality picture with repeated use. Intubation success rates are comparable to those published in studies of the LMA Fastrach™ and CTrach™. Total apnoea time averages less than 30 s. It functions well as a bridging tool at induction and emergence.

The TotalTrack® VLM was found to be easy to insert, with only one case abandoned because the tip of the laryngeal mask folded backwards. Insertion was graded as easy in 77% of patients, and the short time taken for insertion reduced total apnoea time. Whilst haemodynamic data measured during the insertion and tracheal intubation through the device showed statistically significant differences, they were not considered to have clinical relevance.

On inspection of the laryngeal mask component, the TotalTrack® VLM closely resembles the ProSeal™ LMA (which is currently considered to be the gold standard second generation supraglottic airway), and is consistent in providing high sealing pressures. Seal pressures described in the literature regarding the ProSeal LMA vary from 22 cmH₂O to 29.5 cmH₂O.^{12–17} The

Table 1: Patient characteristics

	Mean (SD)	Range
Age (yrs)	41 (14)	18 – 73
Height (kg)	71 (14)	42 – 101
Height (cm)	167 (10)	145 – 189
BMI (kg.m ⁻²)	25 (5)	14 – 34
Neck Circumference (cm)	37 (3)	31 – 47

Table 2: Patient demographics and airway characteristics

		Number
Gender	Male	23 (38%)
	Female	37 (62%)
ASA Class	I	24 (40%)
	II	36 (60%)
Mallampati	I	37 (61.7%)
	II	17 (28.3%)
	III	6 (10%)
	IV	0 (0%)
Thyromental Distance	< 6 cm	1 (1.6%)
	≥ 6 cm	59 (98.3%)

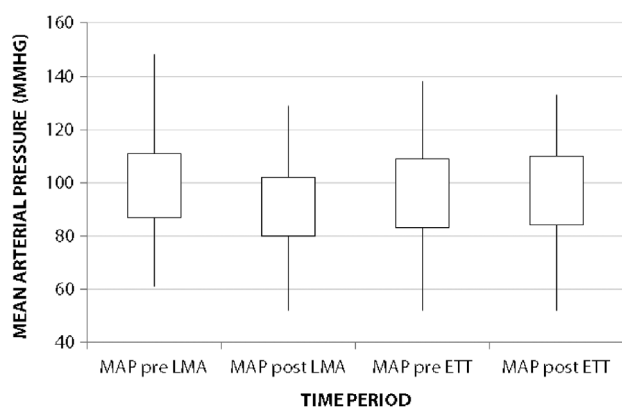


Figure 3: Mean arterial pressure variation with insertion of and tracheal intubation through the TotalTrack® VLM.

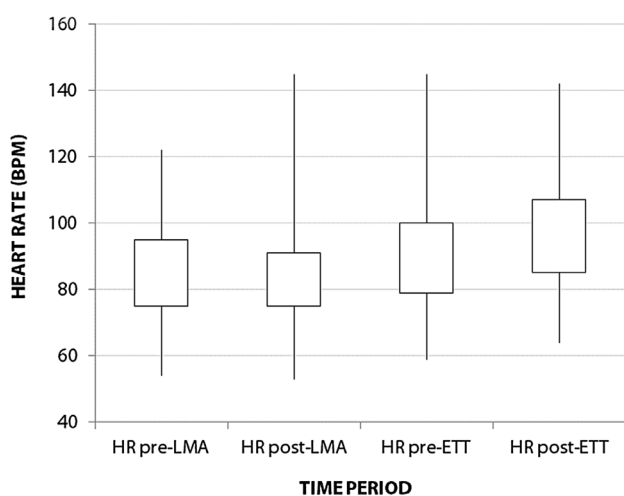


Figure 4: Heart rate variation with insertion of and tracheal intubation through the TotalTrack® VLM

TotalTrack® VLM was shown to have static leak pressures and maximal inflation pressures of above 30 cmH₂O, providing reliable seal pressures and demonstrating excellent function as a supraglottic airway. There was minimal reported leak with changes in head positions. No gastric insufflation was found in any patient.

The TotalTrack® VLM is a video-assisted intubating laryngeal mask, with the Videotrack® display and camera system isolated from the patient and therefore reusable. Whilst the current gold standard for intubating laryngeal masks is the LMA-Fastrach™, the TotalTrack® VLM most resembles the LMA-CTrach™, due to its video capabilities. The Fastrach™ has been widely assessed, with intubation success rates from 70 to 100%.¹⁸⁻²² The CTrach™ has a

reported tracheal intubation success rate of between 89.7%²³ and 96%.²⁴⁻²⁶ A direct comparison of the LMA Fastrach™ and the CTrach™ by Liu *et al.* showed an overall tracheal intubation success rate of 96% for the Fastrach and 100% for the CTrach™.²⁶ In a smaller study in morbidly obese patients, intubation was equivalent in the CTrach™ and Fastrach™ at 100% per group.²⁷ The present study of the TotalTrack® revealed similar success rates for tracheal intubation, with a 95% overall success rate, of which the majority occurred on first attempt (86%), with a mean time of 9 s. View of the glottic opening was good, with a small number requiring repositioning of the device for an improved view. In two of the abandoned cases, intubation did not occur within the two allowed attempts, despite the use of external laryngeal manipulation and the use of the supplied endotracheal tube introducer.

The time taken to insert the TotalTrack® VLM, as well as intubation through the device, was measured. While no ventilation occurred during placement of the TotalTrack® VLM, ventilation did continue during tracheal intubation, even though a leak was present due to tracheal tube cuff deflation. Due to the presence of this leak, total apnoea time was calculated from the sum of insertion and intubation times. There was a mean total apnoea time of 25.6 s. Where Liu *et al.* compared the Fastrach™ to the CTrach™, they found the insertion times of the laryngeal mask component alone averaged 23 and 25 s respectively, and tracheal intubation times averaged 100 s for the Fastrach™ and 116 s for the CTrach™.²⁶ Thus, it can be inferred that the total apnoea time for the TotalTrack® VLM was considerably shorter.

Gastric tube insertion and supraglottic suction via the two dedicated conduits were effective in more than 90% of cases. It is worth noting that while patients in the study were fasted preoperatively, 42% (25/52) had residual gastric contents. However, these residual volumes were small (2 to 40 ml), and although a quarter of devices were soiled with secretions, there was only one occurrence of soiling of the laryngeal mask with gastric content. This occurred despite the passing of a gastric tube, in a patient undergoing laparoscopic surgery. There was no evidence of tracheal aspiration.

Incidence of patient-reported side effects diminished on day 1 post anaesthesia when compared with day 0. Whilst the incidence of side effects on follow up is a concern, the frequency is similar to that of other devices in various studies.^{16,28-31} It should be noted that, in order to achieve the goals of this study, the laryngeal mask portion of the device was left *in situ* until completion of the case. In the normal clinical setting, the laryngeal mask portion can be easily removed, leaving only the endotracheal tube *in situ*. Further studies will show whether the incidence of side effects is reduced with immediate removal of the TotalTrack® VLM once tracheal intubation has been completed.

Table 3: Grading of glottic view

Grading of glottic view	Grade/Score Range	Mean (Percentage)
POGO score	100%	52 (88%)
	90 – 99%	4 (6.6%)
	60 – 89%	1 (1.6%)
	< 60%	2 (3.2%)
Cormack & Lehane grade	1	56 (95%)
	2	3 (5%)

A limitation of this study is the sample size, which does not guarantee future success rates nor allow for the rigorous assessment of safety. Whilst we have provided an initial estimate of function, this device requires further study to ascertain the appropriate applications. Comparative trials with the current gold standards of supraglottic airway devices are warranted for evaluation of its utility in the 'difficult airway' scenario.

Acknowledgements, contributions and conflicts

This manuscript is an honest, accurate and transparent account of the study. No important aspects have been omitted, and any discrepancies from the study as planned have been explained. All authors contributed to performing the study and drafting the manuscript. (JOC: protocol, data collection and capture, primary author; RH: review, data collection and verification, review of submission, editing and submission; NRE: protocol review and training of investigators; MFJ: statistical analysis; NM: principle investigator, review, editing, data collection and verification)

TotalTrack Video Laryngeal Mask equipment was provided for assessment without charge by Medcom Flow, Barcelona. The authors received no external funding and have no conflict of interest to declare.

Note

i The findings of this paper were presented in poster format at the 2015 Networking World Anaesthesia Convention in Vancouver, Canada in April 2015, at the South African Society of Anaesthesiologists National congress in Durban, South Africa in May 2015, and at the World Airway Management Meeting in Dublin in November 2015.

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