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**Clinical evaluation of the use of laryngeal tube verses laryngeal mask airway for out-of-hospital cardiac arrest by paramedics in Singapore**

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## ABSTRACT

**Introduction:** It is unclear which advanced airway device has better placement success and fewer adverse events in out-of-hospital cardiac arrests (OHCAs). This study aimed to evaluate the efficacy of the VBM laryngeal tube (LT) against the laryngeal mask airway (LMA) in OHCAs managed by emergency ambulances in Singapore.

**Methods:** This was a real-world, prospective, cluster-randomised crossover study. All OHCA patients above 13 years old who were suitable for resuscitation were randomised to receive either LT or LMA. The primary outcome was placement success. Per-protocol analysis was performed and association between outcomes and airway device group was compared using multivariate binomial logistic regression analysis.

**Results:** Of 965 patients with OHCAs from March 2016 to January 2018, 905 met the inclusion criteria, of which 502 (55.5%) were randomised to receive LT while 403 (44.5%) were randomised to receive LMA. Only 174 patients in the LT group actually received the device due to noncompliance. Placement success for LT was lower than for LMA (adjusted odds ratio [OR] 0.52, 95% confidence interval [CI] 0.31–0.90). Complications were more likely when using LT (OR 2.82, 95% CI 1.64–4.86). Adjusted OR for prehospital return of spontaneous circulation (ROSC) was similar in both groups. A modified intention-to-treat analysis showed similar outcomes to the per-protocol analysis between the groups.

**Conclusion:** LT was associated with poorer placement success and higher complication rates than LMA. The likelihood of prehospital ROSC was similar between the two groups. Familiarity bias and a low compliance rate to the LT were the main limitations of this study.

*Keywords:* intubation, laryngeal mask airway, laryngeal tube, OHCA, prehospital

## INTRODUCTION

Establishing an airway is integral in the management of out-of-hospital cardiac arrests (OHCAs). There is still some debate as to the benefit of paramedic-performed endotracheal intubation. While previous studies showed improved survival outcomes with endotracheal intubation,<sup>(1,2)</sup> recent data suggest that supraglottic airways in OHCAs result in better outcomes, likely due to reduced interruptions to chest compressions and shorter placement times.<sup>(3-6)</sup> These devices are designed to be inserted without direct laryngoscopy and do not require the level of training and experience that is required for endotracheal tube insertion.

There are several devices available on the market, including the laryngeal mask airway (LMA), VBM laryngeal tube (LT; VBM Medizintechnik GmbH, Baden-Württemberg, Germany) and the Combitube® (Tyco-Healthcare-Kendall-Sheridan, Mansfield, MA, USA). They provide a direct route of ventilation via the trachea and avoid the complication of gastric insufflation that comes with bag-valve-mask (BVM) ventilation. The LT and Combitube have a distal cuff to prevent regurgitation.

In Singapore, about 79% of patients with OHCA receive advanced airway in the form of LMAs.<sup>(7)</sup> The self-reported success rate of LMA insertion by Singapore paramedics is 50%–87%.<sup>(8)</sup> Complications reported internationally include incomplete seal and partial airway obstruction.<sup>(9)</sup> In contrast, the LT is reported to have higher insertion success rates when compared with the LMA in the prehospital setting, together with lower complications of regurgitation, vomiting and dislodgement.<sup>(10,12)</sup> The LT has also been used by minimally trained non-medical staff for OHCAs, with some success.<sup>(12)</sup> This ease of placement was associated with reduced ‘hands-off’ time during chest compressions.<sup>(13)</sup>

The present study aimed to evaluate the placement success and complication rates of VBM LT usage, as compared with the Ambu Aura-i LMA (Ambu A/S, Ballerup, Denmark), by paramedics in patients with OHCAs in Singapore.

## METHODS

We conducted a real-world, prospective, parallel-group, cluster randomised trial. All patients with OHCA aged over 13 years and attended to by the Singapore Civil Defence Force (SCDF) paramedics from March 2016 to January 2018, both medical and traumatic, were included. Patients who did not meet the criteria for resuscitation by paramedics, such as rigor mortis, decapitation and dependent lividity, were excluded. In order to achieve 80% power for detecting a difference of 15% for insertion rates and an alpha level of 0.05, we calculated that 875 patients were required, assuming a dropout rate of 20%.

Stratified randomisation was conducted with four strata based on the number of ambulances each station had, which ranged from 1–4. Block randomisation was then performed within each stratum to assign the ambulances to administer the LMA or LT. Those ambulances randomised to the LT group continued to carry the LMA as a back-up device during their runs.

Because the LT was new to the paramedics, all paramedics attended an eight-hour training programme comprising a lecture and hands-on session conducted by the study investigators and were required to demonstrate competency on a manikin before being allowed to take part in the trial. Paramedics in Singapore are taught the use of the LMA as part of their certification to be a paramedic and participants were presumed competent in the use of LMA for the purpose of this study.

Ethical approval was obtained from the SingHealth Centralised Institutional Review Board and a waiver of consent was obtained. The study was also approved by the SCDF's Medical Advisory Committee, which oversees the medical care delivered by paramedics in Singapore.

The primary outcome was placement success, and the secondary outcomes were complication rates and the presence of prehospital return of spontaneous circulation (ROSC). Per-protocol analysis was done to evaluate the results. We compared association between

outcomes and the airway device group using multivariate binomial logistic regression analysis. Statistical analysis was performed using IBM SPSS Statistics version 24 (IBM Corp, Armonk, NY, USA).

Modified intention-to-treat analysis was conducted using backward selection models as well as comparison of adjusted odd ratios to ensure robustness of models. These were adjusted for age above 65 years, gender, ethnicity, type of case, witness by paramedics, bystander cardiopulmonary resuscitation, initial electrocardiogram rhythm, collapse-to-paramedic arrival time, time at scene and paramedic experience.

## RESULTS

A total of 965 patients were recruited for the study, with 60 excluded due to reasons, such as airway devices could not be used, age less than 13 years and patients deemed not suitable for resuscitation. There were 502 patients allocated to the LT group and 403 to the LMA group. In the LT group, 174 patients actually received LT but none were lost to follow-up. Among the LMA group, 402 patients received LMA, with one patient lost to follow-up and four patients having the intervention discontinued (Fig. 1).

Per-protocol analysis was conducted. The mean age was  $69.7 \pm 16.2$  years, with 62.9% men and 37.1% women (Table I). The ethnic distribution of our cohort was similar to that of Singapore's general population. A majority of patients with OHCA were medical cases, with only 4.0% being trauma-related. Median response time of paramedics and time at scene were comparable for both groups. The median paramedic experience was 8 (interquartile range [IQR] 2–18) years for the LT group and 6 (IQR 4–16) years for the LMA group.

**Table I. Demographics and per-protocol analysis results of study population.**

Variable	No. (%)			p-value
	Overall (n = 571)	LT (n = 174)	LMA (n = 397)	
<b>Patient factor</b>				
Age (yr)*	69.7 ± 16.2	69.9 ± 16.8	69.6 ± 15.9	0.854
<b>Gender</b>				0.572
Men	359 (62.9)	106 (60.9)	253 (63.7)	
Women	212 (37.1)	68 (39.1)	144 (36.3)	
<b>Ethnicity</b>				0.487
Chinese	407 (71.3)	120 (69.0)	287 (72.3)	
Malay	83 (14.5)	28 (16.1)	55 (13.9)	
Indian	51 (8.9)	19 (10.9)	32 (8.1)	
Other	30 (5.3)	7 (4.0)	23 (5.8)	
<b>Type of case</b>				0.489
Medical	548 (96.0)	169 (97.1)	379 (95.5)	
Trauma	23 (4.0)	5 (2.9)	18 (4.5)	
<b>Witnessed by paramedics</b>				0.757
No	518 (90.7)	157 (90.2)	361 (90.9)	
Yes	53 (9.3)	17 (9.8)	36 (9.1)	
<b>Bystander cardiopulmonary resuscitation</b>				0.235
No	259 (45.4)	72 (41.4)	187 (47.1)	
Yes	312 (54.6)	102 (58.6)	210 (52.9)	
<b>Initial electrocardiogram</b>				0.953
Pulseless ventricular tachycardia	4 (0.7)	1 (0.6)	3 (0.8)	
Ventricular fibrillation	79 (13.8)	25 (14.4)	54 (13.6)	
Pulseless electrical activity	199 (34.9)	58 (33.3)	141 (35.5)	
Asystole	289 (50.6)	90 (51.7)	199 (50.1)	
<b>Operator factor</b>				
Collapse-to-paramedic arrival time (min)†	14.0 (6.5–21.5)	13.0 (5.0–21.0)	14.0 (6.8–21.3)	0.554
Paramedic time at scene (min)†	19.0 (13.0–22.0)	19.0 (12.5–22.5)	19.0 (13.0–22.0)	0.925
Paramedic experience (yr)†	6.0 (1.0–11.0)	8.0 (3.0–13.0)	6.0 (1.0–11.0)	0.109

Data presented as \*mean ± standard deviation or †median (interquartile range). LMA: laryngeal mask airway; LT: laryngeal tube

There were more successful placement attempts in the LMA group (89.4%) as compared to the LT group (82.8%) and those in the LMA group had a higher rate of first attempt success rate (75.6% vs. 66.1%) (Table II). There were fewer reported complications in the LMA group than in the LT group (91.4% vs. 81.0%,  $p = 0.001$ ). Overall, dislodgement was the most common complication ( $n = 40$ , 7.0%), followed by bleeding, incorrect placement, tongue or pharyngeal swelling, and air leak. All reported complications were higher in the LT group. About a tenth of the patients resulted in ROSC.

**Table II: Outcome measures by airway management.**

	No. (%)			p-value
	Overall (n = 571)	LT (n = 174)	LMA (n = 397)	
<b>Placement success</b>				0.068
Successful	499 (87.4)	144 (82.8)	355 (89.4)	
1st attempt	415 (72.7)	115 (66.1)	300 (75.6)	
2nd attempt	78 (13.7)	26 (14.9)	52 (13.1)	
3rd attempt	6 (1.1)	3 (1.7)	3 (0.8)	
Not successful	72 (12.6)	30 (17.2)	42 (10.6)	
<b>Complications</b>				
Complications (any)				0.001
No	504 (88.3)	141 (81.0)	363 (91.4)	
Yes	67 (11.7)	33 (19.0)	34 (8.6)	
Dislodgement				0.001
No	531 (93.0)	152 (87.4)	379 (95.5)	
Yes	40 (7.0)	22 (12.6)	18 (4.5)	
Incorrect placement				0.466
No	562 (98.4)	170 (97.7)	392 (98.7)	
Yes	9 (1.6)	4 (2.3)	5 (1.3)	
Tongue/pharyngeal swelling				1.000
No	565 (98.9)	172 (98.9)	393 (99.0)	
Yes	6 (1.1)	2 (1.1)	4 (1.0)	
Bleeding				0.502
No	561 (98.2)	170 (97.7)	391 (98.5)	
Yes	10 (1.8)	4 (2.3)	6 (1.5)	
Air leak				0.168
No	566 (99.1)	171 (98.3)	395 (99.5)	
Yes	5 (0.9)	3 (1.7)	2 (0.5)	
<b>Pre-hospital ROSC</b>				
ROSC				0.763
No	514 (90.0)	158 (90.8)	356 (89.7)	
Yes	57 (10.0)	16 (9.2)	41 (10.3)	

LMA: laryngeal mask airway; LT: laryngeal tube

**Table III. Association between airway management and outcome measures.**

Variable	Per-protocol analysis (n = 571)				Modified intention-to-treat analysis (n = 900)			
	LT vs. LMA (unadjusted)		LT vs. LMA (adjusted)*		LT vs. LMA (unadjusted)		LT vs. LMA (adjusted)*	
	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
Placement success on first attempt	0.63 (0.43–0.93)	0.020	0.61 (0.40–0.91)	0.016	0.56 (0.39–0.80)	0.001	0.53 (0.37–0.77)	0.001
Successful placement <sup>†</sup>	0.57 (0.34–0.94)	0.029	0.52 (0.31–0.90)	0.018	0.48 (0.30–0.76)	0.002	0.45 (0.28–0.74)	0.001
Complications	2.50 (1.49–4.19)	0.001	2.82 (1.64–4.86)	< 0.001	2.44 (1.54–3.86)	< 0.001	2.71 (1.69–4.35)	< 0.001
Prehospital return of spontaneous circulation	0.88 (0.48–1.61)	0.678	0.94 (0.49–1.79)	0.839	0.94 (0.53–1.67)	0.836	0.95 (0.52–1.73)	0.861

\*Age ( $\geq 65$  yr), gender, ethnicity, type of case, witnessed by paramedics, bystander cardiopulmonary resuscitation, initial electrocardiogram rhythm, collapse-to-paramedic arrival time ( $\geq 30$  min), time at scene ( $\geq 15$  min), paramedic experience ( $\geq 5$  yr). <sup>†</sup>Up to three attempts. CI: confidence interval; LMA: laryngeal mask airway; LT: laryngeal tube; OR: odds ratio

On applying modified intention-to-treat analysis, the odds of successful LT placement (odds ratio [OR] 0.53, 95% confidence interval [CI] 0.37–0.77,  $p = 0.001$ ) and LT-related complications (OR 2.71, 95% CI 1.69–4.35,  $p < 0.001$ ) were both significant (Table III).

Use of LT was highest in the first five months of the trial, as were the placement success and complication rates. LT usage then decreased to half during the rest of the trial period. The placement success rate also decreased in the second half of the trial (Fig. 2).

## DISCUSSION

We found that LT was associated with more complications and fewer successful placement attempts by paramedics for patients with OHCA in Singapore. Prehospital ROSC rates were similar between the LT and LMA groups. The main limitation of this study was the high noncompliance rate with the new LT device and familiarity bias. Time to successful placement of airway device was also not recorded.

It was difficult to determine if the poorer outcomes were attributed to the LT itself or to the unfamiliarity with the device. The LMA has been used by Singapore paramedics for over a decade, and prior to the study, none of the paramedics had any experience with LT. For patient safety, the LMA was initially carried by all ambulances allocated to the LT group as a rescue device. The sample size was increased from 875 to 1,015 to account for an unexpected dropout rate of 45% instead of the initially anticipated 20%. This change was performed with institutional review board approval.

Familiarity bias was significant in our study. While a survey done immediately after the LT training was held showed that a majority of paramedics found LT easy to use, and the initial usage rate seemed to support this, it appeared that paramedics were still uncomfortable with using it, possibly due to a much greater familiarity with the use of the LMA. A five-month interruption in LT supply to ambulance stations during the second half of the trial also likely resulted in further unfamiliarity and increased lack of confidence, as evidenced by the decreased placement success rate and increased rates of complications that were associated with the LT group in the latter half of the trial. It is also likely that the placement success and complication rates themselves were affected by this lack of familiarity and confidence, as was self-reported.

Previous studies have suggested that using LT instead of endotracheal intubation improved OHCA survival.<sup>(3)</sup> However, there are also studies that have shown that the use of LT may be associated with severe complications, such as life-threatening tongue swelling, massive gastric distension and incorrect placement.<sup>(14,15)</sup> A follow-up study is thus warranted, with more rigorous study design, after intensive training and involving paramedics with a longer period of experience in using LT to better evaluate the efficacy of whether the LT truly results in improved patient outcomes. Time to placement of airway device should also be assessed. Other clinical outcomes, such as survival to admission and discharge, can also be

looked into, in addition to a qualitative evaluation of paramedic attitudes towards new airway devices.

This preliminary study served to identify gaps to improve the training of paramedics in using LT, since the group had fewer successful placements and more complications as well as low paramedic compliance. With more elaborate studies, the choice for supraglottic airway device for the prehospital care of patients with OHCA will become clearer.

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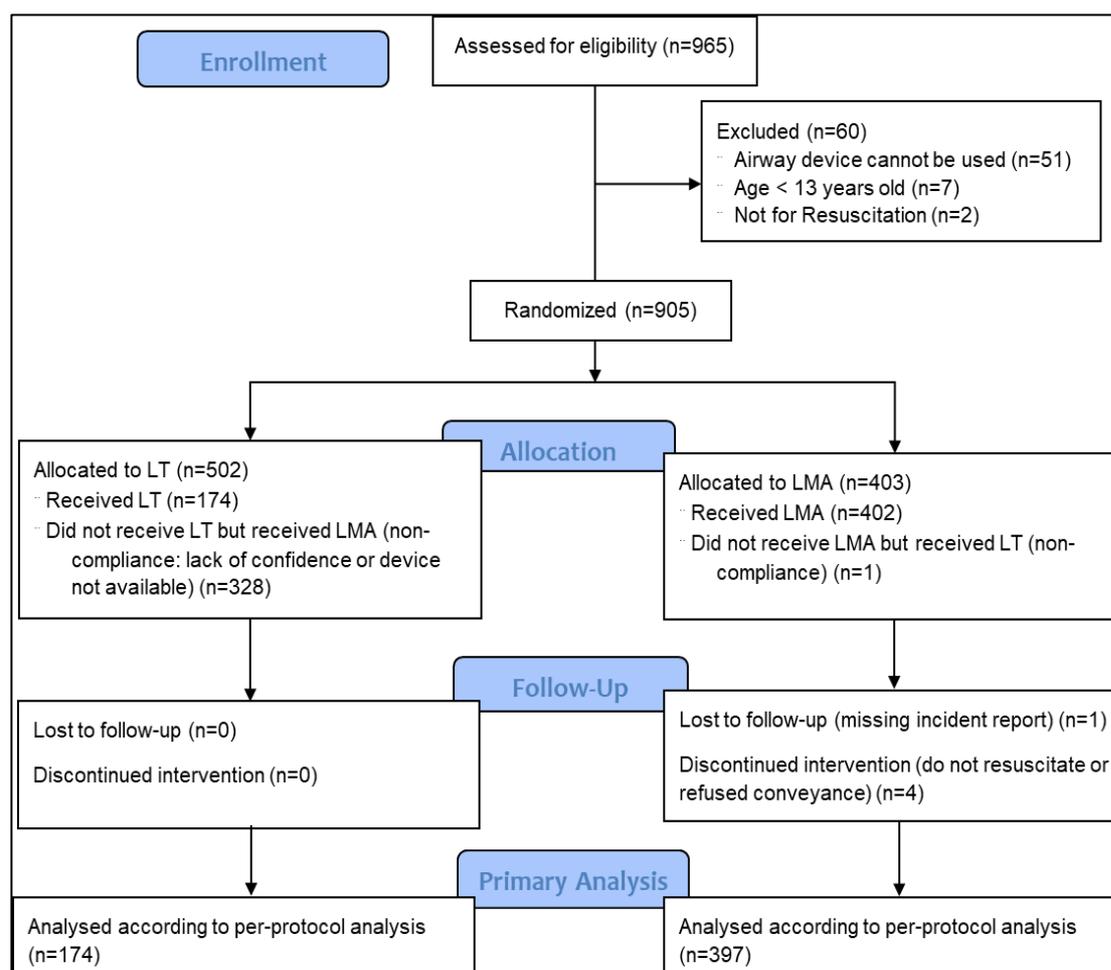
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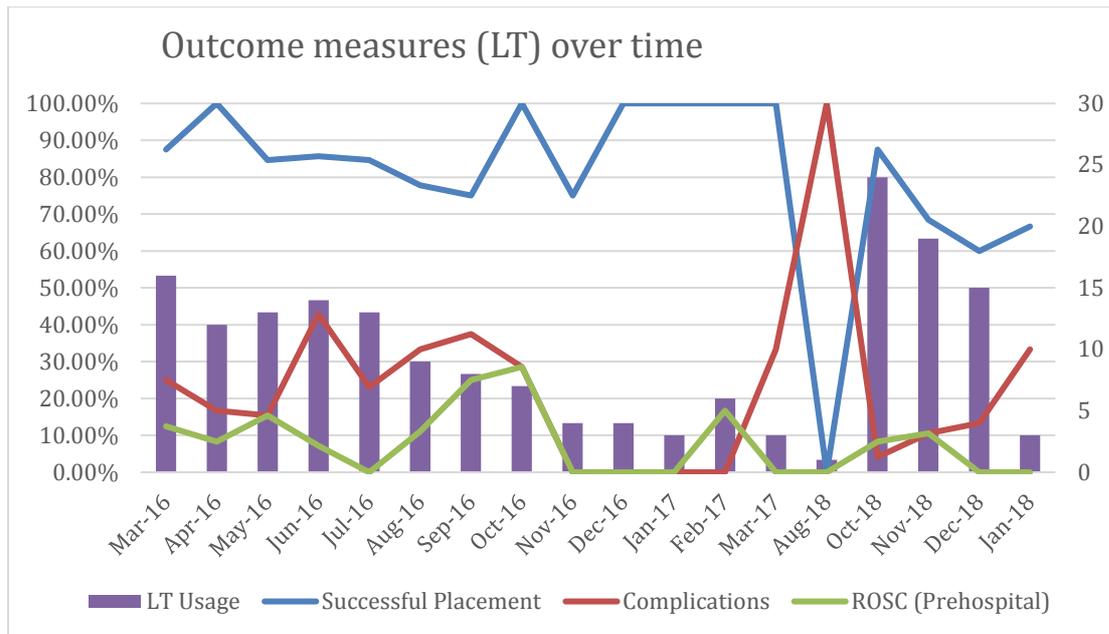
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## FIGURES



**Fig. 1** Flowchart shows recruitment of patients into the study arms. LMA: laryngeal mask airway; LT: laryngeal tube



**Fig. 2** Graph shows monthly outcome measures for the LT group. LT: laryngeal tube: ROSC: return of spontaneous circulation