Introduction

Lifesavers in Australia are taught to use standard basic life support techniques for ventilation during CPR, such as pocket mask (PM) rescue breathing and bag valve mask. First responders may have limited ability to use these devices.(1)(2)(3)(13)(4)(5)(6)(14)(15). Lifesavers in Australia are volunteer emergency service workers, who receive between four and twenty hours of emergency first aid and resuscitation training at the time of qualification followed by annual re-certification. The majority do not have any degree-level medical or paramedical training and are aged under 18 years. In Victoria, Australia, the 1435 lifesavers trained in advanced resuscitation respond to between 5 and 10 cardiac arrest events each year across the state.

Cardiac arrest in drowning may be more likely due to hypoxia. Oxygen administration is essential to restoring spontaneous circulation and avoiding neurological consequences of cardiac arrest. There may be a role for earlier airway management and ventilation with oxygen than in cardiac arrest due to other causes(16). On this basis the Australian Resuscitation Council recommends both in-water rescue breathing if prompt removal from water is impossible and early effective airway management once the patient is removed from the water(17). Whilst endotracheal intubation has been recommended for drowning, it is considered beyond the scope of volunteer first responder practice.

An ideal airway device for use in resuscitation after drowning would be rapidly effective in establishing ventilation, have a high reliability, cause minimal interruption to CPR, and be acceptable to users(18). A supraglottic airway may provide a superior airway technique for post-drowning cardiac arrest resuscitation and may facilitate earlier oxygen administration. Balanced against this is that the performance of supraglottic airways in ventilation of patients after drowning has been called into question in a single case report(19).

The LMA Supreme and iGel devices have been trialed in a number of novice groups after brief training, and superior rates of success in ventilation compared to the pocket mask and bag valve mask devices have been reported(7)(8)(9)(10)(11)(12). A trial of three different supraglottic airways by Danish lifeguards concluded that they could be considered for use in resuscitation scenarios(20). There has been no previous comparison between the pocket mask and bag valve mask compared to the LMA supreme and iGel in terms of the ability to train lifesavers to use these devices for cardiac arrest ventilation. The study aimed to establish if Lifesavers could be trained to use supraglottic airways for cardiac arrest ventilation, and hypothesized that the supraglottic airways would be superior to standard care with a pocket mask or bag valve mask.

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Methods

Design

This study is a prospective educational intervention whereby a group of first-aiders **was** trained to use the LMA and iGel supraglottic airways. Comparisons were made to pocket mask and Bag Valve Mask use and the tests were conducted on plastic manikins. The events were timed and successful ventilation was defined as achieving visible chest rise in the manikin. **Approval was obtained from the Austin Health Human Research Ethics Committee**

Participants

A total of 1,435 lifesavers with existing training in advanced resuscitation techniques from Victoria, Australia, were invited to participate.

Devices

The two devices were chosen to represent the two major shapes of second generation supraglottic airways. The LMA Supreme is representative of the strongly curved and stiff devices (other examples include the ProSeal LMA, AuraGain and myriad other similar devices) and the iGel the straighter, more flexible types. The other major difference is the presence or absence of a cuff, which may affect the time to achieving ventilation. **The LMA Supreme is manufactured by the LMA Company. The iGel is manufactured by Intersurgical. The ResusciAnne manikin is manufactured by Laerdal, a subsidiary of Philips.**

Procedure

Participants were exposed to a pragmatic training intervention consisting of a one hour lecture delivered by a paramedic, including supraglottic airway use, followed by a one hour skills laboratory session practicing with both standard lifesaving devices (pocket mask and bag valve mask with both single and double handed techniques) and supraglottic devices (LMA Supreme and iGel), supervised by a paramedic. This intervention was designed to reflect realistic training practices within the Lifesaving movement in Australia.

The lifesavers then used each device sequentially in a simulated cardiac arrest scenario using a Laerdal ResusciAnne manikin. There was no delay between training and assessment. The devices used for each scenario were the correct size for the manikin, and were presented next to the manikin, with

ancillary devices such as a syringe for inflation immediately available. Lifesavers used the devices in a standard, pre-determined order of pocket mask, bag valve mask, LMA Supreme and then iGel.

Each scenario was video-taped using a standardised video set-up (including lighting, angle, distance from manikin and zoom level) for subsequent analysis. The start time was defined as the commencement of chest compressions (with no artificial airway in place). Event times were measured using a timer and recorded to the nearest whole second. Successful ventilation was defined as achieving visible chest rise, in line with the Australian Resuscitation Council definition(17).

The video camera was focused on the chest area of the manikin, and was set using a standard frame that was limited to the clavicles of the manikin superiorly, the umbilicus inferiorly and the chest wall on either side. As such the airway device being employed was not visible to the observer and blinding was maintained. The camera angle of approach was from the left hand side, above the manikin at a reasonable angle, such to allow observation of chest rise easily, but not allow observation of the airway device used.

The videos were assessed by an independent researcher who was blinded to the device being employed. Where they were unsure, a second researcher was available, and the consensus opinion of the two was used to determine the outcome. The study did not assess inter or intra observer reliability.

Outcomes

The primary outcome was median time to first effective ventilation. Secondary outcomes included: proportion of ventilations achieved by 20 seconds, absolute failure of ventilation (defined as no effective ventilations in a cycle of 2 minutes of CPR), proportion of times ventilation was attempted and was successful, and total hands off time (interruption of CPR due to ventilation). These were compared for each device.

Statistical analysis

We did not perform a sample size estimation for this pragmatic trial.

Two important characteristics of these data is that each outcome involved multiple pairwise comparisons (between the devices) and we needed to account for repeated measurements from individual participants, We therefore performed a Bonferroni correction in order to maintain an alpha

of 0.05 for each outcome and selected tests that account for non-independence of outcome (clustering by participant).

The primary outcome was described using a median and 95% confidence interval, as well as a Cox Proportional Hazards Model. The bag valve mask was the reference standard of care device. Significance was set at $p < 0.017$ using a Bonferroni correction factor of 3 (for comparing the three alternative devices to the reference method). The performance of each device are presented graphically using a Kaplan Meier plot.

The number of ventilations achieved by 20 seconds was assessed using McNemar's test, with significance set at $p < 0.008$, using a Bonferroni correction factor of 6. The same test and significance cut off was used to assess for difference between the devices for the proportion of ventilations achieved at the first attempt.

We performed pairwise comparisons of the number of successful ventilations was compared using the Wilcoxon Signed Ranks test, with significance set at $p < 0.008$ using a Bonferroni Correction factor of 6 (to account for all six pairwise comparisons between the four devices).

The two subsequent measures - the proportion of participants who did not manage to ventilate using each device, and the total time CPR was interrupted during each cycle (referred to as the "hands-off" time) - were examined in three ways. Frequencies were reported and the groups were compared using the Friedman test to detect differences, using a significance of $p < 0.05$. If the Friedman test was significant, then multi-directional comparison between the groups was performed using the Wilcoxon-Nemenyi-McDonald-Thompson test, with significance set at $p < 0.05$.

Statistical analysis was performed using the IBM SPSS 22 package and R version 3.1.0 (R Foundation for Statistical Computing).

Results

A total of 113 (12.7%) were recruited and gave written informed consent. Participants were equally split between males and females, and ages ranged from 16 – 58 years. A small number of participants had prior healthcare education at a degree level, but no airway specialists were enrolled.

Data were captured for all 113 participants.

The median time to first effective ventilation was similar between the pocket mask (16sec, 95% CI 16-17sec), bag valve mask (17sec, 95% CI 16-17sec) and iGel devices (18sec, 95% CI 16-20sec), but significantly longer for the LMA Supreme (36sec, 95% CI 33-38sec). Using the Cox Proportional Hazard ratio for median time to first effective ventilation, the pocket mask was superior to bag valve mask (HR1.45, $p=0.002$), while the LMA Supreme was inferior (HR 0.39, $p=0.00003$), and no difference was detected with the iGel (HR 0.66, $p=0.025$).

The Kaplan Meier plot (fig. 1) curves were similarly matched for the pocket mask, bag valve mask and iGel up to 20 seconds, after which the iGel departed from the other curves and the bag valve mask separated from the pocket mask curve. The LMA Supreme curve did not begin to climb before 30 seconds and crossed the iGel and bag valve mask curves at 50 and 60 seconds respectively.

The proportion of successful ventilation at 20 seconds for the pocket mask (90/113, 89%), bag valve mask (78/113, 69%), LMA Supreme (2/113, 2%) and iGel (84/113, 68%) were similar for the pocket mask and bag valve mask pair ($p=0.137$) and the bag valve mask and iGel pair ($p=0.067$). The pocket mask was superior to both the LMA Supreme and iGel (both $p=0.001$) and the bag valve mask was superior to the LMA Supreme ($p=0.001$). The iGel was superior to the LMA supreme ($p=0.001$).

When considering the proportion of successful ventilation at the first attempt for the pocket mask (102/113, 90%), bag valve mask (88/113, 78%), LMA Supreme (102/113, 90%) and iGel (84/113, 74%), there were no differences detected between the pocket mask and the LMA supreme ($p=1.0$) or the bag valve mask and iGel ($p=0.868$). The pocket mask and the LMA were superior to both the bag valve mask ($p=0.004$ for both comparisons) and iGel ($p=0.003$ for both comparisons).

Examining the mean number of ventilations that were successful with the pocket mask (5.76, 96%), bag valve mask (5.24, 87%), LMA Supreme (5.71, 95%) and iGel (4.97, 83%) the only significant difference was the superiority of the pocket mask over the iGel ($p=0.006$).

The number of participants that failed to achieve ventilation during the CPR cycle was 1 (1%) with the pocket mask, 3 (3%) with the bag valve mask, 3 (3%) with the LMA Supreme and 11 (10%) with the iGel. The groups were significantly different using the Friedman test $p=0.0023$. In the multi-group comparison the pocket mask ($p=0.01$) and LMA Supreme ($p=0.01$) were superior to the iGel.

There was a significant difference in the total time that CPR was interrupted by ventilation between the groups. Hands off time was similar between the bag valve mask, LMA Supreme and iGel (10sec for each device), but significantly worse for the pocket mask (13sec, $p<0.01$).

The number of participants qualified to a health care degree level was four, of one hundred and thirteen participants. Removing these from the analysis did not affect the results.

Discussion

The educational intervention did not result in superior or equivalent performance by lifesavers using the LMA Supreme or iGel devices compared to the current pocket mask or bag valve mask devices. Lifesavers did not demonstrate superior performance in all requirements with any particular device, and our results indicated that the pocket mask and bag valve mask should continue to be used as ventilation devices in cardiac arrest resuscitation by lifesavers. The pocket mask and bag valve mask represented the best compromise between the requirements.

Overall, there appears to be little value in the use of either supraglottic airway by lifesavers after a pragmatic educational intervention, as the major limitations of the devices, with the LMA Supreme having a long time to first effective ventilation and the iGel having a high proportion of failure to ventilate, may result in unacceptable delays in providing oxygen to the patient in cardiac arrest.

The pocket mask demonstrated advantages in terms of time to first effective ventilation (16sec) and reliability in all of: ventilation at first attempt (90%), number of attempted ventilations that were successful (96%) and absolute failure to ventilate (1%). The major disadvantage of the pocket mask was a 3 seconds longer hands off time compared to other devices.

The advantages of the use of bag valve mask were demonstrated in time to first effective ventilation (17sec) and a short hands off time (10sec). The major disadvantage was a lower reliability in first attempt ventilation (78%). The bag valve mask appears to have desirable features without being superior in any one of them for lifesaving use.

The LMA Supreme demonstrated the advantages of being highly reliable in all domains and having a short hands off time (10sec), but had a much longer time to first effective ventilation (36sec), often requiring two cycles of CPR to be inserted, consistent with previous research⁽⁹⁾⁽²¹⁾. The mean time

to first effective ventilation exceeded the standard of care value of 20 seconds. This device does not appear optimal for use by first responders following a pragmatic training intervention.

The iGel demonstrated advantages in time to first effective ventilation (18 sec), and hands off time (10sec), but had a major disadvantage in terms of reliability across all domains, in keeping with previous research(22)(23). Overall the iGel performed similarly to the current standard of care, the bag valve mask. However, with 10% of participants unable to achieve ventilation at all using this device, it is not suitable for use as a sole airway management tool for lifesavers.

Strengths

The study was a novel, pragmatic trial. The trial was the first to compare a range of supraglottic airways with standard devices in simulated resuscitation conditions in lifesaving population.

Limitations

The study is based on a manikin simulator and success with the pocket mask and bag valve mask devices is lower in human patients than on plastic manikins, which may overestimate the effectiveness of the pocket mask and bag valve mask devices. Similarly, the ability of the thermoplastic iGel device to mold to manikin airway may be limited, potentially underestimating the efficacy of the iGel. The manikin is also unable to simulate the low pulmonary compliance after drowning that the failure of the supraglottic airways in the case report was attributed to.

The study is a single measurement directly after training was delivered, and this may overestimate the success of the intervention given the expected deterioration of skills over time. The study design did not allow for a washout or retest period between devices. **Learning effects could have occurred due to the standardised order of device use.** The study did not reassess the participants to measure the retention of the acquired knowledge over time. The study also examined only one population in a single centre, despite the sample representing a significant proportion of the Victorian eligible Lifesaving population.

There may exist a further confounding effect of trialing both novel devices and also a new education package using the same outcome data.

Conclusions

Overall this trial does not demonstrate benefit of pragmatic training using the supraglottic airway devices over traditional devices (pocket mask and bag valve mask) in the lifesaver population and manikin context studied for rapidly establishing an airway and beginning ventilation. To definitively answer the question, further research involving ventilation in humans should be undertaken.

Supraglottic airways such as the iGel and LMA Supreme may not be suitable for use by first responder lifesavers during aquatic resuscitation as suggested by increased failure rates and increased time to first ventilation in a manikin.

This study demonstrates the currently used pocket mask and bag valve mask provide appropriate standards of care for lifesavers in Australia for simulated cardiac arrest when tested in the manikin context.

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Conflicts of interest

No author had any competing or conflicts of interest, including but not limited to employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

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