**WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care**

**Worksheet author(s)**

| P M Middleton, S R Davies |  
| Date Submitted for review: 01 January 2010 |

**Clinical question.**

In adult cardiac arrest (prehospital [OHCA], in-hospital [IHCA]) (P), does the use of supraglottic devices (I) compared with bag-valve-mask alone for airway management (C), improve any outcomes (e.g. ventilation, oxygenation, reduce hands-off time, allow for continuous compressions and/or improves survival)(O)?

**Is this question addressing an intervention/therapy, prognosis or diagnosis?** Intervention/therapy

**State if this is a proposed new topic or revision of existing worksheet:** New topic

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**Conflict of interest specific to this question**

Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet? No

**Search strategy (including electronic databases searched).**

**Medline (1950 – September 2009):** [“heart arrest” OR “cardiopulmonary resuscitation” as MeSH headings OR [heart or cardiac].mp. and (massage or therapy or compression$)].ti,ab OR (CPR or cardiopulmonary resuscitation or cardio-pulmonary resuscitation).ti,ab OR ([advanced or cardiac] and life support).ti,ab.) AND [“masks” OR “respiration, artificial as MeSH headings OR ((supra?glottic adj airway adj device) or (supra?glottic adj airway) or (supra?glottic adj device) or (supra?glottic adj ventilatory adj device)].ti,ab. OR (LMA-Supreme or LMA-S or LMA Supreme or i-gel or LMA or ProSeal or Combitube or LT or (Easytube or Easy tube) or Fastrack or LTS-II or (Classic LMA or LMA-Classic or clLMA) or SoftSeal or (PLA Cobra or Cobra PLA or CPLA or Cobra peri-laryngeal airway) or SLIPA or (Ambularyngeal mask or ALM) or Airway management device or (intubating laryngeal mask or ILMA)).mp. or (King and (LT or LT-D or LAD or LTS-D) or (adjunct airway)).ti,ab. OR (oropharyngeal airway or oro-pharyngeal airway or cuffed-oropharyngeal airway or cuffed oropharyngeal airway).mp. or COPA.ti,ab. OR (naso-pharyngeal or nasopharyngeal) and (airway or device)].ti,ab.) AND (((bag-mask or (bag adj mask)) and ventilation or system)) OR (BMV or BVM or (bag adj valve adj mask)).mp. or (bag-valve adj mask).ti,ab. OR mask ventilation.mp. or mask-ventilation.ti,ab.)

**Embase (1996 – Week 36 2009):** [“resuscitation” OR “heart arrest” OR “heart massage” OR “heart stimulation” as Emtree terms OR (CPR or (cardiopulmonary adj resuscitation) or (cardio-pulmonary adj resuscitation)).ti,ab. OR ((advanced or cardiac) and (life adj support)).ti,ab. OR ((heart or cardiac) and (massage or therapy or compression$)).ti,ab. OR ] AND [ “assisted ventilation” OR “laryngeal mask” OR “airway” as Emtree terms OR ((supra?glottic adj airway adj device) or (supra?glottic adj airway) or (supra?glottic adj device) or (supra?glottic adj ventilatory adj device)].ti,ab. OR (LMA-Supreme or LMA-S or LMA Supreme or i-gel or LMA or ProSeal or Combitube or LT or (Easytube or Easy tube) or Fastrack or LTS-II or (Classic LMA or LMA-Classic or clLMA) or SoftSeal or (PLA Cobra or Cobra PLA or CPLA or Cobra peri-laryngeal airway) or SLIPA or (Ambularyngeal mask or ALM) or Airway management device or (intubating laryngeal mask or ILMA)).mp. or (King and (LT or LT-D or LAD or LTS-D) or (adjunct airway)).ti,ab. OR (oropharyngeal airway or oro-pharyngeal airway or cuffed-oropharyngeal airway or cuffed oropharyngeal airway).mp. or COPA.ti,ab. OR ((naso-pharyngeal or nasopharyngeal) and (airway or device)).ti,ab.) AND (((bag-mask or (bag adj mask)) and ventilation or system)) OR (BMV or BVM or (bag adj valve adj mask)).mp. or (bag-valve adj mask).ti,ab. OR mask ventilation.mp. or mask-ventilation.ti,ab.)

**AHA Endnote Master Library:** Searched with the following text words (in the citation abstract field): bag-valve-mask OR laryngeal mask OR supraglottic airway management. Also searched with the following keywords (discarding duplicate references) “Laryngeal Masks” OR “Respiration, Artificial/*methods”. Limited the results to “Comparative Studies” OR “Randomized Controlled Trials” as keywords.

**Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (3rd Quarter 2009):** Both searched with the combination of text words outlined in the search strategies for Medline and Embase.

**Scopus:** Scopus used for forward searching (citations) and backward searching (author-based)

**Google Scholar/Google:** Used for text-word based search of grey literature

**Reference reviews:** Extensive revision of references from all relevant papers.
• State inclusion and exclusion criteria
The following studies were excluded: Non-systematic reviews, letters, case series n<10, studies not involving bag-mask-ventilation or supraglottic/extraglottic airways, studies not published in English.
The following studies were included: Animal studies, human studies, studies using mechanical, manikin or ‘bench’ models, studies using anaesthetized patients as a cardiac arrest model.

• Number of articles/sources meeting criteria for further review:
29 studies meet the inclusion/exclusion criteria for further review. Of these 1 was LOE 1 (RCT), 2 were LOE 2 (non-randomised, concurrent controls), 5 were LOE 4 (no controls) and 21 were LOE 5 (anaesthetised/surgical patients, or mechanical/simulated models of cardiac arrest patients)

Summary of evidence

Evidence Supporting Clinical Question

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<th>Good</th>
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Doerges 1999a E  
Dorges 2001 E  
Ocker 2001 E  
Timmerman 2007(a) E |
|        |            | Alexander, 1993 E  
Casati 1998 E  
Clayton 2002 E  
Dimitriou 2003 E  
Doerges 1999b E  
Frass 1989 E  
Genzwuerker 2001 E  
Ho-Tai 1998 E  
Kurola 2004 E  
Martin 1993 E  
Wharton 2008 E  
Wiese 2008 E |
|        | Kette 2005 E  
Kokkinis 1994 E  
Martin 1999 BCE  
Timmerman 2007(b) E |        |
|        |            |            |

1 2 3 4 5

Level of evidence

A = Return of spontaneous circulation  
B = Survival of event  
C = Survival to hospital discharge  
D = Intact neurological survival  
E = Other endpoint  
*Italics = Animal studies*

Evidence Neutral to Clinical question

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<td>Rumball 1996 C E</td>
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<td>Bailey, 1994 E</td>
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|        | Dimitriou 2003 E  
Ho-Tai 1998 E  
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1 2 3 4 5

Level of evidence

A = Return of spontaneous circulation  
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D = Intact neurological survival  
E = Other endpoint  
*Italics = Animal studies*
Evidence Opposing Clinical Question

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<td>Garcia-Gausch 2001 E</td>
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**Level of evidence**

A = Return of spontaneous circulation  
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D = Intact neurological survival  
E = Other endpoint  
**Italics** = Animal studies

**REVIEWER’S FINAL COMMENTS AND ASSESSMENT OF BENEFIT / RISK:**

There is no high level evidence that the use of a supraglottic airway device, instead of a bag-valve-mask (BVM), improves any outcomes for adults in cardiac arrest. Studies to date consist of an approximately equal mix of LOE 5 studies in manikins, or in healthy, fasted, anaesthetised patients, neither of which are valid models of cardiac arrest patients. The majority of these LOE 5 studies report findings supportive of the use of supraglottic airway devices, however the outcomes are generally poorly defined, poorly measured and essentially consist of process outcome measures. Most commonly reported outcomes for these LOE 5 studies were insertion success and/or ventilation success – again these outcomes are often self-reported and poorly/subjectively measured and defined (or not defined at all).

Of the eight studies undertaken in human cardiac arrest patients, five were small, uncontrolled case-series’ (LOE 4) evaluating the use of a supraglottic airway device (1 x laryngeal tube, 1 x Combitube, 4 x LMA). Again, outcomes were poorly defined and measured.

The remaining three studies consisted of one cluster randomised trial (Rumball, 1996), one multicentre cohort (SOS-KANTO 2009) and one single-hospital cohort (Stone 1998). These studies provide the only high level evidence to date, and two have significant methodological problems. Stone’s cohort study provides the highest level evidence supporting the choice of an LMA over a BVM, but only in respect to regurgitation risk.

**Stone** compared the incidence of regurgitation between the bag-valve-mask and the laryngeal mask airway (LMA) for 797 in-hospital cardiac arrest patients undergoing CPR, over a 3 ½ year period in one English hospital. Regurgitation was recorded to have occurred at some stage in 180 (22.6%) patients. Stone excluded patients who had regurgitated prior to CPR (84) from his final analysis. For patients who were ventilated with the BVM alone or BVM followed by endotracheal intubation (ETI) the incidence of regurgitation was 12.4%. For the patient group that were ventilated with an LMA alone, or an LMA followed by ETI, the incidence of regurgitation was significantly lower at 3.5%. (p<0.05). The non-randomisation of airway management strategy introduces the potential for bias, and Stone does not address this issue nor report the rationale/protocol for airway management for the study participants. The description of regurgitation measurement as an outcome measure is also rather subjective and imprecise, and depends on assumptions about the nature and characteristics of aspirated fluid.

The SOS-KANTO group prospectively collected data from EMS and hospital records of 373 out-of-hospital cardiac arrest (OHCA) patients who were admitted to 57 hospitals in Japan, in order to compare the efficacy of BVMV with LMA ventilation. Authors report that subject inclusion criteria were designed to meet the Utstein guidelines for reporting OHCA. Data was analysed on an intention-to-treat basis.

- **Inclusion criteria:** adult patients with witnessed OHCA of presumed cardiac aetiology, confirmed on scene (initial rhythm) as VF or pulseless VT, patients ventilated with either an LMA or a BVM.

- **Exclusion criteria:** ROSC in ED, airway management with adjuncts other than LMA or BVM, age <16yrs
Primary Outcome: ABG data taken immediately on arrival at ED.

LMA group n=173   BVM group n=200
The percentage of patients who survived to hospital discharge was significantly higher for the LMA group than for the BVM group (13.4% vs 6.1%, p=0.03)
There was no significant difference detected between the groups for ROSC or survival to ED/24hours/7 days. Median arterial pH was higher in the LMA group (7.117 vs 7.075, p=0.02)
There was no significant difference detected in the median PaCO₂ or the median PaO₂ between the two groups.

This study has a number of limitations:

- The multicentre nature of the study (across 9 pre-hospital prefectures) meant that paramedics had varying levels of training and experience with airway adjuncts, the types of airways available to paramedics was not consistent across the study.
- The national pre-hospital cardiac arrest protocol in Japan states that the BVM is to be used as the first choice airway, with the LMA to be inserted only in cases where (1) the patient’s chest does not rise ‘sufficiently’, or (2) a long transport time is anticipated. This non-random allocation of airway device prevents any valid comparison being made between the groups. Also, each pre-hospital region was free to modify the cardiac arrest protocol ‘as needed’. Variations were not reported in the study.
- Study authors report that there was a statistically different time interval from hospital arrival to the ABG sampling between the two groups, and that there was no confirmation of the status of the patient when the sample was taken (post intubation?), potentially leading to inaccurate ABG data.

Rumball’s 1996 study was a cluster-randomised, controlled trial comparing the pharyngeal tracheal lumen airway (PTL), Combitube, LMA and the BVM/oral airway for ventilatory effectiveness in OHCA. The study took place in four non-ALS ambulance districts in British Columbia, with each district trialing a different airway, all using the BVM/OA as the control group. Over the 4 ½ year study period, districts rotated through the different airways in what was termed a ‘modified cross-over design’. Total n = 470.

To be included in the study, a patient was to be in cardiac or respiratory arrest, or have a RR <5/min with an absent gag reflex. The attending paramedic opened an envelope that randomised the patient to the BVM/OA or a study device.

Study outcomes were successful insertion (self-reported) and successful ventilation, as assessed by the receiving ED physician, ABG data, episodes of emesis and survival-to-hospital-discharge.

No statistically significant difference was found for mean or median PaCO₂ or PaO₂ values between all groups.

The LMA group had a significantly lower success of insertion rate ($\chi^2 = 6.07, p=0.048$) compared with the PTL and the Combitube (BVM not included in this analysis) (Insertion rates not reported)

Emesis episodes (during and post-insertion) were not significantly different between the four groups ($\chi^2 = 2.47, p=0.29$)

Survival-to-discharge was reported as not significantly different between the four groups (no test statistic, no p-value reported)

Study limitations:

- Arterial blood gas data was obtained for only 27% of cases – the study authors make no attempt to address this as a likely source of bias.

- Ventilatory success was not defined – subjectively assessed by receiving physician as a dichotomous outcome. Also, ventilatory success (ED physician assessed) was not measured or reported for the control group (BVM), making any comparison for this outcome impossible.
### Summary of comparative human studies:

<table>
<thead>
<tr>
<th>Citation:</th>
<th>Values:</th>
<th>Supraglottic airway (LMA)</th>
<th>Bag-valve-mask</th>
<th>p-value</th>
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<tbody>
<tr>
<td></td>
<td>Gastric regurgitation (during ventilation)</td>
<td>3.5%</td>
<td>12.4%</td>
<td>p&lt;0.05</td>
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</table>

<table>
<thead>
<tr>
<th>Citation:</th>
<th>Values:</th>
<th>Supraglottic airway</th>
<th>Bag-valve-mask</th>
<th>p-value</th>
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<tbody>
<tr>
<td></td>
<td>Successful ventilation (subjective self assessment)</td>
<td>82%</td>
<td>86%</td>
<td>73%</td>
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<td></td>
<td>ABG: (reported for 27% of all cases)</td>
<td>Mean PCO₂ (mmHg)</td>
<td>55.6</td>
<td>43.3</td>
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<td></td>
<td>Mean PO₂ (mmHg)</td>
<td>153</td>
<td>214</td>
<td>115</td>
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<tr>
<td></td>
<td>Gastric regurgitation (during ventilation)</td>
<td>40%</td>
<td>42.5%</td>
<td>31%</td>
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<td></td>
<td>Survival to hospital discharge</td>
<td>2%</td>
<td>4%</td>
<td>7%</td>
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Citation:

Values:

Supraglottic airway (LMA)  Bag-valve-mask  p-value


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<th>Citation</th>
<th>Values</th>
<th>Supraglottic airway (LMA)</th>
<th>Bag-valve-mask</th>
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<tr>
<td>n (insertions)</td>
<td>173</td>
<td>200</td>
<td>N/A</td>
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<td>ROSC (post ED admission)</td>
<td>38.7%</td>
<td>40.0%</td>
<td>p=0.89</td>
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<td>Survival at 24hrs</td>
<td>21.5%</td>
<td>17.3%</td>
<td>p=0.48</td>
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<tr>
<td>Survival to hospital discharge</td>
<td>13.4%</td>
<td>6.1%</td>
<td>p=0.03</td>
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<tr>
<td>ABG (on ED admission)</td>
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<tr>
<td>Arterial pH</td>
<td>7.117</td>
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<td>p=0.02</td>
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<tr>
<td>PaCO₂ (mmHg)</td>
<td>52.9</td>
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<td>PaO₂ (mmHg)</td>
<td>64.6</td>
<td>71.9</td>
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Acknowledgements:

Citation List


Level 5 comparative study (anaesthetised, fit, surgical patients). Fair. Supportive. Cross-over study (n=200 insertions) comparing rates of successful insertion and ventilation between bag-valve-mask ventilation (BVMV) and laryngeal mask airway (LMA) in anaesthetised patients. Ventilation was considered successful if PaO₂>90% at all times, and EtCO₂≤ baseline after two minutes of ventilation. Patients were fasted and low-risk (ASA I/II, Mallampati I/II, with no history of gastro-oesophageal reflux, no dentures). This study also examined differences in airway management skill acquisition and retention (by previously inexperienced medical staff) between BVM and LMA. Successful ventilatory rates for the LMA and BVMV were 87% and 43% respectively (p< 0.001) and the average insertion times were 27.4 s and 15.8 s (p>0.05). Study authors report that ineffective mask seal, failure to maintain head tilt/jaw lift (airway patency) and early onset of hand fatigue were responsible for the high rate of ventilation failure with the BVM (based on observation by authors). Successful ventilation rates with the LMA increased with subsequent insertions for individual practitioners, whereas BVMV rates did not improve, suggesting that skill acquisition and consolidation is superior for the LMA.


Level 4 case series. Supportive. Good
A prospective case series (of n=52 insertions) examining the use of the Combitube in all OHCA patients transported by one US EMS
provider over a period of 22 months. The Combitube was used as the primary airway adjunct on even days, and as a rescue airway after failed ETI on odd-numbered days (there was no comparator/control group). The study authors provided initial training for all paramedics involved in the study.

The assessment of Combitube placement was made by the receiving ED physician. The study reported 72% successful placement when the Combitube was used as a primary airway, 64% successful placement when used as a rescue airway. Paramedics correctly identified oesophageal or tracheal placement 100% of the time. 83% of Combitube placements were reported as oesophageal. The authors identified weaknesses in initial training as the primary reason for the failed Combitube insertions – a follow-up study in manikins showed that paramedics required additional training in insertion techniques. The authors also recommend regular refresher training, as skill retention was poor.


Level 5 comparative study (anaesthetised, ASA I/II, elective surgical patients). Good. Neutral (No significant differences between the three techniques)
This study compared rates of successful ventilation for one-handed BVMV, two-handed BVMV and LMA for operators with minimal LMA training (however they had extensive BVM ventilation training). Ventilation was considered successful if SaO₂ remained >90%, and EtCO₂ baseline.
The study reported 80% successful ventilation with one-handed BVMV, 87% successful ventilation for both two-handed BVMV and LMA (p>0.1). The study authors suggest that the relatively high rates of successful ventilation with the bag-valve-mask may be due to a combination of operator experience, optimal patient positioning and skilled assistance.


Level 5 (anaesthetised surgical patients), good, supportive (for O₂ saturation, hand fatigue, ease of placement), opposing (for increased risk of ‘oesophageal reflux’).
This meta-analysis of controlled trials compared ventilation using an LMA to ventilation with either facemask (FM/BVM) or tracheal tube (TT) in anaesthetised surgical patients (to December 1994). The author detected three advantages of the LMA over the FM applicable to cardiac arrest scenarios, and one advantage of the FM over the LMA. No estimates of size differences were given due to the heterogeneity of the study designs and data included in the meta-analysis. No evidence of improvement in patient outcomes/survival was reported in the meta-analysis.


Level 5 (anaesthetised, spontaneously breathing, ASA I/II surgical patients). Fair. Supportive (for LMA and COPA over BVM)
Small (n=20), prospective, cross-over trial comparing BVMV/ LMA/cuffed oropharyngeal (COPA) airways in spontaneously breathing, anaesthetised, fit patients. All airways were inserted/managed by an anaesthetist.
Respiratory rates and minute volumes were significantly lower for both the LMA and the COPA as against BVMV. The physiological dead space: tidal volume ratio was also significantly lower for both the LMA and the COPA (compared to the BVM).


Level 5 (anaesthetised, ASA I/II, elective surgical patients). Fair. Supportive
Small (n=40), cross-over trial comparing single-handed BVMV with cuffed oropharyngeal airway (COPA) ventilation in fit, anaesthetised patients. Airway management was by medical staff inexperienced in use of COPA, but given basic training prior to trial. Ventilation was assessed as clinically adequate if SaO₂ ≥ 94% and chest movement judged adequate by attending anaesthetist. Ventilation was reported as clinically adequate in 95% of COPA patients, 80% of BVMV patients. COPA ventilation was successful in 7 of the 8 patients in whom BVMV was reported as inadequate. Mean expired tidal volume was reported as 525ml for COPA ventilation, 391ml for BVMV.

Dimitriou V, Voyagis GS. et al. A comparison of the PExpress and face mask plus Guedel airway by inexperienced personnel after
mannequin-only training. Anesth Analg 2003; 96(4): 1214-1217

Level 5 comparative study (anaesthetised, ASA I/II, pre-oxygenated elective surgery patients), Fair. Neutral (for successful ventilation), Supportive (for tidal volume, peak airway pressure). Opposing (for airway trauma)

A prospective, cross-over trial of the PAxpress supraglottic airway and BVMV in 45 anaesthetised fit patients, ventilated by three different operators (15 patients each). The order of airway insertion was not randomised. All assessment was unblinded. There was no significant difference reported between the airways in the time taken to achieve successful ventilation (pre-determined as 7 ml/kg expired tidal volume). Significantly higher tidal volumes (1261 +/− 306 versus 958 +/− 220 ml; P < 0.0001) and peak airway pressures (37 +/− 5 versus 28 +/− 6 cm H2O; P < 0.0001) were reported with the PAxpress. Mild airway trauma was reported with the PAxpress in ten cases, no trauma was associated with the use of the BVM.


Level SComparative study (manikin). Good. Supportive.

Cross-over study (n=63) comparing ventilation and gastric inflation with the use of BVMV, LMA and Combitube in a manikin configured to simulate cardiac arrest physiological parameters (decreased oesophageal sphincter pressure, decreased lung compliance).

Operators were inexperienced in any form of airway management (student nurses). Ventilation was assessed as adequate when tidal volume exceeded 200ml. Ventilation was assessed as failed if adequate tidal volume (200ml) was not reached within 180s. Peak airway pressure, tidal volumes, minute ventilation and total lung volume were measured with flow sensors/respiratory monitors. Gastric inflation was measured with a volumeter attached to manikin stomach model. Operators were blinded to ongoing respiratory/gastric measurements.

Tidal volumes and total lung volumes after 1 minute were significantly higher for the LMA and the Combitube than for the BVM. (Study authors report ventilation with BVM inadequate in 80% of attempts by operators) Gastric inflation was significantly higher for BVMV than for either the LMA or the Combitube. Time for insertion was significantly higher for the BVM and the LMA over the Combitube.


Level 5 (manikin) comparative study, fair. Supportive.

This study employed a modified cross-over design to compare a paediatric self-inflating bag (max 700mL) to an adult self-inflating bag (max 1500 mL) for lung ventilation and gastric inflation parameters. The bags were each used (in turn) with a bag-valve-face mask, a laryngeal mask airway and a Combitube. An intubation training manikin was modified to (i) allow for respiratory, oesophageal and gastric volume and pressure measurements and (ii) to simulate the decreased lower oesophageal opening pressure and decreased lung compliance normally associated with cardiac arrest.

Lung tidal volumes were below the European Resuscitation Council recommendation with both self-inflatable bags in the bag-valve-face mask group (paediatric versus adult self-inflatable bag 256 +/- 77 mL versus 334 +/-125 mL), coupled with relatively high oesophageal tidal volumes (compared to the Combitube and LMA). Using the paediatric self-inflating bag (compared to the adult bag) reduced the mean oesophageal volume associated with BVM ventilation by ~40%.

Use of a paediatric versus adult self-inflating bag resulted in a significantly (p<0.01) lower mean (+/- SD) tidal lung volume with both the laryngeal mask airway and Combitube (laryngeal mask airway 349 +/- 149 mL versus 725 +/- 266 mL, Combitube 389 +/-113 mL versus 1061 +/- 451 mL), however the tidal volumes achieved with the paediatric bag were just below the 400mL minimum recommended by the European Resuscitation Council. Authors report that these tidal volumes were achieved with ventilation rates of 20 ventilations/minute (adult bag) and 30 ventilations/minute (paediatric bag) continuously for a minimum of two minutes (with no interruptions for chest compressions). An appropriately reduced ventilation rate may have resulted in an increase in tidal volume, and a concomitant reduction in gastric inflation (with all three airway strategies).


Level 5 comparative study (manikin). Good. Supportive for ventilation, gastric inflation.

This non-randomised cross-over study compared rates of successful ventilation and rates of gastric inflation with the use of BVMV, the LMA or the Combitube (with two different tidal volumes delivered via paediatric/adult ventilation bags. The manikin used was
modified to simulate cardiac arrest physiological parameters (decreased oesophageal sphincter pressure, decreased lung compliance).

31 operators inexperienced in advanced airway management (non-anaesthesia house officers) attempted to ventilate a manikin with either a paediatric or an adult self-inflating bag in combination with each of the three airways. Ventilation was assessed as adequate when the tidal volume exceeded 200ml. Ventilation was assessed as failed if adequate tidal volume (200ml) was not reached within 180s. Peak airway pressure, tidal volumes, minute ventilation and total lung volume were measured with flow sensors/respiratory monitors. Gastric inflation was measured as gastric tidal volume.

Gastric inflation was significantly reduced by using the BVM in combination with the paediatric bag, compared to using the BVM with the adult bag (149ml vs 272 ml, p< 0.001). However, the use of the paediatric bag + BVM resulted in a mean tidal volume of 245ml, significantly below the ERC recommended value of 500ml. The LMA and the Combitube were the superior devices in regards of minimising gastric inflation, gastric inflation was 0ml with the Combitube + either bag, and 0ml/8ml respectively with LMA + paediatric/adult bag.

The LMA and the Combitube, when used with the paediatric bag, both produced mean tidal volumes below the ERC recommended volume (368ml, 376ml). When used with the adult bag, tidal volumes for both airways were well above 600ml.


Level 5 comparative study (anaesthetised, fasted, ASA I/II adult patients), fair, opposing.

Cross-over trial (n=48) assessing the effect of ventilation with small tidal volumes (paediatric bag) using a BVM, LMA, Combitube or COPA. All airways were tested in non-pre-oxygenated, fasted, anaesthetised adult patients using a 700ml self-inflating bag. Operators were German paramedics with no prior experience with supraglottic airways or intubation. All received training prior to trial. Patients were randomised to one of four groups of 12 each. Each patient was ventilated for 3 minutes (with 100% O2 /15 breaths/min) with the LMA, the BVM, the COPA or the Combitube. The time to reach an expiratory tidal volume >200ml, the inspired/exhaled tidal volumes, peak airway pressure, oxygen saturation and EtCO2 were all measured. Ventilation was assessed as successful when the exhaled tidal volume reached 200ml.

The SaO2 fell below 90% during the insertion of 3/12 COPAs, 2/12 LMAs and one Combitube, resulting in the termination of the experiment with these patients. The SaO2 remained >90% during airway placement for all 12 BVMV patients.

The time to successful ventilation was faster with the BVM (median 20sec) than for the other airways (p<0.05)

No difference was reported in exhaled tidal lung volumes between the three airway devices (however, no values were reported).

End-tidal CO2 was comparable between the Combitube, the LMA and the COPA (33 +/- 1, 32 +/- 2 and 32 +/- 1 mmHg respectively), but significantly higher than with BVM ventilation (26 +/- 2 mmHg): no P-value reported.

Peak airway pressure was reported as significantly higher when the Combitube was used compared with all other airways (p<0.05)


Level 5 comparative study (anaesthetised, ASA I/II surgical patients). Fair (underpowered). Supportive.

Cross-over study of 12 anaesthetised routine abdominal surgery patients. In a randomised sequence, patients were ventilated via BVM, endotracheal Combitube in the oesophageal position and endotracheal airway for 20 minutes each (using a ventilator).

Measurements were recorded for PaCO2, PaO2, airway leakage and endotracheal pressure curves.

PaO2 was significantly higher for the ETC than for the ETA [151.1mmHg, 124.7mmHg, p<0.01], but not significantly different to the BVMV. The authors suggest that this may be due to auto-peep induced by higher expiratory resistance of the ETC in the oesophageal position, compared to ETA.

PaCO2 was significantly higher for the BVMV than for either the ETC or the ETA (p<0.001)

Air leakage was higher for BVMV (29.8%) than for the ETC (15.1%) or the ETA (6.3%)

Garcia-Guasch R, Ferra M, et al. Ease of ventilation through the cuffed oropharyngeal airway (COPA), the laryngeal mask airway

Level 5 comparative study (manikin), fair (not randomised, not blinded). Opposing (for time to ventilation)
Cross-over trial of COPA, LMA and BVMV during ventilation of a manikin. Operators were divided into inexperienced (n=54) and experienced (n=54).
The LMA and the BVM required significantly fewer attempts than did the COPA to achieve correct placement, for both inexperienced and experienced operators (P<0.01).
BVMV took significantly less time to achieve adequate ventilation (time from insertion to first sequence of 10 ventilations >200ml) than did the LMA or COPA, for both inexperienced and experienced operators (P < 0.01).
The average tidal volume during the first 10 'correct' ventilations was not significantly different between the three airways (p not reported)
Study authors commented on unsuitability of this manikin for COPA study.


Level 5 comparative study (manikin), fair. Supportive (for decreased gastric inflation and increased tidal volume)
Cross-over study comparing ventilation using the laryngeal tube (LT), the BVM or endotracheal tube during 3minute CPR sessions on a CPR training manikin. The laryngeal tube (LT) is a single lumen silicon tube with oesophageal and pharyngeal cuffs and a ventral opening between the cuffs for ventilation.
Gastric inflation was detected in 4/10 CPR sequences using BVMV. No gastric inflation was reported with either the LT or the ETT. At a compression/ventilation ratio of 5:1, the LT achieved a significantly higher tidal volume than the BVMV (0.96L vs 0.66L, p<0.0002). The tidal volume achieved with the LT dropped to 0.85L during continuous cheat compressions.


Level 5 comparative study (anaesthetised, ASA I/II surgical patients, highly experienced operators), fair, supportive (gastric inflation), neutral (ventilation)

Randomised cross-over trial (n=60) comparing BVM with LMA in ventilated, fit surgical patients at three different ventilator pressure settings. Patients were excluded if they had a history of respiratory or cardiac disease, oesophageal/gastric/airway abnormalities, were not fasted or had facial hair or a facial abnormality that might prevent adequate mask seal. Airway management was by the attending anaesthetist (various). Gastro-oesophageal insufflation, expiratory volume and presence of airway leak were assessed and recorded for each airway and setting.
Ventilation was reported as adequate at all pressures with both airway management strategies (all expiratory volumes were > 890mL, meeting AHA resuscitation recommendations at the time).
Airway leak was higher with the LMA (increasing for increasing ventilatory pressures) than for the BVMV. Airway leak was constant over all pressures for the BVMV (F_{2,119}=4.66, p<0.02)
The frequency of gastric insufflation was significantly higher with the BVMV than with the LMA ($\chi^2=9.34, p<0.01$). Gastric insufflation was assessed via auscultation over the stomach during ventilation. Gastric insufflation increased with increasing ventilatory pressures for both devices.
Study authors propose that the LMA allowed air to vent into the atmosphere, whereas the operator increasing/adjusting the facemask seal when an audible leak was detected increased airway pressure, subsequently forcing air back into the stomach.


Level 4 (case series.) Fair. Supportive (ventilation)

Small Italian case series (n=30) examining the use of the laryngeal tube (LT) by minimally trained nurses in out-of-hospital cardiac arrest patients requiring ventilatory support. All outcomes were subjectively assessed and reported by the nurses administering resuscitation - significant potential for reporting bias. Ventilation was assessed as effective if chest movement during inflation was observed, breath sounds were auscultated and no epigastric 'gurgling' was heard. No patient survival outcome data was reported. The nurses reported ventilation as effective in 24/30 cases.
Insertion of LT reported by nurses as successful within two attempts in 25/30 cases.


Case series reporting the use of the LMA for airway management by ‘inexperienced’ staff (junior anaesthetists) in 50 resuscitation attempts in one hospital over a nine month period. Paediatric and multi-trauma patients were excluded from the study. Patient selection criteria was not explicitly stated, therefore there may be the potential for significant selection bias. The CPR protocol was not given (compressions? ventilations? time to LMA insertion? use of BVM prior to LMA insertion?) Study outcomes were assessed by an experienced anaesthetist, who attended the resuscitation attempt (not blinded). Ventilation was assessed as effective by means of auscultation, chest wall expansion and arterial blood gas values taken during the arrest period (PaCO₂, PaO₂, pH).

Insertion was reported as successful within two attempts in 49/50 patients.

Ventilation was reported as effective in all 49 patients who received an LMA.

No cases of regurgitation or aspiration were detected.

Blood gases were collected and analysed for 42 patients, with the study reporting all ABG values as ‘excellent’, even for patients who did not survive.


Level 5 comparative study (manikin). Fair (not blinded, pseudo-randomised, outcome measures not clearly defined). Supportive.

29 pairs (teams) of student emergency technicians were allocated to ventilate a manikin with either a laryngeal tube airway (LT), a BVM (one-handed) or via an endotracheal tube (ETI). The students delivered 1.5 minutes of ventilations and compressions (BVMV, LT; 15:2 compression: ventilation ratio - ETI with continuous uninterrupted compressions, with one ventilation delivered for every 5 compressions). Student pairs were then assigned to another airway and repeated the procedure. Outcomes were assessed by an observer.

All teams reported successfully inserting LT and ETI on first attempt.

No air leaks observed with LT (no explanation of how this was assessed)

Mean time to initiation of ventilation (no statement as to what constituted successful ventilation) was shortest for the LT (64s) than for ETI (95s) or BVMV (81s)(p<0.0001 for LT vs ETI, not significant for LT versus BVMV)

Mean expired minute ventilation was significantly higher for the LT (7.1 L/min) than for the BVM (2.6 L/min) (p<0.0001).


Level 5 comparative study (anaesthetised, ASA I/II, gynaecological day-patients), fair (underpowered, not blinded). Neutral.

30 student EMTs were randomised to ventilate a pre-oxygenated, anaesthetised patient with either a BVM or a LT (for 1 minute) 15/15 students successfully inserted LT within three attempts.

No significant difference between BVM and LT for tidal volumes, minute volumes, EtCO₂, SpO₂, peak airway pressures.

Students were able to continuously monitor the effectiveness of their ventilation during the study via a respiratory monitor (not blinded). Authors state this may have led to more effective BVMV than previously reported.


Level 5 comparative study (pre-oxygenated, anaesthetised, ASA I elective surgical patients), fair. Supportive

Cross-over trial, not randomised, not blinded, n=52 insertions. 30 nurses unfamiliar with the use of the LMA, but experienced with the BVM, undertook a basic 30 minute airway management training session. The nurses then attempted to ventilate one anaesthetised patient each, firstly with the BVM (oropharyngeal airway optional) and then with the LMA. Patients were ventilated for 10 breaths with each airway – the attending anaesthetist resumed control of the patient airway between the use of the BVM and the LMA. Respiratory measurements were taken during the last 5 breaths for each airway.

Four patients were not included in the final analysis, authors state they became ‘light’ during ventilation.

The mean expired tidal volume was significantly higher for LMA (435mL, 385-485mL) than for the BVM (239mL, 170-309mL)
(p<0.01)


Level 4 prospective case series. Fair. Supportive.
A prospective case series in Georgia, USA. EMS flight crewmembers were trained in the use of an LMA. The indications for the use of the LMA (subject selection criteria) were (i) a GCS ≤8 with signs of respiratory compromise, (ii) failed endotracheal intubation (after two attempts or 5 minutes), (iii) traumatic face/neck injuries inhibiting ETI or (iv) entrapment with limited patient access. Exclusion criteria were gross obesity, pregnancy or recent opiate ingestion.
During the study period, 25 patients met the inclusion criteria for LMA insertion. Eight (8) patients were excluded from the final analysis (five patients had no blood gas analysis performed and the remaining three were not transported to the study hospital). LMA insertion was reported as successful in 16/17 patients.
There were no signs of emesis or gastric aspiration (assessed both clinically and via chest radiography).
During in-flight monitoring, the O₂ saturation ranged between 97 – 100% for all patients in whom an LMA was placed.
During in-flight monitoring, the EtCO₂ concentration ranged between 24 – 35mm Hg for all patients in whom an LMA was placed.
Arterial blood gas analysis done on arrival at hospital (timing?) indicated adequate oxygenation in all patients, and adequate ventilation in 15/16 patients.
The mortality rate for the 17 patients was reported as 47%, the mean ICU stay was 9 days and the mean total hospital stay was 15 days.


Level 5 comparative study (manikin). Good (randomised sequence). Supportive (for gastric inflation, tidal volume)
A cross-over trial of BVM, Combitube and LMA in a cardiac arrest model manikin (↓ respiratory system compliance, ↓ lower oesophageal sphincter pressure [6cm H₂O]). Operators were German paramedics with airway management experience, but no previous experience with LMA or Combitube. All underwent the same basic LMA/Combitube training prior to the study. All paramedics (n=20) used each of the three ventilatory devices in a randomised sequence for a 2 minute ventilation attempt on the manikin. Successful ventilation was pre-defined as an end-expiratory tidal lung volume > 200mL. The ventilation attempt was reported as failed if successful ventilation was not achieved within 180sec.
There were two (2) ventilation failures with the BVM, none with either the LMA or the Combitube.
The time to successful ventilation was significantly faster with the BVM (median time 9s, range 4-20s), than with the LMA (median=35s, range=17-101s) or the Combitube (median=48s, range=5-73s) (p<0.001).
Tidal volumes were significantly higher with the LMA and the Combitube (743+/− 70mL, 702+/− 59mL) than with the BVM (353+/− 26mL) (p<0.001).
Gastric inflation was significantly higher with the BVM (313+/− 30mL) than with the LMA (25+/− 13mL) (p<0.001). No gastric inflation was recorded with the Combitube.


Level 1 randomised, controlled trial. Fair (not blinded, poorly constructed outcomes). Neutral.
A modified, randomised cross-over design trial comparing BVM to the pharyngeal-tracheal lumen airway (PTL), the LMA and the Combitube in the airway management of pre-hospital cardiac or respiratory arrest by emergency medicine assistants (EMAs). Fifty one (51) EMAs from four districts in British Columbia received the same basic training in the use of the LMA, the PTL and the Combitube.
Each district was assigned one airway adjunct (either the LMA or the PTL or the ETC) with all districts using the BVM oropharyngeal airway as the comparator airway management strategy. Randomisation was via a sealed envelope opened after the diagnosis of cardiac/respiratory arrest was made by the attendant EMA.

Each district was reassigned to a different airway adjunct (still using BVM ventilation as comparator) on a one-year rotational basis. An analysis of demographic and aetiological data detected no significant differences between the four airway groups.
Ventilatory ‘success’ was assessed subjectively by the physician at the receiving hospital (no definition of how ‘ventilatory success’
was assessed is given) Ventilatory success rates were reported for the three advanced airway adjuncts, not for the BVM ventilation group, making any comparison with ‘usual care’ impossible.

Arterial blood gas analysis was recorded for only 27% of the cases. For this 27% no statistical difference was detected between the four airway management devices for either mean PCO₂ (F=0.76 p=0.564) or mean PO₂ (F=2.12 p=0.99). However, no comment was made on the potential difference(s) between those patients who had ABG analysis and those who didn’t, or on the low frequency of obtaining ABG analysis.

Survival-to-discharge was similar for the four airway management strategies; however the study was underpowered to detect significance for this outcome.

Episodes of emesis during, or post-insertion were not significantly different for the four airway management strategies ($\chi^2=2.47$ p=0.29)

Using a Likert Scale, EMAs subjectively evaluated BVM ventilation as ‘best’ for ease of use, preparation, storage and insertion; but ‘worst’ for adequacy of airway patency and overall performance. The Combitube was subjectively evaluated as ‘best’ for adequacy of airway patency and overall performance.

There were no signs of oesophageal, gastric or upper airway trauma in those cases that underwent autopsy.


A multicentre, prospective cohort study (non-randomised) comparing the efficacy of BVM ventilation and the ventilation using an LMA in the management of out-of-hospital cardiac arrest (OHCA) in Japan. The primary outcomes were PaO₂, PaCO₂ and arterial pH, determined via ABG sampling taken on ED admission. The inclusion criteria for a patient were; a witnessed OHCA of presumed cardiac aetiology that was confirmed on scene, with CPR attempted, plus either VF or pulseless VT on the initial ECG at scene and the use by paramedics of either an LMA or BVM for airway management. Exclusions: patients less than 16 years of age, ROSC at scene, resuscitation not attempted in the ED or airway management using other airway adjuncts. Data was analysed on an intention-to-treat basis. The inclusion/exclusion criteria and data collection followed the Utstein-style template (with additional study specific criteria).

LMA group n=173, BVM group n=200.

The potential for selection bias exists as LMA/BVM use was not randomised; local protocol determined that BVM ventilation was to be used as the first choice, unless the EMS personnel determined that ventilation was inadequate (‘insufficient’ chest rise), or a long transport time was anticipated.

Sampling procedures for the arterial blood gases were inconsistent across the ED departments; the time from arrival to ABG sampling in the BVM group was significantly shorter than in the LMA group (P=0.01), also, some samples were taken before intubation, some after.

The study detected no significant difference in ROSC, or survival to ED/24hrs/7days between the LMA and the BVM group.
Survival-to-hospital discharge was significantly higher in the LMA group (13.4% vs. 6.1%, p=0.03), however there was no significant difference in the median PaCO₂ or the median PaO₂ between the LMA group and the BVM group.
Median arterial pH was higher in the LMA group (7.117 vs 7.075, p=0.02)


Level 2 comparative study (IHCA retrospective cohort, not randomised). Good. Supportive (regurgitation)

Data was collected on the incidence of gastric regurgitation for every cardiopulmonary resuscitation attempt in one English hospital over a 3 ½ year study period, where airway management involved either an LMA and/or a BVM. Patients were excluded if regurgitation occurred prior to ventilation. No data was collected on tidal volumes, ventilation rates or evidence of pulmonary
Overall, the incidence of regurgitation in IHCA (where an LMA and/or BVM ventilation was used) for this study was 22.6%.
For patients ventilated with the LMA alone, or the LMA followed by ETI, the incidence of regurgitation during CPR was 3.5%, which was significantly lower than regurgitation using a BVM or BVM followed by ETI (12.4%) (p<0.05)


Level 5 comparative study (pre-oxygenated, anaesthetised surgical patients). Good. Supportive.
Prospective cross-over trial (randomised sequence) comparing the BVM and the ILMA for ventilatory success. Operators (final year med students) completed basic training in airway management with both devices. Study subjects were anaesthetised, fit surgical patients, with no indications for difficult airway management. Ventilation was considered successful when there was a capnography trace showing a plateau with a minimum end-tidal CO₂ partial pressure of 3kPa.
Students were also randomly allocated to intubation via ILMA or laryngoscope (for second part of trial)

Ventilation via ILMA was successfully performed in 88/90 (97.8%) of patients compared with 77/90 (85.6%) with BVM. (χ² = 8.8, p<0.01)
The time required for successful ventilation was shorter with the ILMA than with the BVM (35.6 +/- 8.0s. vs. 44.3 +/- 10.8 s; P < 0.01).
The study authors proposed that all failed BVM ventilation was due to inadequate face seal – 80% of the operators that achieved successful ventilation via BVM required two-hands on the face mask (and hence an extra operator to ventilate) – a situation rarely feasible/possible in most cardiac arrest scenarios.


Level 4 case series (n=11) Fair (underpowered). Supportive (ILMA for guided intubation)

A prospective case series, where 21 anaesthesia-trained emergency physicians (EPs) were assigned to out-of-hospital emergency medical teams in Germany. The EPs were instructed to use the intubating laryngeal mask airway (ILMA) as a rescue airway to perform guided intubations in cases where multiple ETI attempts had failed, or where trauma/access prevented ETI. Eleven (11) patients received an ILMA during the study period, 8 after failed ETI, and 3 as a first line airway.
All were successfully ventilated (EP self-reported outcome – assessed via bilateral auscultation of chest sounds and EtCO₂ detection).
10/11 ILMA-guided intubations were self-reported as successful on the first attempt. 1/11 was reported as successful on the second attempt.


Level 5 case series (anaesthetised, healthy surgical patients and manikins). Fair. Supportive.

The i-gel (supraglottic airway) was evaluated for successful ventilation, time to successful ventilation, insertion attempts and complications in both a manikin (n=50) and in anaesthetised patients (n=40). Operators were volunteers inexperienced in airway management, and completed the same basic training in the use of the i-gel. How study authors assessed ‘successful’ insertion was not stated.

Manikin Study: 88% placed in first attempt, median insertion time 14 sec. Airway leak reported in one case.

Patient Study: 82.5% were successful on first insertion attempt, 15% were successful by second insertion attempt. One case took 3 attempts. The median time to successful insertion was 17.5 sec (range 7 – 197 sec). One case of regurgitation was reported after insertion of the i-gel. There were no episodes of laryngospasm, bronchospasm, airway bleeding or hypoxia reported.
The time to successful ventilation was not reported, despite authors stating that this would be measured in the study methods section.


Level 5 comparative study (manikin). Fair. Supportive (for no-flow-time).

A cross-over study comparing the total no-flow-time (NFT) in a cardiac resuscitation scenario using a BVM to a scenario using a disposable Laryngeal Tube Suction (LTS-D). Fifty German ICU nurses, inexperienced in the use of supraglottic airways, took the role of a single-rescuer in two separate cardiac resuscitation scenarios requiring defibrillation and chest compressions; one scenario with each airway management strategy.

The LTS-D reduced mean NFT time significantly compared to the BVM (105.2sec vs 149.7sec, p<0.01) Adherence to the time frame of ERC guidelines was 96% in the LTS-D group versus 30% in the BVM group.