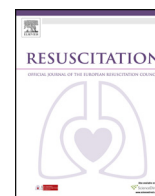




Contents lists available at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation



Clinical Paper

Higher insertion success with the i-gel[®] supraglottic airway in out-of-hospital cardiac arrest: A randomised controlled trial^{☆,☆☆}

Paul MacConachie Middleton^a, Paul Michael Simpson^b,
Richard E. Thomas^c, Jason Charles Bendall^{d,*}

^a Discipline of Emergency Medicine, The University of Sydney, Camperdown, NSW 2006, Australia

^b School of Science and Health, The University of Western Sydney, Campbelltown, NSW 2560, Australia

^c School of Medicine, University of Tasmania, Rozelle, NSW 2039, Australia

^d Department of Anaesthesia, Gosford Hospital, Gosford, NSW 2250, Australia

ARTICLE INFO

Article history:

Received 28 December 2013

Received in revised form 28 January 2014

Accepted 23 February 2014

Available online xxx

Keywords:

Out of hospital cardiac arrest

Prehospital emergency care

Airway management

Laryngeal mask

Paramedics

Controlled clinical trial

ABSTRACT

Background: Since their emergence from the operating theatre over a decade ago, supra-glottic airways (SGA) have become increasingly common in the management of out-of-hospital cardiac arrest (OOHCA) with laryngeal masks (LM) the most common SGA. The proliferation of LMs in the prehospital setting has occurred despite lower than expected rates of successful insertion being reported.

Methods: We conducted a single-centre, prospective parallel-group, ‘open label’ randomised controlled trial in subjects with OOHCA (aged greater than or equal to 12 years of age; weighing greater than or equal to 30 kg) were allocated to either the i-gel[®] supraglottic airway (IG-SGA) or the Portex[®] Soft Seal[®] Laryngeal Mask (PSS-LM) within a large Australian ambulance service. Our hypothesis was that use of the IG-SGA, when compared to the Portex[®] PSS-LM, would result in a higher rate of successful insertion in patients presenting with OOHCA. The primary outcome was successful insertion of the SGA.

Main findings: There were 51 patients randomised. Subjects had an average age of 65 years and 40% were female. There were no apparent differences in key demographic characteristics between groups. The IG-SGA had a significantly higher success rate than the PSS-LM (90% versus 57%; $p = 0.023$), resulting in a 58% greater likelihood of successful insertion than the PSS-LM (RR 1.58; 95% CI 1.11–2.24). The IG-SGA was associated with significantly lower median “ease of insertion” scores.

Conclusion: The i-gel[®] supraglottic airway was associated with higher successful insertion rates in subjects with out-of-hospital cardiac arrest.

© 2014 Published by Elsevier Ireland Ltd.

1. Introduction

Since their emergence from the operating theatre over a decade ago, supra-glottic airways (SGA) have become increasingly common in the management of out-of-hospital cardiac arrest (OOHCA). The laryngeal mask¹ is perhaps the most widely used SGA, adopted by many emergency medical services (EMS) jurisdictions as the frontline primary airway for all paramedics, and as a ‘rescue’ airway

for intensive care paramedics (ICP) when endotracheal intubations (ETI) has been unsuccessful.

However the proliferation of LMs in the prehospital setting has occurred despite lower than expected rates of successful insertion being reported. Success rates for insertion of ‘first generation’ LMs, such as the Portex[®] Soft Seal[®] LM (Smiths Medical, Kent, UK) by Australian paramedics for OOHCA are consistently lower than those seen when inserted by paramedics into fasted, anaesthetised patients in theatre-based studies.^{2,3} The more recent advent of ‘second generation’ SGAs such as the i-gel[®] (Intersurgical, Berkshire, UK) have seen insertion success rates of close to 100% in anaesthetised patients when performed by anaesthetists⁴ and novices,⁵ but whether this translates to higher success rates compared to first generation LM s when performed by paramedics for patients with OOHCA is not yet known. Early data are promising however, with recent observational evidence from Europe suggesting i-gel[®]

[☆] A Spanish translated version of the summary of this article appears as Appendix in the final online version at <http://dx.doi.org/10.1016/j.resuscitation.2014.02.021>.

^{☆☆} Clinical Trial Registration Number: ACTRN1261000472077.

* Corresponding author.

E-mail addresses: drjasonbendall@gmail.com.au, drjasonbendall@gmail.com (J.C. Bendall).

success rates of 90–94% when inserted by paramedics for patients in this context.^{6,7}

The i-gel[®] is a streamlined SGA incorporating a non-inflatable, heat-labile laryngeal cuff, an in-built bite block, and a suction port for aspiration of gastric contents. While the i-gel[®] has been compared to LM s in several clinical trials involving mannequins or anaesthetised patients,^{4,8–10} a direct comparison of insertion success rates for first and second generations SGAs when used by paramedics for OOHCA has not been reported.

Following a review within this Australian ambulance service, which reported an insertion success rate of 64% for OOHCA using the Portex[®] Soft Seal[®] Laryngeal Mask, we designed a randomised controlled trial to determine whether the i-gel[®] resulted in superior insertion success rates. Our hypothesis was that use of the i-gel[®] SGA (IG-SGA), when compared to the Portex[®] Soft Seal[®] LM (PSS-LM), would result in a higher rate of successful insertion in patients presenting with OOHCA.

2. Methods

2.1. Study design

We conducted a single-centre, prospective parallel-group, ‘open label’ randomised controlled trial in which patients in cardiac arrest were allocated to either the IG-SGA or the PSS-LM.

2.2. Setting

The study was conducted in a large Australian ambulance service between August 2010 and October 2011. This EMS incorporates a two-tiered ambulance response system, consisting of qualified paramedics (QP) and intensive care paramedics (ICP). Use of the PSS-LM has been an established procedure within the service for all qualified paramedics since their introduction in 2005. Intensive care paramedics also use the PSS-LM, but also have endotracheal intubation at their disposal. The study was conducted within the response areas of 6 selected non-ICP stations within a metropolitan operational foot print.

2.3. Study outcomes

The primary outcome was successful insertion of the SGA (yes/no), as determined by the paramedic who inserted the device. Success was determined by the paramedic inserting the airway by visualisation of rise and fall of the chest and auscultation for bilateral breath sounds. For this study paramedics were additionally required to apply a colorimetric carbon dioxide detector (*Nellcor[™] Adult Colorimetric CO₂ Detector, Boulder, CO, USA*) to aid in the assessment of successful placement. Capnography was unavailable. Paramedics were allowed a maximum of two attempts, after which if unsuccessful they reverted to standard bag-valve-mask ventilation. The secondary outcomes were the number of insertion attempts (1 or 2) and return of spontaneous circulation (ROSC) at emergency department (yes/no), and paramedic-recorded ‘ease of insertion’. Ease of insertion was recorded after the case on a 5-point scale (very easy/easy/neutral/difficult/very difficult).

2.4. Study inclusions/exclusions

The inclusion criteria were patients aged greater than or equal to 12 years of age; weighing greater than or equal to 30 kg; who were in out-of-hospital cardiac arrest; and for whom the insertion of a SGA was indicated. The exclusion criterion was if a patient was declared dead on arrival by the first paramedic on scene.

2.5. Study procedures

Qualified paramedics at participating stations were provided with brief training in the insertion of the IG-SGA, which included an education package and practical sessions during which airway insertion was practiced on a resuscitation manikin. Training in the use of the PSS-LM was not required as this was already an existing skill within this EMS system.

Each ambulance from the participating stations was equipped with a study airway equipment kit, containing three sizes of each type of SGA (IG-SGA and PSS-LM). Each kit also contained a randomisation envelope to determine group allocation. A clinical trial data sheet detailing group allocation was folded up inside a sequentially numbered, opaque, sealed envelope. That envelope was in turn sealed within an adhesive-backed ‘packing slip’ which was stuck to the outside of the study airway kit. The inclusion and exclusion criteria were clearly typed on the outside of the envelope, allowing quick and easy checking of the eligibility criteria by paramedics on scene. Group allocation was determined by a computer-generated randomisation schedule created by an external biostatistician using Microsoft Excel 2003.

Upon arriving on scene at a patient and confirming cardiac arrest, paramedics commenced standard resuscitation according to the guidelines practiced within this system. Initial airway management for both groups involved a short period of manual bag-valve-mask ventilation following the insertion of an oropharyngeal airway while chest compressions and defibrillation were performed as indicated. Compression to ventilation ratio was 30:2 until such time as a SGA was inserted after which chest compressions were continuous. Paramedics assessed the patient for inclusion into the study against the inclusion/exclusion criteria and upon confirming eligibility, opened the sealed envelope and inserted the allocated SGA as indicated on the data sheet. The size of the device was determined by the paramedic with size selection based on the manufacturer’s recommendations. Assessment of the primary outcome was performed on scene immediately following insertion of the airway device by the attending paramedic. Assessment of the secondary outcomes was made after handover to the resuscitation team in the emergency department.

2.6. Statistical analysis

Previous epidemiological research within this system identified an insertion success rate of 64% for the PSS-LM. Based on this rate of successful insertion in the control group, and with a two-sided 5% significance level and a power of 80%, it was calculated that 50 patients per group would be required to detect a clinically important difference in rate of successful insertion. Based on the frequency of cardiac arrests attended by paramedics at participating stations, it was predicted that patients would be recruited occur over a 12 month period.

Due to the relatively small sample size required, no interim analyses were planned, and no specific stopping rules were stipulated. However, enrolment of patients into the study occurred at a rate much slower than expected, and after the projected 1 year recruitment period only 40 patients had been enrolled. Enrolment of patients continues until the i-gel[®] SGAs passed their expiry dates. At this time, the study investigators decided that as the trial had already surpassed the expected recruitment period, and with the intervention equipment expired, continuation of the trial had become logistically infeasible and thus recruitment into the study ceased. At the time of this early stoppage, 51 patients had been enrolled into the study. The decision to stop the study was made prior to the conduct of any data analysis.

Table 1
Primary and secondary outcomes.

Outcome	Portex® Soft Seal Laryngeal Mask	i-gel® supraglottic airway	<i>p</i>
Successful insertion <i>n/N</i> (%)	16/28 (57)	18/20 (90)	
Number of attempts Q2 (Q1–Q3)	1 (1–2)	1 (1–1)	0.67
Ease of insertion Q2 (Q1–Q3)	3 (2–4)	2 (1.0–2.75)	<0.001
ROSC <i>n/N</i> (%)	7/28 (25)	7/20 (35)	0.66

2.7. Study approvals

Ethical approval was granted by the South Western Sydney Human Research Ethics Committee (Protocol X09-0348). Due to the emergency nature of the presentation, a waiver of consent was granted so the paramedics did not have to engage in that process on scene. The study was registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR) prior to the commencement of patient enrolment (ACTRN12610000472077).

3. Results

A total of 163 cardiac arrests were identified within the study footprint during the enrolment period. The study profile is shown in Fig. 1. There were 62 eligible patients identified during the enrolment period who were not enrolled. The most common reasons were the presence of intensive care paramedics ($n=26$) and no paramedic trained to participate ($n=21$). Less common reasons included failure to take study kit to patient ($n=6$), arrest witnessed by paramedics ($n=4$) or working alone ($n=2$) and unknown ($n=3$). There were 49 cases where paramedics did not commence resuscitation as death had clearly been established. Of the 51 patients randomised, three were not in cardiac arrest at the time of intervention and therefore the intervention was no longer indicated. Data from these three patients was not included in the final analysis (Fig. 1). All other patients were included in the intention to treat analysis.

Overall the average age was 65 years. The mean (SD) age for the PSS-LM and IG-SGA was 66 (17) and 70 (19) respectively. Overall, 40% were females with 13/28 (46%) and 6/20 (30%) for the PSS-LM and IG-SGA respectively. The origins of the arrests were considered likely to be cardiac in 73% of instances with 22/28 (78%) and 13/20 (65%) for the PSS-LM and IG-SGA respectively. There were no apparent differences in key demographic features between groups in this out-of-hospital cardiac arrest population.

Primary and secondary outcomes are shown in Table 1. The IG-SGA airway had a 33% (95% CI 26%–47%) higher insertion success rate than the PSS-LM. The use of the IG-SGA airway was associated with a 58% greater likelihood of successful insertion than the PSS-LM (RR 1.58 95% CI 1.11–2.24 $p=0.023$). Paramedics inserting the IG-SGA device reported significantly lower median “ease of insertion” scores than paramedics inserting the PSS-LM. There were no observed differences in number of insertion attempts or in rates of restoration of spontaneous circulation between the IG-SGA and the PSS-LM groups.

4. Discussion

This study was carried out in order to investigate paramedic success in the insertion of two differing types of SGA, following the introduction into Australia of the i-gel®, a unique device which simplifies airway management by abolishing the need to inflate a perilaryngeal cuff, with its associated requirements of accurate positioning and adequate cuff pressure and volume.⁹

Intubation skills were introduced into paramedic practice in the USA and Australia in the 1970s,¹¹ and into the UK in the mid

1980s,¹² however in recent years it has become increasingly clear that there may be other, less invasive means by which to manage a patient's airway when this is considered necessary. A growing body of evidence exists which suggests that paramedic intubation is associated with poorer outcomes,¹³ and concerns have also been expressed regarding the unavailability of training and lack of opportunity to practice the skill in many jurisdictions.^{14,15} Furthermore, the primary circumstance in which invasive airway management has been practiced is in cardiac arrest, but the 2010 guidelines from the International Liaison Committee on Resuscitation (ILCOR) highlighted that there are no data to support the routine use of any specific approach to airway management in these circumstances,¹⁶ but also imply that extended periods of attempted endotracheal intubation is inappropriate.

Studies in both manikins and anaesthetised patients have shown that paramedics are more successful and faster at securing an airway when using a supraglottic device rather than an endotracheal tube.^{17,18} The use of SGAs which both minimises interruption to other processes, such as chest compressions in cardiac arrest, and which minimises demand for training and practice in order to achieve a successful placement, is clearly desirable.

In our study, the use of the IG-SGA was associated with a 58% greater likelihood of successful insertion than the PSS-LM. Although there have been comparisons between the IG-SGA and other LM models, investigating outcomes such as speed of insertion,^{19,20} ease of insertion¹⁹ and mucosal pressures,⁸ data on comparative insertion success rates are unavailable. We found that the IG-SGA had a 33% absolute higher insertion success rate than the PSS-LM. The observed 57% success rate with the PSS-LM interestingly was in accord with the intra-institutional review of SGA insertion success which preceded this study, and which found a 64% success rate in first time placement in cardiac arrest patients. This concordance in success rates seems so consistent that it may be due to a systematic problem, but whether this is in training, equipment or clinical practice was impossible to determine in the current study. The insertion success rate for the PSS-LM is much lower than LM success rates reported in a number of other studies, both for doctors²¹ and paramedics,⁶ where success rates between 86 and 100% have been reported. Specific clinical reasons for failure are not known and should be evaluated in future studies. Within this ambulance jurisdiction there are an estimated 3000 cardiac arrests attended by paramedics annually.²² This equates to less than one per paramedic suggesting that opportunities for SGA insertion are limited. The 90% success rate for the IG-SGA is consistent with expectations from the literature despite few opportunities (on average) to insert a SGA.

The IG-SGA has also been found to achieve significantly higher leak pressures compared to the Classic® LM, which is important in the formation of a laryngeal seal and consequent prevention, or at least reduction, of regurgitation of gastric contents or blood in the context of continuous chest compressions. Paramedics in our study reported a median ease of insertion score of ‘2’ (very easy) for the iGel versus ‘3’ (easy) for the PSS-LM. One of the reasons for presuming that the IG-SGA would prove to be a superior device in this setting was its simplicity and therefore its supposed ease of use. Indeed, several studies have reported precisely this ease of use in both manikin and patient⁴ settings, however one study suggested that better first time success rate, fewer failures, and a better seal was found with the LM Supreme® compared with the IG-SGA.¹⁰

While this was a randomised controlled trial this study has limitations. Firstly, this was a study which was performed only at selected urban stations within this ambulance jurisdiction, largely determined by geography, accessibility, staff skill-mix (non-ICP stations) and enthusiasm. This could lead to bias due to any of these factors. That being said, our standardised system-wide

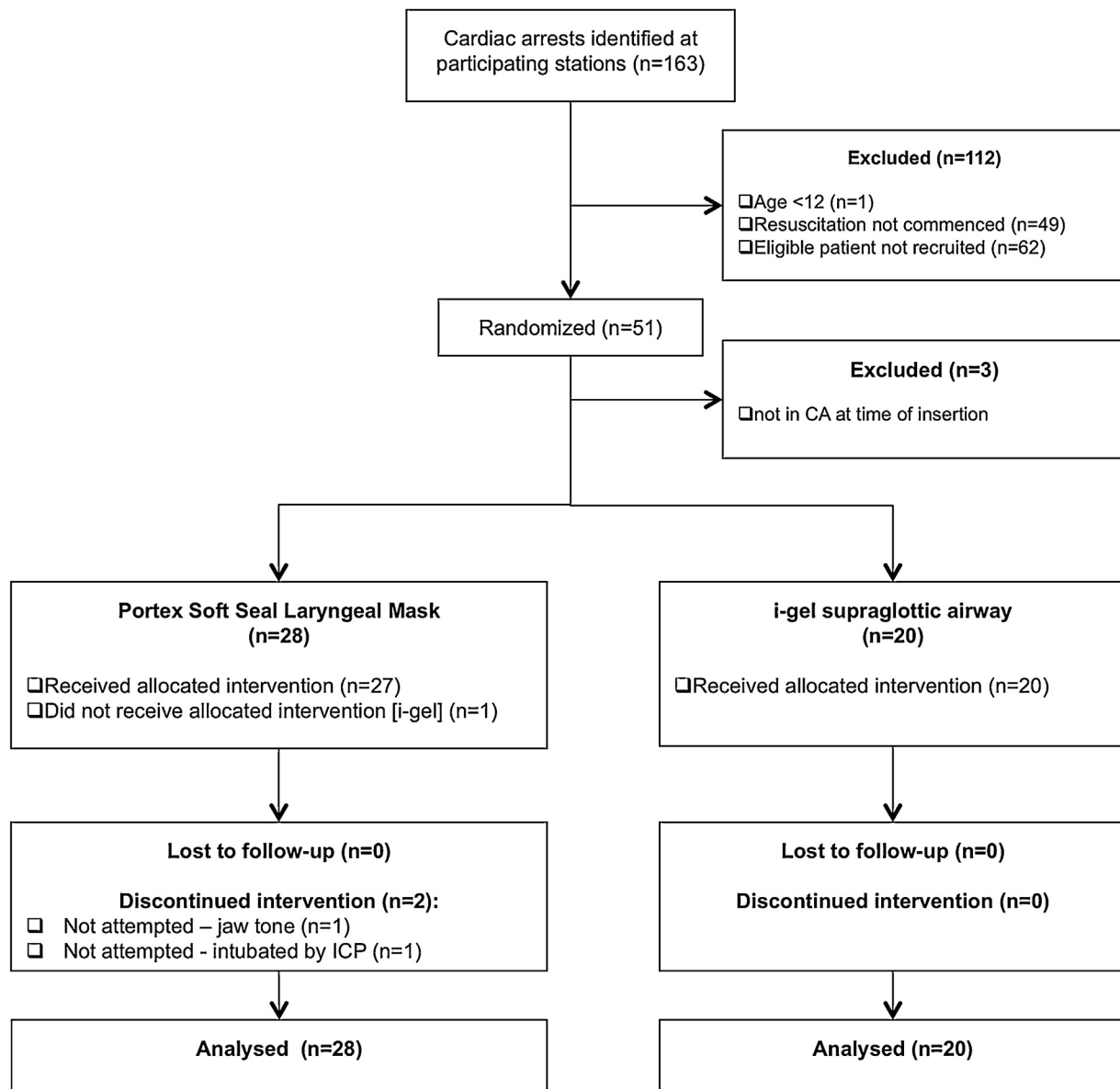


Figure 1: Study profile (CA = cardiac arrest)

Fig. 1. Study profile (CA = cardiac arrest).

approaches to practice and education are likely to minimise any risk of bias.

Secondly, we were unable to achieve full patient recruitment as planned as outlined in the methods. These most likely accounts for the imbalance between groups which we believe occurred by chance rather than due to any systematic bias. Whilst it was estimated that 50 patients per group would be required to detect a clinically important difference in rate of successful insertion, our study of 51 randomised subjects was still able to demonstrate a statistical significant (and clinically important) difference between the IG-SGA vs the PSS-LM groups.

It is not clear whether the findings are of this study can be extrapolated to other first or second generation supraglottic airways or other ambulance services or systems. Although there is clearly further research to be done into the use of this novel SGA in prehospital practice, the overall simplicity of use and favourable characteristics such as the intrinsic bite block, gastric tube channel

and high leak pressures appear to make it an ideal airway for initial use in cardiac arrest by paramedics, allowing rapid and effective airway management.

5. Conclusion

The i-gel[®] supraglottic airway was associated with higher successful insertion rates in subjects with out-of-hospital cardiac arrest. The i-gel[®] supraglottic appears easier for paramedics to use and appears a suitable first line supraglottic airway for out-of-hospital cardiac arrest.

Conflict of interest statement

No conflict of interest to declare.

Acknowledgements

The investigators would like to acknowledge the support of Ambulance NSW and the paramedics who were willing to participate in the study. Appreciation is extended to Mayo Healthcare Australia Pty Ltd who provided the i-gel supraglottic airways (Intersurgical Ltd., Berkshire, UK) used in this study. Mayo Healthcare Australia nor Intersurgical Ltd. had no involvement in any aspect of study design, conduct or analysis. We wish to also thank paramedics Mark Goodger for his role in the quality assurance project which led to this trial and Monika Sitkowski for her assistance in the study roll out to operational sites.

References

1. Brain A. The laryngeal mask: a new concept in airway management. *Br J Anaesth* 1983;55:801–6.
2. Hein C, Owen H, Plummer J. A 12-month audit of laryngeal mask airway (LM) use in a South Australian ambulance service. *Resuscitation* 2008;79:219–24.
3. Goodger MS, Bendall JC, Simpson PM, Middleton PM. Prehospital airway management: Ambulance Service of New South Wales experience since the introduction of the laryngeal mask airway. Conference proceedings of the Australian College of Ambulance Professionals National Conference, October 2009, Auckland, New Zealand. *J Prim Emerg Healthc* 2009;7.
4. Shin W-J, Cheong Y-S, Yang H-S, Nishiyama T. The supraglottic airway I-gel(R) in comparison with ProSeal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients. *Eur J Anaesth* 2010;27:598–601, <http://dx.doi.org/10.1097/EJA.0b013e3283340a81>.
5. Wharton NM, Gibbison B, Gabbott DA, Haslam GM, Muchatuta N, Cook TM. I-gel(R) insertion by novices in manikins and patients. *Anaesthesia* 2008;63:991–5.
6. Duckett J, Fell P, Han K, Kimber C, Taylor C. Introduction of the i-gel(R) supraglottic airway device for prehospital airway management in a UK ambulance service. *Emerg Med J* 2014.
7. Häske D, Schempf B, Gaier G, Niederberger C. Performance of the i-gelTM during pre-hospital cardiopulmonary resuscitation. *Resuscitation* 2013;84:1229–32.
8. Eschertzhuber S, Brimacombe J, Kaufmann M, Keller C, Tiefenthaler W. Directly measured mucosal pressures produced by the i-gelTM and laryngeal mask airway SupremeTM in paralysed anaesthetised patients. *Anaesthesia* 2012;67:407–10.
9. Jang YE, Kim JT, Byon HJ, Lee JR. A randomised trial comparing the i-gelTM airway with the laryngeal mask airway classicTM in children: 19AP2-5. *Eur J Anaesth* 2012;29:230.
10. Ragazzi R, Finessi L, Farinelli I, Alvisi R, Volta CA. LMA SupremeTM vs i-gel(R)TM – a comparison of insertion success in novices. *Anaesthesia* 2012;67:384–8.
11. Katz SH, Falk JL. Misplaced endotracheal tubes by paramedics in an urban emergency medical services system. *Ann Emerg Med* 2001;37:32–7.
12. Deakin CD, Clarke T, Nolan J, et al. A critical reassessment of ambulance service airway management in prehospital care: Joint Royal Colleges Ambulance Liaison Committee Airway Working Group. *Emerg Med J* 2008;27:226–33.
13. Stiell IG, Nesbitt LP, Pickett W, et al. The OPALS Major Trauma Study: impact of advanced life-support on survival and morbidity. *Can Med Assoc J* 2008;178:1141–52.
14. Wang HE, Yealy DM. Out-of-hospital endotracheal intubation – it's time to stop pretending that problems don't exist. *Acad Emerg Med* 2005;12:1245.
15. Wang HE, Yealy DM. Out-of-hospital endotracheal intubation: where are we? *Ann Emerg Med* 2006;47:532–41.
16. Morrison LJ, Deakin CD, Morley PT, et al. Part 8: advanced life support: international consensus on cardiopulmonary resuscitation and emergency cardiovascular care science with treatment recommendations. *Circulation* 2010;122:S345–421.
17. Wahlen BM, Roewer N, Lange M, Kranke P. Tracheal intubation and alternative airway management devices used by healthcare professionals with different level of pre-existing skills: a manikin study. *Anaesthesia* 2009;64:549–54.
18. Pennant JH, Walker MB. Comparison of the endotracheal tube and laryngeal mask in airway management by paramedical personnel. *Anesth Analg* 1992;74:531–4.
19. Jackson KM, Cook TM. Evaluation of four airway training manikins as patient simulators for the insertion of eight types of supraglottic airway devices. *Anaesthesia* 2007;62:388–93.
20. Gatward JJ, Thomas MJC, Nolan JP, Cook TM. Effect of chest compressions on the time taken to insert airway devices in a manikin. *Br J Anaesth* 2008;100:351–6.
21. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: a randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. *Anesthesiology* 2000;93:104–9.
22. Flynn M, Fugaccia E, Thanakrishnan G, Milliss DM, Cheung W. Survival after out-of-hospital cardiac arrest in Sydney, Australia. *Crit Care Resusc* 2006;8:321–7.