Full Title: Paramedic views regarding clinical research in out of hospital cardiac arrest

Running Title: Paramedic views regarding research

Megan RHYS[1], Sarah VOSS[2], Sian Emma DAVIES[3], Dave COATES[4], Jonathan BENGER [2,3]

[1]South Western Ambulance Service NHS Foundation Trust, UK
[2]Faculty of Health and Applied Sciences, University of the West of England, Bristol, UK
[3]Behavioural and Clinical Neuroscience Institute, University of Cambridge, United Kingdom
[4]Academic Department of Emergency Care, University Hospitals Bristol NHS Foundation Trust
[5]GP Out of Hours Service, BrisDoc Healthcare Services, Bristol, UK

CORRESPONDING AUTHOR
Dr Sarah Voss, Associate Professor in Emergency and Critical Care, Glenside Campus (1H14) Blackberry Hill, Bristol BS16 1DD, t. 0117 328 8906, e. sarah.voss@uwe.ac.uk

CONFLICT OF INTEREST STATEMENT
The authors declare no conflicts of interest.

FUNDING
This article presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0110-20288). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

ACKNOWLEDGEMENTS
We are grateful to all the paramedics who participated in the REVIVE-Airways study, and returned data for this research, and to South Western Ambulance Service NHS Foundation Trust for its support.

ETHICS COMMITTEE APPROVAL
Approval was obtained from the Cambridge Central NHS Research Ethics Committee (Ref: 11/EE/0407).

CONTRIBUTORS
Data were collected and analysed by MR, SED and SV under the supervision of DC and JB. The manuscript was drafted by MR, SED and SV, and subsequently revised and approved by all authors.

ABSTRACT

Background: The success of pre-hospital research relies on positive engagement from paramedics. Without adequate participation and protocol compliance trials will not succeed.

Aims: To seek feedback from paramedics about trial participation and determine their preferences regarding a future large-scale research study.

Methods: Paramedics participating in REVIVE-Airways were sent a feedback questionnaire according to their study allocation.

Findings: 99% of respondents were willing to participate in a further large-scale trial. Participants offered recommendations for future pre-hospital trials.

Conclusion: There was strong support for further clinical trials of alternative airway management strategies during OHCA. Paramedics welcome opportunities to participate in research and receive feedback about trial progress and patient outcomes.

KEY WORDS

Cardiac arrest

Airway management

Resuscitation

Pre-hospital care

Paramedics

Research

KEY POINTS

- The success of pre-hospital research relies on positive engagement from paramedics.
- Paramedic feedback regarding their involvement in research is valuable to inform future trials and develop the pre-hospital evidence base.
- Feedback from paramedics was sought regarding airway management techniques in out of hospital cardiac arrest (OHCA), and their future preferences regarding a large-scale research study.
- There was strong support for opportunities to engage with and participate in prehospital research trials.

REFLECTIVE QUESTIONS

- What are the main challenges associated with research on airway management?
- What are the barriers to taking part in research for paramedics?
- What are the research priorities in prehospital care ?

Introduction

Despite continuing research to improve outcomes from out-of-hospital cardiac arrest (OHCA), survival rates remain poor (Berdowski et al, 2010, DoH, 2012). Cardiopulmonary resuscitation (CPR), combined with effective airway management, maximizes the chances of survival (Wang and Yealy, 2013). However, the best method of initial airway management in OHCA is unknown (Woollard and Furber, 2010). Recommendations from the Airway Working Group of the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) conclude that the previously accepted standard of tracheal intubation may not be the optimal approach, and newer supraglottic airway devices (SADs) should be investigated (Deakin et al, 2012).

Evidence regarding the best initial approach to airway management in OHCA has been observational to date, leading to calls for a large-scale, prospective, randomized trial (Soar and Nolan, 2013). REVIVE-Airways (ISRCTN: 18528625), funded by the National Institute for Health Research, was designed to assess the feasibility of completing such a trial, comparing two second-generation supraglottic airway devices; the i-gel (Intersurgical; Wokingham, UK) and the laryngeal mask airway supreme (LMAS) (LMA/Teleflex; San Diego, USA) with current practice during OHCA (Benger et al, 2013). This study was successfully completed during 2013 (Benger et al, 2016).

The successful completion of REVIVE-Airways relied on the positive engagement of participating paramedics. Without this vital factor, clinical trials in pre-hospital care are unlikely to succeed, and this is a challenge that has been reported previously. In addition, paramedic compliance to research protocols may not always be possible, due to the emergency nature of their work (Turner et al, 2000, Burges et al, 2012). As a result, feedback from these clinicians regarding their involvement in the feasibility study is valuable to inform future trials and develop the pre-hospital evidence base. This study presents a companion paper to the main REVIVE-Airways research. We aimed to gather and

analyse the views of paramedics who participated in the REVIVE-Airways feasibility study regarding their future preferences regarding airway management in OHCA and a further large-scale clinical trial.

METHODS

Trial Design and Randomisation

REVIVE-Airways used a cluster randomised design to compare the effectiveness of the early use of the i-gel and LMAS with current practice during resuscitation for OHCA. Cluster randomisation by paramedic was chosen because of the challenges associated with a patient randomised design. The full trial protocol has been published previously (Taylor et al, 2016).

Participants and Setting

Following training and assessment approved by device manufacturers, all participating paramedics were asked to initiate their allocated approach to initial airway management for every eligible OHCA patient that they attended between March 2012 and February 2013. 169 paramedics working within the former Great Western Ambulance Service (now South Western Ambulance Service NHS Foundation Trust) consented to participate in the study, were randomised to one of the three trial arms (i-gel, LMAS or usual practice), and completed the study.

Following trial completion all eligible paramedics were sent one of three postal questionnaires, according to their allocated study arm (Appendix A). Questionnaires were anonymised and participants were not personally identifiable. A generic email reminder was sent to all participants two and four weeks after the initial survey was distributed.

Outcomes

The survey was designed to gain feedback and views from the participating paramedics. Seven of the ten questions related to the paramedic's allocated airway strategy and are not reported in this paper. The other 3 questions related to the paramedic's experience of taking part in the study itself, and their willingness to take part in further research:

a) Please comment on how paramedic involvement and patient recruitment could have been improved in the study.
b) If a larger scale study was run in future what aspects of the study would you like to see changed?
c) Would you be willing to participate in a similar, but larger scale, study in future?

RESULTS

60% of eligible paramedics responded to the exit survey [n=101].

Table 1 shows data from Question 1 on paramedic reports of device use during REVIVE-Airways. Devices were used on average between 2.42 and 3.72 times during the study. For the usual practice arm, this refers to advanced airway management in accordance with JRCALC guidelines.

Table 1: Paramedic report of number of times devices used

Table 2 provides a summary of the free text responses to Questions 8 and 9: These relate to how paramedic involvement and patient recruitment could have been improved in the study and suggestions for changes for a larger scale future study. Participating paramedics praised the opportunities provided by the research, and some requested a larger study with longer data

collection time and wider inclusion criteria. Many requested more feedback on patient outcomes and trial progress, and an opportunity to gain experience in the other device arms.

Table 2: Summary of free text responses to questions 8 and 9.

For Question 10, 100/101 paramedics indicated that they would be willing to participate in a further large-scale trial; only one paramedic (in the usual practice arm) did not answer this question.

DISCUSSION

The response rate and free text replies indicated a number of promising outcomes relating to paramedic involvement in research. The response rate of 60% exceeds previously quoted rates of 20-30% for similar studies in healthcare research (Burns and Gove, 2009). A particularly encouraging finding is the almost unanimous willingness to participate in further studies in this area. Pre-hospital research relies heavily on the engagement and participation of paramedics. Barriers such as ethics approvals, data collection, protocol training and compliance and adequate study staffing have been identified as limiting factors for prehospital research (Lerner et al, 2016). However, in this study participating paramedics praised the opportunities provided by the research. Moreover, a number of paramedics requested a larger study with longer data collection time and wider inclusion criteria. Many requested more feedback on patient outcomes and trial progress, and an opportunity to gain experience in the other device arms. Participants responded to questions about further research and made suggestions as to how a further trial might be improved. These findings suggest that these paramedics have an interest in the subject with a proactive attitude to participation. There is

enthusiasm within the paramedic profession to generate research that is specifically conducted in, and relevant to, the pre-hospital environment.

These findings are indicative of prehospital research being a rapidly growing field, with an increasing number of prehospital clinicians engaging in research. The National Institute for Health Research (NIHR) have recently reported on prehospital research studies that are completed or in progress and shown that between 2014/15 and 2016/17, the number of studies has increased fivefold from nine to 46. Recruitment figures have increased significantly in this time period, from 270 to more than 8,300 (NIHR, 2017). UK ambulance services are developing research frameworks to support the strategic development of research (Siriwardena et al, 2010).

There were, however, some limitations to this study. Responding paramedics were a self-selected group who both volunteered to participate in the REVIVE-Airways trial, and responded to a request to provide data for this study. Therefore, this report may not be wholly representative of trial participants and the wider paramedic profession. The response rate was excellent but nonetheless we were unable to include the views of a proportion of paramedic participants. Furthermore, differences between respondents and non-respondents cannot be described because the survey was anonymous. Data collection took place over one year, and some free text responses indicated that many paramedics felt this did not give them a sufficient number of chances to enrol patients into the trial; indeed, 9% of participating paramedics did not attend any cardiac arrests for the duration of the study. Paramedics suggested that a longer data collection period, clearer guidance on inclusion criteria and a reminder system that activated when they were en route to a cardiac arrest would support protocol compliance and yield more opportunities for them to enrol patients into the study.

CONCLUSION

The findings from this study support the concept of prehospital research as an area of growing interest with increasing levels of engagement from clinicians and practitioners. Responding paramedics were highly positive regarding their research experience, and demonstrated a high degree of willingness to participate in further trials in this subject area. Participants praised the conduct of the study, and requested a larger study with longer data collection time and wider inclusion of patients. A number desired more feedback on patient outcomes and trial progress, and an opportunity to gain experience in the other device arms. Ongoing engagement with the paramedic profession is essential to continue the development of the pre-hospital evidence base. Therefore, it is important to provide opportunities for paramedics to participate in research and provide them with feedback about study progress to ensure their involvement is maintained and that research becomes embedded in professional development.

ETHICS COMMITTEE APPROVAL

Approval was obtained from the Cambridge Central NHS Research Ethics Committee (Ref: 11/EE/0407).

FUNDING

This article presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0110-20288). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

REFERENCES

Benger JR, Voss S, Coates D, Greenwood R, Nolan J, Rawstorne S, Rhys M, Thomas, M. Randomised comparison of the effectiveness of the laryngeal mask airway supreme, i-gel and current practice in the initial airway management of prehospital cardiac arrest (REVIVE-Airways): A feasibility study research protocol. *BMJ Open* 2013; 3:e002467. doi:10.1136/bmjopen-2012-002467

Berdowski J, Berg RA, Tijssen JG, Koster RW. Global incidence of out-of-hospital cardiac arrest and survival rates; systematic review of 67 prospective studies. Resuscitation. 2010;81 (11):1479-87

Burges Watson DL, Sanoff R, Mackintosh JE, Saver JL, Ford GA, Price, Starkman S, Eckstein M, Conwit R, Grace A, Murtagh MJ. Evidence from the scene: paramedic perspectives on involvement in out-of-hospital research. Ann Emerg ed. 2012; 60 (5):641-50

Burns N, Grove S. The Practice of Nursing Research, appraisal, synthesis and generation of evidence, 6th ed, St Louis, MO, Saunders, Elsevier; 2009

Deakin CD, Clarke T, Nolan J, Zideman D, Gwinnutt C, Moore F, Ward M, Keeble C, Blancke W, Furber R, Woollard M. A critical reassessment of ambulance service airway management in prehospital care: Joint Royal Colleges Ambulance Liaison Committee Airway Working Group, June 2008. Emerg Med J. 2012;27:226–33.

Department of Health (2012) http://transparancy.dh.gov.uk/2012/06/19/ambqidownloads/

Lerner EB, Weik T, Edgerton EA. Research in prehospital care: overcoming the barriers to success. Prehospital Emergency Care. 2016 Jul 3;20(4):448-53.

National Institute for Health Research (2017): Research on the rise in ambulance services https://www.nihr.ac.uk/news/research-on-the-rise-in-ambulance-services/7257 (Accessed 02/02/2018)

Soar J, & Nolan, JP. Airway management in cardiopulmonary resuscitation. Current Opinion in Critical Care, 2013;19(3):181-187

Siriwardena AN, Donohoe R, Stephenson J, Phillips P. Supporting research and development in ambulance services: research for better health care in prehospital settings. Emergency Medicine Journal. 2010 Apr 1;27(4):324-6.

Taylor, J., Black, S., Brett, S. J., Kirby, K., Nolan, J. P., Reeves, B. C., ... & Stokes, E. A. (2016). Design and implementation of the AIRWAYS-2 trial: A multi-centre cluster randomised controlled trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest. Resuscitation, 109, 25-32.

Turner J, Nicholl J, Webber L, Cox H, Dixon S, Yates D. A randomised controlled trial of prehospital intravenous fluid replacement therapy in serious trauma. Health Technology Assessment. 2000; 4(31):1-57

Wang HE, Yealy DM. Managing the airway during cardiac arrest. The Journal of the American Medical Association. 2013;309:285-286

Woollard M, Furber R. The College of Paramedics (British Paramedic Association) position paper

regarding the Joint Royal Colleges Ambulance Liaison Committee recommendations on paramedic intubation. Emerg Med J. 2010;27:167-170 doi:10.1136/emj.2009.088443

Table 1: Paramedic report of number of times devices used

Q1.	No of uses	Mean	*SD*	Min	Max
	I-gel (n=39)	3.72	*2.93*	0	10
	LMAS (n=31)	2.42	*1.67*	0	6
	Usual Practice (n=28)	3.36	*2.60*	0	11

Table 2: Summary of free text responses to questions 8 and 9.

	i-gel (40)	LMAS (32)	Usual Practice (29)
8. Comments on recruitment	• Include traumatic arrests • Define hanging • More publicity and information on purposes • Not very often 1st on scene, REVIVE paras targeted to arrests • Recruit all patients requiring Ventilation not just OOHCA • REVIVE para logged on Cad so EOC can remind them on route • Well advertised • Well run study	• Allow students to insert • Form for DNAR or DOA patients • Having access to 3 devices • Increase length of study • Recruit larger number and include solo responders • Have paramedics on research team • Online data collection via portal • Mark REVIVE paramedics on CAD for target • Shame LMAS was removed • Well run study • Wider patient inclusion	• Didn't attend many • Face to Face recruitment by CTLs • Log REVIVE paras with EOC • More paramedics- bigger study • Theatre placements to encourage participation. • DOA box to tick on forms • Well run study
9. Changes	• Widen patient inclusion criteria: not just cardiac arrest • Paediatric trauma • Clearer guidance over inclusion criteria and who should manage airway • Feedback on patient outcomes • Statistical feedback throughout trial • Larger number • Longer trial for 18months • More detailed audit form vomit, time taken to insert • Qualitative aspect on paramedic preferences	• Allow students to insert • Better CRFs • Cake • Clear guidance over who should manage airway • Include other skill grades • Intubating laryngeal mask • More feedback on how devices are performing and study progress • More and locally based refresher days • Replacement stock held locally • Research forum • Use all three devices in rotation design	• More emphasis on utilising REVIVE paramedics to arrests • Better CRF: difficult to fill in, more text space, why certain device was chosen in each case, E-Form option • Use of all 3 devices in a rotation • design • Include all cardiac arrests • Correct intubation kit: ET Tube holders, fibre optic laryngoscopes

	• Replacement stock held locally		