

The Tulip Airway: Man and Manikin; The First Comparison of Identical Protocol RCT Results in Both Human and Manikin Studies

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Abstract : To the best of our knowledge, this is the first study to compare identical protocols in man and manikins. No previous studies were found. The ~Tulip airway device has been specifically designed for everyone, including hospital, theatre and anaesthetic use, especially for inexperienced users both inside and outside hospital, and for home use. It is a hands-free, directly-connectable, first-line, low stimulation oropharyngeal airway that has been designed to replace the Guedel and Facemask technique. Both studies have been peer-reviewed and published in "Anaesthesia" (UK) previously. Two randomized, controlled, cross-over trials (RCTs) using Basic Life Support (BLS) airway providers, defined as inexperienced users (IU's), with annually trained Guedel airway and Facemask skills, compared ventilation using either the Tulip® airway or a Guedel airway with Facemask in 60 subjects, first in manikins and then in humans after the induction of anaesthesia, using identical protocols but within the limitations of equipment that prevented the estimation of end expiratory CO₂ in manikins. The manikin study showed that the Tulip® airway increased ventilation by 9.1% ($p < 0.0423$) in the manikin study but by 76.6% ($p < 0.0002$) in the human study. In both man and manikin, 100% of IU's were able to ventilate with a Tulip® airway on their first-ever encounter with the device, with 0% requiring assistance in either man or manikin. 20% of IU's using a Guedel airway and Facemask required assistance in the manikin study ($p < 0.0003$) and 25% in the human study. There were no significant differences in the number of attempts made to insert each airway device in either trial, with manikin results revealing 98.3% (59/60) IU's introducing the Guedel first time and 93.3% (56/60) introducing the Tulip® first time, whilst the human study showed 78.3% (47/60) for the Guedel and 96.7% (59/60) for the Tulip®. The Tulip® was considered easier to use in both studies (man $p < 0.005$, manikin $p < 0.05$), with the manikin study 76.7% (46/60) of IU's preferred the Tulip® with a nearly identical 78.3% (47/60) of IU's preferring the Tulip® in the human study. Our twin RCTs revealed both similarities and differences in man and manikin results, revealing the actual worth of manikins by replicating the same protocol in both sets of test subjects.

Keywords : anaesthetic airway management, resuscitation, oropharyngeal airway, basic life support

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