Dr. A. Shaikh

Northwick Park Hospital

Watford Rd

Harrow

Middlesex HA1 3UJ

Man and Manikin: The Tulip Airway; the first comparison of identical protocol RCT results in both Human and Manikin Studies.

A. Shaikh[1], P.N. Robinson[2]

1 Managing Director, Age of Aquarius Limited, United Kingdom

2 *Consultant Anaesthetist (Retired), Department of Anaesthesia, Northwick Park Hospital, London, Middlesex, HA1 3UJ, United Kingdom*

Correspondence to:

Dr. A. Shaikh

email: dramershaikh@hotmail.com

Summary

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 (see Table 1).

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 near identical 78.3% (47/60) of IU's preferring the Tulip airway 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.

Introduction

The Tulip airway device has been specifically designed for everyone, including hospital, theatre and anaesthetic use, but especially for inexperienced users both inside and outside hospital and for home use as a hands-free, directly-connectable, first-line, low stimulation oropharyngeal airway to replace the Guedel and Facemask technique, hence twin RCT's to investigate its viability in use.

In response to multiple articles [1, 2, 3, 4], we wish to forward another view that challenges the conclusions proposed relating to the role of manikins in anaesthetic research. Whilst manikins may understandably not be accurate in the simulation of difficult airways due to the stiffness of plastic and the softness of mucosal tissue, we have found that they do have a significant, if not irreplaceable role in airway research. We now compare the results of a manikin and a human study to reveal the close correlation between the two studies and their results when the same protocol is applied within the limitations of manikins.

New anaesthetic airway equipment and the pathway to introduction has been a topic of debate and is a conversation in which we have participated [5, 6, 7, 8]. The 2012 ADEPT recommendations [6, 9] were noted to reflect the Tulip airway process through which the airway had been developed, tested and researched starting with bench testing in 2007, manikin studies in 2007 and 2012 [7, 8] and ultimately producing level 1 evidence with a human randomized controlled trial [8] in 2014. The Tulip is the first airway to utilize this method of introduction.

The discussion included the role of simulation and manikins in initial research, with some suggesting that they were of little value and that research should only involve humans [4]. This was not our finding, as our studies in manikins and humans showed a close correlation between the two types of study. It was suggested that there was no record of the same study being done in manikins and in humans, so to that end we did so using identical protocols

Methods

Both studies have been peer reviewed and published in *Anaesthesia* [8, 10] previously.

A randomized crossover manikin study comparing the Tulip (Guedel Type) airway and the Guedel with Facemask in the hands of BLS (Basic Life Support) trained IU's was conducted [8] in 2012 with a follow on randomized controlled crossover human study [10] in 2014.

Results

Table 1;

a) Consultant vs. Guedel

The first set of analyses compared the outcomes from the consultant ventilation to those using the Guedel.

The figure presented are the mean and standard deviation for each method. Also presented are the mean difference in outcome between methods, along with a corresponding confidence interval. The difference between methods is calculated as value for Guedel minus value for the consultant. P-values indicating the significance of each comparison also reported.

Outcome	Consultant Mean (SD)	Guedel Mean (SD)	Difference (*) Mean (95% CI)	P-value
pCO2 kPa - First breath	3.8 (0.9)	2.4 (1.5)	-1.4 (-1.8, -0.9)	**<0.001**
pCO2 kPa - Average	3.9 (0.8)	2.5 (1.5)	-1.4 (-1.8, -0.9)	**<0.001**
TV mls - First breath	409 (147)	266 (192)	-143 (-201, -85)	**<0.001**
TV mls - Average	445 (114)	286 (196)	-159 (-214, -103)	**<0.001**
IPPV cmH2O - First breath (†)	19.4 (3.2)	13.4 (7.1)	-6.0 (-7.9, -4.0)	**<0.001**
IPPV cmH2O - Average (†)	19.4 (2.6)	13.6 (7.0)	-5.8 (-7.7, -4.0)	**<0.001**
Oxygenation (60%) mls - First	245 (88)	159 (115)	-86 (-121, -51)	**<0.001**
Oxygenation (60%) mls - Average	267 (69)	172 (118)	-95 (-129, -62)	**<0.001**
Oxygenation (80%) mls - First	327 (117)	213 (154)	-114 (-161, -68)	**<0.001**
Oxygenation (80%) mls - Average	356 (91)	229 (157)	-127 (-171, -82)	**<0.001**

(*) Difference reported as value for Guedel minus value for Consultant
(†) Analysis based on 58 subjects, due to two consultant values

Table 2:

b) Consultant vs. Tulip

A similar set of analyses was performed to compare the outcomes obtained from the consultant and the Tulip method.

Outcome	Consultant Mean (SD)	Tulip Mean (SD)	Difference (*) Mean (95% CI)	P-value
pCO2 kPa - First breath	3.8 (0.9)	5.0 (0.7)	1.2 (1.0, 1.5)	**<0.001**
pCO2 kPa - Average	3.9 (0.8)	5.0 (0.7)	1.1 (0.9, 1.4)	**<0.001**
TV mls - First breath	409 (147)	499 (204)	90 (33, 147)	**0.002**
TV mls - Average	445 (114)	494 (175)	49 (0, 97)	0.05
IPPV cmH2O - First breath (†)	19.4 (3.2)	18.3 (3.9)	-1.1 (-2.3, 0.1)	0.06
IPPV cmH2O - Average (†)	19.4 (2.6)	18.3 (3.4)	-1.2 (-2.1, -0.2)	**0.02**
Oxygenation (60%) mls - First	245 (88)	499 (204)	253 (201, 305)	**<0.001**
Oxygenation (60%) mls - Average	267 (69)	494 (175)	227 (182, 272)	**<0.001**
Oxygenation (80%) mls - First	327 (117)	499 (204)	172 (118, 226)	**<0.001**
Oxygenation (80%) mls - Average	356 (91)	494 (175)	138 (91, 184)	**<0.001**

(*) Difference reported as value for Tulip minus value for Consultant
(†) Analysis based on 58 subjects, due to two consultant values

Table 3;

c) Guedel vs. Tulip

A final set of analyses compared the Guedel and Tulip methods.

Outcome	Guedel Mean (SD)	Tulip Mean (SD)	Difference (*) Mean (95% CI)	P-value
pCO2 kPa - First breath	2.4 (1.5)	5.0 (0.7)	2.6 (2.2, 3.0)	**<0.001**
pCO2 kPa - Average	2.5 (1.5)	5.0 (0.7)	2.6 (2.1, 3.0)	**<0.001**
TV mls - First breath	266 (192)	499 (204)	232 (170, 294)	**<0.001**
TV mls - Average	286 (196)	494 (175)	207 (153, 261)	**<0.001**
IPPV cmH2O - First breath	13.4 (7.1)	18.1 (4.0)	4.7 (3.1, 6.3)	**<0.001**
IPPV cmH2O - Average	13.6 (7.0)	18.0 (3.6)	4.5 (2.9, 6.2)	**<0.001**
Oxygenation (60%) mls - First	159 (115)	499 (204)	338 (286, 390)	**<0.001**
Oxygenation (60%) mls - Average	172 (118)	494 (175)	320 (277, 364)	**<0.001**
Oxygenation (80%) mls - First	213 (154)	499 (204)	285 (228, 341)	**<0.001**
Oxygenation (80%) mls - Average	229 (157)	494 (175)	264 (216, 312)	**<0.001**

(*) Difference reported as value for Tulip minus value for Guedel. Differences adjusted for period effects.

Table 4;

Comparisons of the binary target variables were also made, with the analysis results summarised in the next table. The figures reported are the number and percentage of patients taking each outcome for each method, along with the percentage difference in outcome between methods.

Outcome	Consultant N (%)	Guedel N (%)	Difference (*) % (95% CI)	P-value
pCO2 target	48 (80%)	16 (27%)	-53% (-70%, -37%)	**<0.001**
TV target	57 (95%)	35 (58%)	-37% (-51%, -22%)	**<0.001**

(*) Difference reported as value for Guedel minus value for Consultant

Again significant differences between the two methods were obtained. The targets were significantly less likely to be met using the Guedel method compared to values obtained by the consultant. The results indicated highly significant differences in all outcomes between the two methods. In each instance, values obtained from the Guedel were significantly smaller than those obtained from the consultant.

Table 5;

Outcome	Consultant N (%)	Tulip N (%)	Difference (*) % (95% CI)	P-value
pCO2 target	48 (80%)	59 (98%)	18% (6%, 31%)	**0.003**
TV target	57 (95%)	56 (93%)	-2% (-12%, 9%)	1.00

(*) Difference reported as value for Tulip minus value for Consultant

The pCO2 target was significantly more likely to be met using the Tulip method than the by the consultant. However, there was no difference in TV target between methods, with the target being met in over 90% of patients for both methods.

Table 6;

The results for the binary outcomes are given in the final table.

Outcome	Guedel N (%)	Tulip N (%)	P-value
pCO2 target	16 (27%)	59 (98%)	**<0.001**
TV target	35 (58%)	56 (93%)	**<0.001**
Outcomes in <60 seconds (†)	49 (83%)	59 (100%)	**0.004**
Parameters in 2 attempts	49 (82%)	60 (100%)	**0.002**

(†) Analysis based on 59 subjects, due to missing values for one patient

Table 7; Comparative results for inexperienced user (IU) Man and Manikin studies, using both the Tulip and the Guedel/ Facemask method with identical study protocols.

IU Tulip GT vs. Guedel/Facemask	MAN	MANIKIN
Tulip Insertion First time	96.7%	93.3%
Guedel Insertion First time	78.3%	98.3%
p-value	$p < 0.001$	$p < 0.001$
Tulip Success Rate	100%	100%
Guedel Success Rate	58.3%	80%
p-value	$p < 0.001$	$p < 0.001$
Tulip Inadequate Vent.	5%	0%
Guedel Inadequate. Vent.	41.7%	20%
Tulip Assistance Required	0%	0%
Guedel Assistance Required	25%	20%
p-value	$p < 0.0001$	$p < 0.0003$
Tulip as IU Preference	78.3%	76.7%
p-value	$p < 0.005$	$p < 0.05$
Tulip Average Tidal Volume	501mls	397mls
Guedel Average Tidal Volume	284mls	364mls
Increase by Tulip Ventilation	+76.6%	+9.1%
p-value	$p < 0.0001$	$p < 0.0423$
Tulip Average Vent. Pressure	17.5cmH2O	
Guedel Average Vent. Pressure	13.4cmH2O	
Increase in Vent. Pressure	+30.6%	
p-value	$p < 0.0001$	
Tulip pCO2	4.89	
Guedel pCO2	2.36	
Increase in pCO2 with Tulip	+107.8%	
p-value	$p < 0.0001$	

The results of both studies, when compared showed close correlation, suggesting that not only are manikin studies of value, they are an essential and safe step in the research and development of new airway devices such as the Tulip airway. Manikins are not good at simulating everything but certain aspects of study make them worthwhile in data collection and study.

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. This was the biggest difference between the man and manikin study, with the remainder of the results being remarkably similar. The studies suggested manikins, if anything, are harder to ventilate than humans, which raises the bar for training through added difficulty.

In both studies 100% of IU's were able to ventilate with a Tulip airway on their first ever contact with the device, with 0% requiring assistance in man or manikin but 25% (15/60) of Guedel airway and Facemask users required assistance in the human study and 20% (12/60) required assistance in the manikin study ($p < 0.0003$). 5% (3/60) of Tulip airway users failed to achieve the required ventilation parameters in humans with total 41.7% (25/60) of Guedel users failing to achieve adequate ventilation parameters in the same 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) IU's 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.

In the manikin study 76.7% (46/60) of users preferred the Tulip with a near identical 78.3% (47/60) of users preferring the Tulip in the human study, with no significant difference in the number of attempts made to insert each airway device and the Tulip being considered easier to use in both studies (man $p < 0.005$, manikin $p < 0.05$).

Interestingly, whilst 25% (15/60) of IU's requested assistance in the human study, an additional 16.7% (10/60) of Guedel airway and Facemask users failed to ventilate at all but did not ask for assistance, showing high combined failure rates of 41.7% (25/60) in BLS Guedel and Facemask airway management by IU's in real patients.

In the manikin study [8] 20% (12/60) IU's required assistance to generate satisfactory tidal volumes using a Guedel and BVM, which was significantly more than when using the Tulip (0% assistance requested, $p < 0.0003$). The average tidal volumes generated, when used as a single-operator technique, was significantly greater with the Tulip and BVM (397ml) compared with the same IU's using the Guedel and BVM (364ml, $p = 0.0423$). There was no significant difference noted between the number of attempts to insert either device first time, 93% (56/60) for the Tulip and 98.3% (59/60) for the Guedel. There was a significant difference noted when the IU's were asked to state which device they found easier to use. 76.6% (46/60) stated that they preferred using the Tulip and only 23.3% (14/60) preferred using the Guedel (one-sample z scores of -4.15 to 4.15, $p < 0.05$).

In humans [10] the analysis of the binary outcome data showed that the outcome of adequate ventilation in less than 60 seconds and within 2 attempts was achieved with 58.3% (35/60) of Guedel and Facemask users demonstrating 16.7% (10/60) total failures and 25% (15/60) inadequately ventilated patients (Total 41.7%). With the Tulip airway 95% (57/60) of users achieved the required outcome variables with 0% (0/60) total failures and 5% (3/60) inadequately ventilated patients. This study showed that when comparing the Tulip airway to the Guedel airway with Facemask ventilation the BLS trained user on average generated 77% bigger tidal volumes, 101% higher end-tidal CO_2 readings and 36% higher ventilation pressures and no failures with the Tulip airway.

This was statistically significant in favour of the Tulip airway at a $p < 0.001$ level. In terms of user preference 78.3% (47/60) of users favoured the Tulip airway in humans.

In humans the end-tidal carbon dioxide, tidal volume and peak inspiratory pressures were significantly better ($p < 0.0001$) for all parameters with the Tulip airway. The Tulip airway was found to be easier to insert and demonstrated a steep learning curve for the BLS trained airway providers. These results are similar to the manikin study and this suggests a close correlation between human and manikin studies for this airway device. No other studies comparing an identical protocol in both manikins and humans could be found on searches. The Tulip is the first airway device to be introduced using this method of testing and study.

Discussion

A potential problem with this type of study is that one commonly used familiar method (Guedel and Facemask) is being compared to a previously unknown piece of equipment and technique such as the Tulip airway. The rationale and reasoning for using this method as an acceptable study basis is that this is the reality of the clinical situation when a new device is introduced into clinical practice. Any new device is introduced without retraining on the current equipment in use. As this is a first-contact study it is, in reality, the worst-case clinical scenario for a new device in that any bias is against the new device. Despite this user familiarity with the old device, this study shows that a new device appears to work significantly better that the existing current equipment. A Consultant Anesthetist was used as a bench-line for performance with experienced users.

One perceived advantage of the Tulip airway is its ease of use and steep learning curve. This study confirms that manikin learning skills for the Tulip airway are easily transferred to the clinical environment, which is in contrast to a recent study in this journal of inexperienced users using the LMA Supreme™ airway [11]. They concluded that results in manikin studies cannot be easily transferred to the clinical situation, but in our study manikin teaching was transferred to the clinical environment without any difficulty, after a solitary manikin teaching session. Furthermore when we compared our human results [10] to our previous manikin study [8] there was a close correlation between ventilation in man and manikin, and if anything, manikins were found to be harder to ventilate than humans. Furthermore, the Tulip airway is capable of generating >100cmH_2O ventilation pressure without a leak in manikins, which is clearly undesirable in humans, so manikins, in our experience, enable gross study and the evaluation of extreme parameters such as ventilation pressure, with safety and ease, preventing potential harm to patients in whom such evaluations may be detrimental, if not unethical.

These studies raise the question as to why BLS airway management using the Guedel and Facemask is still performed when failure rates are as high as 41.7%, despite annual BLS training with the Guedel and Facemask and out of hospital cardiac arrest survival without neurological deficit is approximately 1.25-2.5% [12]. It should be noted that a significant number of IU's failed to ventilate at all in humans (16.7%) with a Guedel and Facemask but still did not ask for assistance (41.7% inadequate ventilations), perhaps due to the NHS mandatory requirement of competency for airway management in BLS. This may be unrealistic, as Inexperienced Users clearly find current Guedel and Facemask management difficult, with high failure rates, yet IU's have had no other alternative airway available until now.

Regurgitation is an issue which is commonly raised, but evidence has existed for some time that regurgitation is actually more frequent with Laryngeal Masks than Guedel airways due to the forced opening of the upper oesophagus by these supraglottic devices [13, 14, 15, 16] and that gastric insufflation is uncommon when ventilation pressures are maintained below 20cmH20 [16]. Our studies revealed that whilst ventilation pressures are increased when IU's use the Tulip airway (17.5cmH2O) when compared to a Guedel and Facemask combination (13.4cmH2O) in humans (30.6%) this is because the high failure rate of IU's to form a Facemask seal at all is the primary cause.

The average Vt generated, in manikins, was significantly greater with the Tulip and BVM (397ml) compared with the same IU's using the Guedel and BVM (364ml, $p=0.0423$). In humans this was

501mls for Tulip GT and 283.7mls for a Guedel and Facemask combination technique, an increase of 76.6% ($p<0.0001$).

Ventilation pressures, whilst raised by IU's using a Tulip (17.5cmH2O), were actually lower than when a Consultant Anaesthetist used a Guedel and Facemask (19.4 cmH2O), yet the IU's provide a higher tidal volume with a Tulip (501mls) than the Consultant using a Guedel and Facemask combination (420.6mls), so the Tulip actually provides higher tidal volumes for lower ventilation pressures, increasing ventilation, and reducing the likelihood of reflux and regurgitation by maintaining low ventilation pressures <20cmH2O.

The Consultant Anaesthetist generated excess ventilation pressure (>20cmH2O) in 39.7% of Guedel and Facemask ventilations to achieve an average tidal volume of 420.6mls, but the IU's generated >20cmH2O only 18.9% of the time for a greater average tidal volume (501mls), which may also be of benefit for experienced users to reduce potential regurgitation risks. Initially, using a Guedel and Facemask, the Consultant generated 48.2% greater tidal volumes, 44.7% higher ventilations pressures and removed 58.3% CO2 than an IU, but when using a Tulip, the IU then generated 19.1% greater tidal volumes, but at safer and lower ventilation pressures of -10.8%, and yet IU's still registered 30.78% more pCO2. Tulip seems to improve ventilation and CO2 elimination, and seems to do so at lower ventilation pressures.

Additionally, ease of use, higher ventilation volumes, lower ventilation pressures and a higher inspired O2% (estimated at >200% more O2 per breath) is further assisted by the hands-free, directly-connectable design of a Tulip, which has lower dead space and rebreathing volumes than a Guedel and Facemask combination. As such the Tulip can be directly connected to a ventilator and secured through head-ties or optional headband assemblies (see picture).

Both studies showed that the Tulip increased ventilation when compared to a Guedel and Facemask, by 9% ($p < 0.05$) in the manikin study but by 77% ($p < 0.001$) in the Human version with both results being statistically significant. This was one of the biggest differences between man and manikin. In both studies 100% of users were able to ventilate with a Tulip, with the manikin study showing $p < 0.0003$ and the human study demonstrating $p < 0.001$. Again, in both studies a similar number of Guedel users required assistance with 20% requiring assistance in the manikin study ($p < 0.0003$) and 25% requiring assistance in the Human study but with $p < 0.001$. In the manikin study 76.6% of users preferred the Tulip with a near identical 78.3% of users preferring the Tulip in the human study. Not all results are similar in man and manikin, but we believe the significant correlation to be of note.

The Tulip airway have been shown to be easier to use and more effective with our combined studies suggesting that the Tulip should be used for initial airway management, especially by inexperienced users for BLS both inside hospital, outside hospital and operating theatre settings [18]. These studies were conducted by the team at Northwick Park Hospital, Harrow, and with the assistance of the inventor, so it may now be time for others to investigate the efficacy of the Tulip airway range, with consideration given for assistance by the ADEPT [9] policy of exclusion of weaker devices whilst assisting the most promising new equipment by fast-tracking research and use. In this case investigating whether the Tulip should replace the 93 year old Guedel airway, as what else of such age, and poor function, do we still use in modern clinical practice?

Our studies suggest that this should be considered as the Tulip is a low stimulation airway when compared to a Guedel available and offers significant results, despite the inexperienced users being annually trained with a Guedel and Facemask combination, and these studies being the first contact the IU's had with the Tulip airway device. It is well documented that IU's have difficulty with the Guedel and Facemask combination [19, 20, 21] but how much better would the results be if the IU's were annually trained in Tulip use as well as the Guedel and Facemask combination used in these studies by the IU's? Practice makes more perfect.

With previous publications [22, 23] highlighting the need for randomized controlled trials (RCT) rather than observational studies to observe new airway devices, we have now provided multiple confirmed statistically significant results with trials conducted as RCT's in both man and manikin, which do provide parallel control groups and have demonstrated ventilation failure rates below 1%. This then raises the question, how good can the Tulip actually be? [7, 8, 10, 17, 24]. Especially after annual training, as is used in the current Guedel and Facemask BLS method.

These studies were part of a sequence of studies logically designed to assess a new airway [9]. We have previously stressed the importance of manikin studies in supraglottic airway studies and this view has been recently supported [25]. The human study [10] is an in-vivo reproduction of an identical manikin study [8] and to our knowledge, the first for any airway device, in keeping with ADEPT guidelines [9].

With confirmation from an observational human studies [10, 17], our own manikin studies [7, 8] and an independent manikin study [24], we conclude that manikin studies are effective in the evaluation of new airway devices such as the Tulip airway and should be taken seriously for the development of pre-emptive data, but again we state, that the results will only as good as the manikin and the simulation. Ventilation seems to be harder in manikins, but airway management and Facemask seal formation seems to be harder in humans, suggesting that difficult airway simulation may well be suboptimal in manikins. Also the high frictional component of the iGEL and LMA places them at a disadvantage in manikins, but this is a true reflection of their actual size and resistance, but amplified by dry, plastic-on-plastic surfaces.

Through these twin studies we found that it isn't man or manikin, it is man and manikin, especially when studying new devices such as the Tulip airway. Manikins form part of a logical pathway by minimizing potential harm and accelerating both study and development of new airway devices, and as such, the Tulip airway pathway and process is thus the first to confirm both the benefits and reliability of manikins and the ADEPT [9] process of introduction of new airway devices.

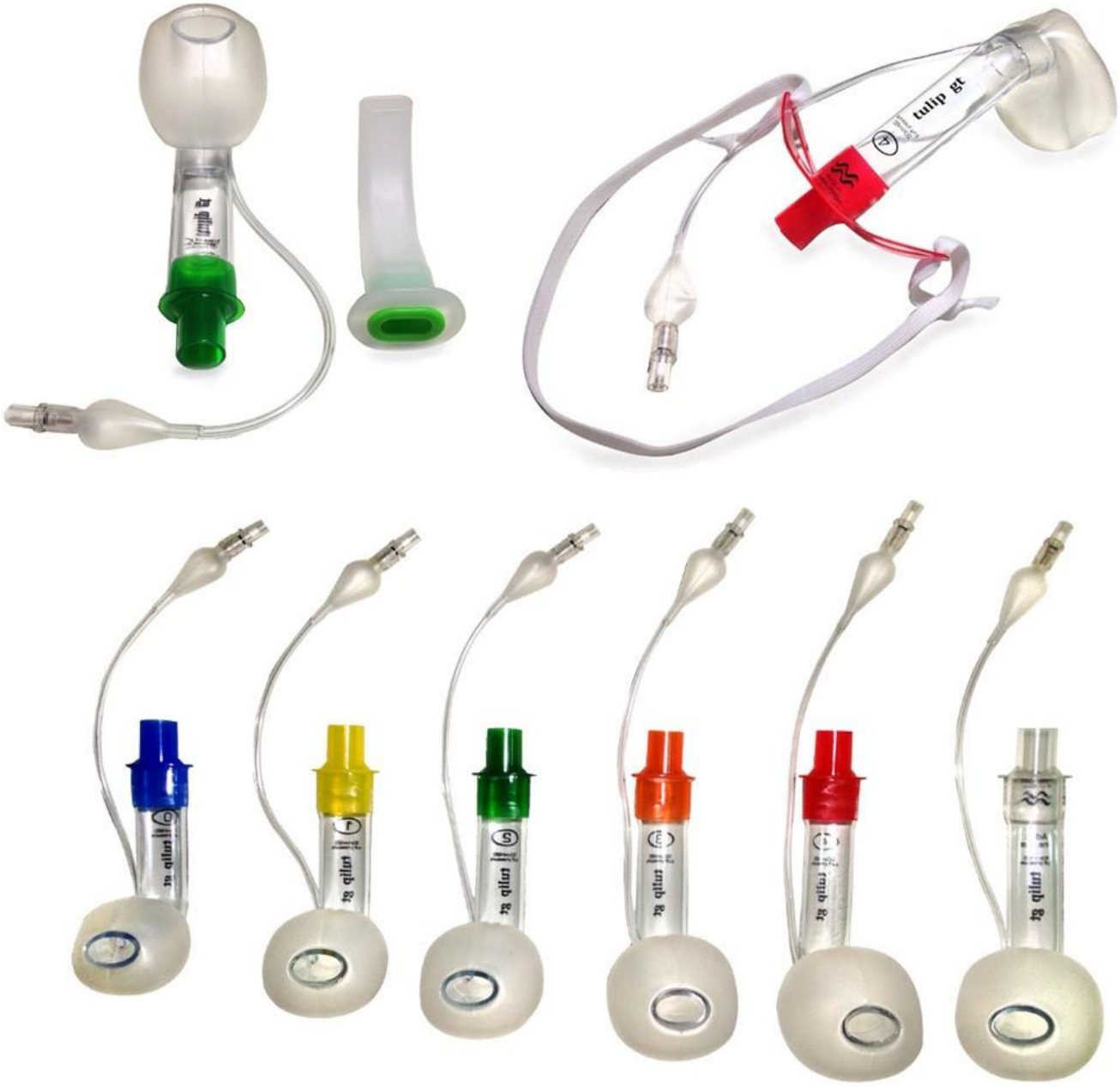
Acknowledgements

The Tulip devices were purchased by the North West London Hospitals NHS Trust and no funding for the study was sought. Paul Bassett provided statistical input to the results of both studies.

Competing interests

Dr. Amer Shaikh is the inventor of the Tulip airway and was not involved in the conduct of the clinical study but was involved in its writing, planning and design. The airways used in the study were purchased by the North West London Hospitals Trust from ~ AoA™ (~ Age of Aquarius™, UK), of which Dr. Shaikh is the owner and director. No other competing interests declared.

Illustrations;



References

1) Ahmad I, Onwochei DN, Muldoon S, Keane O, El-Boghdadly K. Airway management research; a systematic review. *Anaesthesia* 2019; **74**: 225-236.

2) Ahmad I, El-Boghdadly K. From evidence based on practice to evidence-based practice; time for a difficult airway management strategy. *Anaesthesia 2019; **74**: 135-139.*

3) Ward PA, Irwin MG. Man vs. Manikin revisited – the ethical boundaries of simulating difficult airways in patients. *Anaesthesia* 2016; **71**: 1399-1403

4) Popat MT, Rai MR. Evaluation of airway equipment: Man or Manikin. *Anaesthesia* 2011; **66**: 1-3.

5) Robinson NP, Shaikh A. Manikin studies are essential. *Anaesthesia* Correspondence, September 2011.

6) Robinson NP, Shaikh A. An ADEPT apology; *Anaesthesia* 2012; **67**: 432-433.

7) Harrison S, Robinson NP, Shaikh A, Yentis SM. Manikin evaluation of the Tulip – a new supraglottic airway. *Anaesthesia* 2009; **64**: 807.

8) Kynoch M, Saini R, Robinson PN, Shaikh A, Hasan M, Vaughan D. Randomized crossover comparison of the Tulip airway compared with the Guedel airway for inexperienced users in a manikin. *Anaesthesia* 2013; **68**: 317.

9) Pandit JJ, Popat MT, Cook TM, Wilkes AR, Groom P, Cooke H, Kapila A, O'Sullivan E. The Difficult Airway Society 'ADEPT' guidance on selecting airway devices: the basis of a strategy for equipment evaluation. *Anaesthesia* 2011; **66**: 726-37.

10) Shaikh A, Robinson NP, Hasan M. The Tulip airway versus the Guedel airway and facemask: a randomized, controlled, cross-over clinical study comparing airway ventilation with Basic Life Support (BLS) trained airway providers in anaesthetised patients. *Anaesthesia* 2016; **71**: 315-9.

11) Russo SG, Bollinger M, Strack M, Crozier TA, Bauer M, Heuer JF. Transfer of airway skills from manikin training to patient: success of ventilation with facemask or LMA-Supreme™ by medical students. *Anaesthesia* 2013; **68**: 1124-31.

12) Hasegawa K, Hiraide A, Chang Y, Brown DFM. Association of pre-hospital advanced airway management with neurologic outcome and survival in patients with out of hospital cardiac arrest. *Journal of the American Medical Association* 2013; **309**: 257-266.

13) Rabey PG, Murphy PJ, Langton JA, Barker P, Rowbotham DJ. Effect of the laryngeal mask airway on lower oesophageal sphincter pressure in patients during general anaesthesia. *British Journal of Anaesthesia* 1992; **69**: 346-8.

14) Keller C, Brimacombe J, Radler C, Puhringer F. Do laryngeal mask airway devices attenuate liquid flow between the oesophagus and the pharynx? A randomized, controlled cadaver study. *Anesthesia and Analgesia* 1999; **88**: 904-7.

15) Ho-Tai LM, Devitt JH, Noel AG, O'Donnell MP. Gas leak and gastric insufflation during controlled ventilation: facemask versus laryngeal mask airway. *Canadian Journal of Anaesthesia* 1998; **45**: 206-11.

16) Schmidbauer W, Genzwurker H, Ahlers O, Proquitte H, Kerner T. Cadaver study of oesophageal insufflation with supraglottic airway devices during positive pressure ventilation in an obstructed airway. *British Journal of Anaesthesia* 2012; **109**: 454-8.

17) Robinson PN, Shaikh A, Sabir NM, Vaughan DJA, Kynoch M, Hasan M. A pilot study to examine the effect of the Tulip oropharyngeal airway on ventilation immediately after mask ventilation following the induction of anaesthesia. *Anaesthesia* 2014; **69**: 707-711.

18) Cook TM, Woodall N, Frerk C. Fourth national Audit Project. Major complications of airway management in the UK. *British Journal of Anaesthesia* 2011; **106**: 617-642

19) Alexander R, Hodgson P, Lomax D, Bullen C. A comparison of the laryngeal mask airway and Guedel airway, bag and facemask for manual ventilation following formal training. *Anaesthesia* 1993; **48**: 231-4.

20) Tolley PM, Watts AD, Hickman JA. Comparison of the use of the laryngeal mask and facemask by inexperienced personnel. *British Journal of Anaesthesia* 1992; **69**: 320-1.

21) Martin PD, Cyna AM, Hunter WA, Henry J, Ramayya GP. Training nursing staff in airway management for resuscitation. A clinical comparison of the facemask and laryngeal mask. *Anaesthesia* 1993; **48**: 33-7.

22) J. J. Pandit. If it hasn't failed, does it work? On 'the worst we can expect' from observational trial results, with reference to airway management devices. *Anaesthesia* 2012; **67**(6): 578-83.

23) Hodzovic I, Wilkes AR. Observational trials and airway devices: more to it than just sample size. *Anaesthesia* 2012; **67**: 1287-89.

24) Murashima K, Ozaki M. New supraglottic airway device Tulip is easy to insert: a manikin study. *Anesthesia and Analgesia* 2011; **112**: S05.

25) Kristensen MS, Teoh WH. Which supraglottic airway will serve my patient best? *Anaesthesia* 2014; **69**: 1189-92.