



ORIGINAL ARTICLE

The effect of pilot balloon design on estimation of safe tracheal tube cuff pressure

K. M. Janossy,¹ J. Pullen,² D. Young³ and G. Bell⁴

1 Consultant Anaesthetist, Nevill Hall Hospital, Abergavenny, UK

2 Product Design Engineer, Arc Product Design Ltd., UK

3 Consultant Statistician, Department of Mathematics and Statistics, University of Strathclyde, Glasgow, UK

4 Consultant Anaesthetist, Royal Hospital for Sick Children, Glasgow, UK

Summary

We studied the effect of pilot balloon design on the ability of experienced anaesthetists to assess and inflate tracheal tube cuffs to safe pressures. A model trachea was designed, incorporating a degree of compliance and an air leak, to evaluate six different pilot balloons grafted onto identical tracheal tubes. Pilot balloons were inflated to one of four pressures and anaesthetists were asked to estimate whether the pressure was acceptable, too low or too high. Anaesthetists were then asked to inflate the cuff of each tube. Overall, 103 (42.9%) of anaesthetists' assessments of tracheal tube cuff pressures were correct (33% correct would be expected by chance, $p = 0.002$). Pressures generated by anaesthetists inflating tracheal tube cuffs were very variable. Median (IQR [range]) pressures for each pilot balloon ranged from 29 (17–43 [9–56]) cmH₂O to 74 (49–114 [4–140]) cmH₂O ($p < 0.001$). The design of the pilot balloon significantly affects anaesthetists' ability to inflate tracheal tube cuffs to safe pressures.

Correspondence to: Dr G. Bell

Email: Graham.bell@ggc.scot.nhs.uk

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Over-inflation of tracheal tube cuffs reduces tracheal mucosal blood flow [1] and has been implicated in post-intubation tracheal stenosis [2]. Seegobin and van Hasselt demonstrated a reduction in tracheal mucosal blood flow in humans with tracheal cuff pressures of greater than 30 cmH₂O, and total obstruction of blood flow above 50 cmH₂O [1].

The incidence of post-intubation tracheal stenosis is difficult to estimate. Severe morbidity is reflected by the incidence of airway reconstruction. The population incidence of cases requiring referral to a specialist airway reconstructive service has been estimated at 4.9 cases per million per year (or 197 cases in England per year) [3]. Tracheal stenosis may develop after intubation of less than 2 days [4], although the duration of intubation is associated with increased risk in some studies [5, 6]. The largest case series of over 500 patients requiring surgical treatment [4] found over 50% of lesions at the site of the cuff. A prospective study in 150 critically ill patients [5] found a 10% incidence of tracheal stenosis in survivors,

of which one was symptomatic. Nearly all patients who died had tracheal injury at autopsy. This was related to prolonged tracheostomy with cuff pressures of > 20 cmH₂O, although there was no correlation with mean cuff pressure. A similar study in patients with neurological disease [7] found a 20% incidence of airway stenosis of which one quarter required surgery or a permanent tracheostomy, or died.

Post-intubation tracheal rupture is rare and there are no data on its incidence. Difficult intubation, use of a stylet and cuff over-inflation may be associated factors. In a case series of 30 patients, mortality was 20%, half of which was related to tracheal rupture [8]. Tracheal tube cuff pressure has also been implicated in sore throat but a direct association has not been demonstrated.

Two telephone surveys of UK intensive care units found that tracheal tube and tracheostomy tube cuff pressures are checked regularly in only 17% [9] or 42% [10] of units. A subsequent Intensive Care Society guideline [11] recommends that tracheostomy cuff pressure

should be checked regularly with a manometer and kept below 25 cmH₂O. It is not standard practice to check tracheal tube cuff pressures routinely during anaesthesia [12] despite several studies concluding that this is best practice [13–15]. Evaluation of cuff pressures using clinical endpoints, such as palpation or air leak, has been shown to be inaccurate in patients in theatre [14, 15], intensive care [10, 16, 17], and the emergency department [18]. Dangerously high tracheal tube cuff pressures were generated with mean pressures > 108 cmH₂O by US paramedics [19], 93 cmH₂O by experienced emergency physicians [18], and 35 cmH₂O by anaesthetists [15], and median values of 40–60 cmH₂O in anaesthetised children [14].

Diffusion of nitrous oxide into tracheal tube cuffs during anaesthesia leads to a progressive increase in cuff pressure. Various tubes, cuffs and pilot balloons have been designed to limit this, with very limited or short-lived efficacy. These include the Portex Profile Soft-seal™ (PSSC; Sims Portex, Kent, UK) [20], Trachelon™ gas barrier (Terumo Co. Ltd., Tokyo, Japan) [21], Micro-cuff™ (GmbH, Weinheim, Germany) [22], Brandt™ (Mallinckrodt, Athlone, Ireland) [23, 24] and Lanz® (Mallinckrodt Medical, St. Louis, MO, USA) [25] tubes. Numerous pressure limiting and regulating devices have been tested [17, 26–37]. Whilst these devices should, theoretically, help to ensure correct cuff pressure, none have gained widespread adoption into routine clinical practice.

Previous *in vitro* studies of tracheal tubes have been conducted using 2-cm diameter non-compliant glass or plastic tubes to simulate a human trachea [20, 24, 26, 29, 30, 38]. The aim of the present study was to investigate whether the type of pilot balloon affects the ability of experienced anaesthetists to estimate tracheal tube cuff pressure by palpation, and to inflate tracheal tube cuffs to the correct pressure, using a more realistic trachea model incorporating an air leak.

Methods

Written consent was obtained from all participants and ethical review was not required. We developed a trachea model consisting of plastic tubes with slits to increase compliance surrounded by rubber sheaths to simulate a human trachea. A size 9.0-mm internal diameter Smiths-Portex Blue Line tracheal tube with a Profile Soft-Seal cuff and an external diameter of 12.3 mm (Smiths Medical International Limited, Watford, UK) was placed in a 20-mm diameter 20-ml BD syringe barrel (Becton Dickinson UK Limited, Oxford, UK). This size was chosen as the majority of anaesthetists tested would be most familiar with adult patients and this was consistent

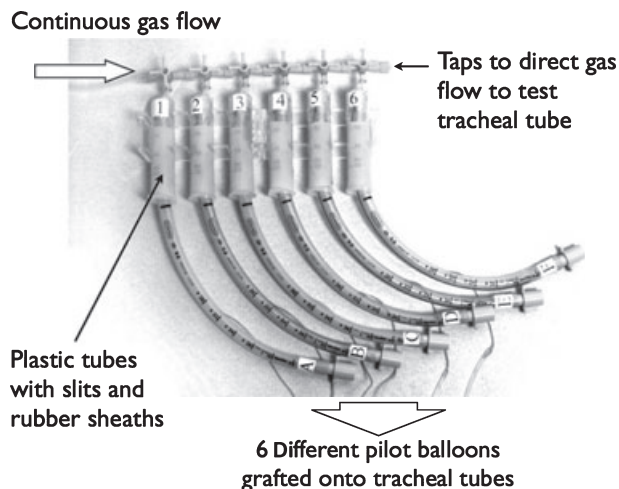


Figure 1 Test rig for comparing pilot balloons.

with the majority of previous studies. The precise length of the slit was determined by asking experienced anaesthetists and operating department practitioners to evaluate several prototypes for their resemblance to the feel of a human trachea. Middle fingers from standard size-8 Biogel surgical gloves (Mölnlycke Health Care Limited, Dunstable, UK) were placed around the slit tubes. A continuous gas flow of 4 l.min⁻¹ past the lubricated tracheal tube cuff was added to simulate the air leak in a real patient (Fig. 1).

Six different pilot balloons were each grafted onto the tracheal tubes: three tracheal tube pilot balloons and three laryngeal mask airway pilot balloons (Fig. 2). The pilot balloon tubing was joined without constricting the tubing. If possible one tube was fitted inside the other; otherwise both ends were inserted into an external sheath. The join was sealed using a silicone compound. Twenty anaesthetists, each with more than 2 years' experience, were tested.

Pilot balloons were inflated to one of four pressures: low (5–15 cmH₂O); acceptable (20–30 cmH₂O); high (35–45 cmH₂O); or very high (50–60 cmH₂O). Anaesthetists assessed the pilot balloons in random order and were asked to estimate whether the pressure was acceptable, too low or too high. They were given two randomly selected pressures for each tube. Randomisation was using an online true random number generator (<http://www.random.org>).

Anaesthetists were then asked to inflate the cuff of each tube from fully deflated, judging the pressure using cessation of the air leak, palpation of the pilot balloon or the feel of the syringe as they would in a real patient. The cuff pressure was simultaneously measured using a Druck DPI 700 IS manometer (Druck Limited, Leicester, UK), calibrated before and on completion of testing. The

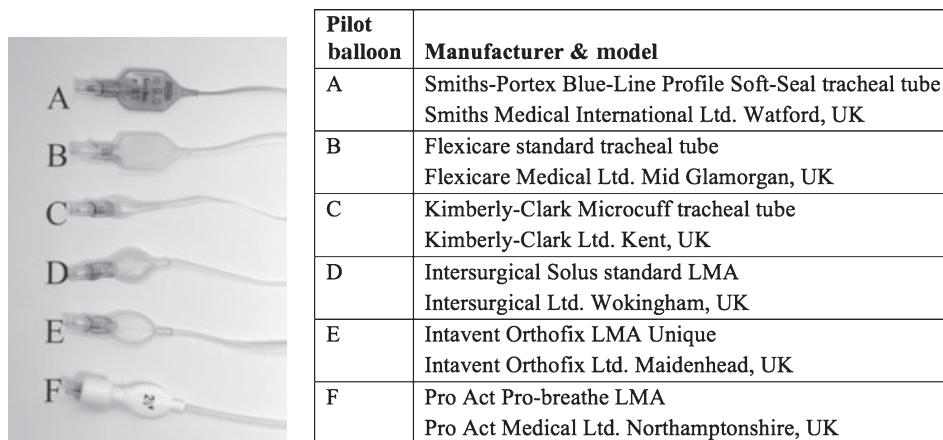


Figure 2 Pilot balloons tested.

pressure was recorded when the anaesthetist stated it was acceptable. Each cuff was inflated twice. The sequence of inflation of the cuffs was determined using an online random number generator.

Results of estimated balloon pressure assessments were reported as percentage correct for each balloon and for all results combined. These results were then compared to those expected by chance using Z-tests, or Fisher’s exact test for $n < 5$.

Agreement between the pressure measurements on the two occasions was investigated by computing limits of agreement. Differences in mean pressure measurements between the pilots were tested using a general linear model while correcting for differences between assessors and between the two assessments. All analyses were performed using Minitab version 15 (Minitab Inc. State College, PA, USA.) at a significance level of 5%.

Results

Overall, anaesthetists’ assessment of tracheal tube cuff pressures was only slightly better than chance, with 50 (41.7%) of guesses correct on the first assessment and 53 (44.2%) on the second assessment of too high/acceptable/too low cuff pressure. Table 1 shows the number and percentage of correct guesses for each pilot balloon. The p values represent the probability that the proportion of correct guesses differ from that expected by chance (33.3%). There is a trend to worse performance using balloon C, the Kimberly-Clark Microcuff pilot balloon, where the pressure was never estimated as being too high despite 14/40 pressures’ being high or very high.

Anaesthetists inflated each pilot balloon twice, in random order, and Fig. 3 shows the limits of agreement between the two pressure assessments. The difference between the two readings increased with the mean

Table 1 Assessment of tracheal tube cuff pressure. The p values represent the probability that the proportion of correct guesses differ from that expected by chance using a Z-test for two proportions. Values are number (proportion).

Balloon	Guess 1 correct	p value	Guess 2 correct	p value
A	12/20 (60.0%)	0.011	10/20 (50.0%)	0.113
B	10/20 (50.0%)	0.113	12/20 (60.0%)	0.011
C	6/20 (30.0%)	0.754	3/20 (15.0%)	0.098
D	10/20 (50.0%)	0.113	11/20 (55.0%)	0.039
E	5/20 (25.0%)	0.431	10/20 (50.0%)	0.113
F	7/20 (35.0%)	0.872	7/20 (35.0%)	0.872
ALL	50/120 (41.7%)	0.052	53/120 (44.2%)	0.012

pressure (correlation $p < 0.001$). The variance was stabilised using a logarithmic transformation. The mean difference (pressure 1–pressure 2) was -0.054 on a log scale and the limits of agreement were -0.62 and 0.51 . Taking the antilogs, these limits are 0.24 and 3.26 . Therefore, for about 95% of the cases, the pressure 2 estimates may differ from the pressure 1 estimates by about 76% below to 226% above, illustrating extremely poor agreement.

Figure 4 shows a box plot of the mean pressure (from the two assessments by all anaesthetists) for each pilot balloon. The pressure measurements were not normally distributed (Anderson–Darling $p < 0.005$) and a Johnson transformation was performed on the pressure measurements ($p = 0.362$). A general linear model was then used to test for differences between the pilot balloons while adjusting for anaesthetist and assessment, taking balloon A as the baseline and adjusting for multiple comparisons using the Bonferroni correction factor. The table in Fig. 4 shows the adjusted p values for comparisons between pilot balloons using balloon A, the original Portex Profile Soft-Seal, as baseline.

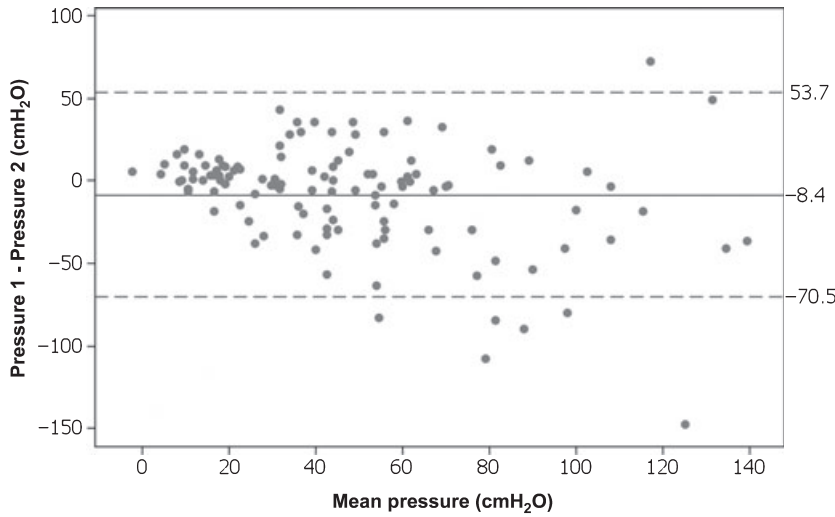


Figure 3 Scatter plot showing limits of agreement between the two inflation pressures for each pilot balloon by each anaesthetist.

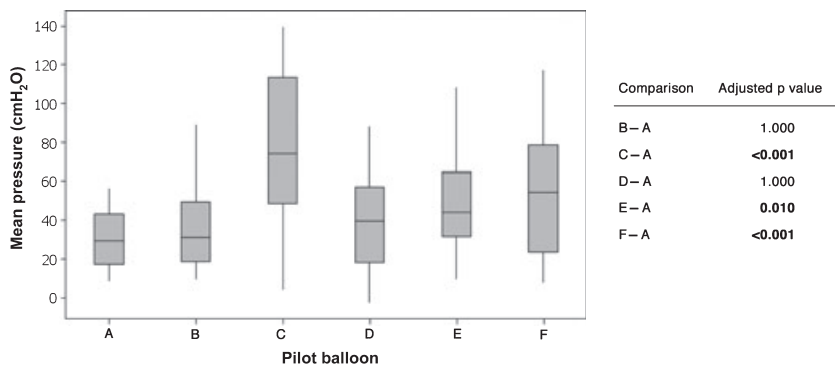


Figure 4 Box plot of mean inflation pressure for each pilot balloon showing median, IQR, and range. The table shows adjusted p values for comparisons between pilot balloons.

Pilot balloon C, the Kimberly-Clark Microcuff balloon, performed particularly poorly and there were statistically significant differences between pilot balloon C and each of the other balloons (adjusted $p < 0.001$ for all). Pilot balloons E (Intavent Orthofix laryngeal mask airway) and F (Proact laryngeal mask airway) also showed statistically significant differences from pilot balloon A.

Discussion

Our trachea model allowed bench testing of tracheal tubes more realistically than in previous studies by incorporating realistic tracheal compliance and an air leak in addition to palpation of the pilot balloon. As all pilot balloons were used with the same tracheal tube cuff, we can be sure that the differences found are due solely to the performance of the pilot balloon.

We confirmed that the pressure generated by anaesthetists inflating tracheal tube cuffs is very variable, inconsistent and usually too high, which is in agreement with the findings of previous studies. This is significantly affected by the type of pilot balloon. We also confirmed

that estimation of tracheal tube cuff pressure by pilot balloon palpation is inaccurate, which is also consistent with the findings of previous studies. The pilot balloons for which estimation of tracheal tube cuff pressure was most inaccurate seem to be those that generated the highest inflation pressures. Some pilot balloons may allow less accurate estimation than others.

The clear outlier for both the inflation and palpation tests was balloon C, the Kimberly-Clark Microcuff balloon. This is an ovoid shaped tracheal tube balloon with the smallest volume of all the balloons tested. Balloons D, E and F were laryngeal mask airway balloons, slightly broader and flatter than balloon C. Balloons E and F also showed significant differences in performance compared to balloon A. All these balloons have a resting volume at atmospheric pressure, and when completely emptied generate a negative pressure. Balloons A and B performed best for both inflation and palpation. These are both thin-walled tracheal tube pilot balloons with a broader flat shape and a relatively high volume. They do not generate a significant negative pressure when completely empty. The size, shape, thickness and material of

the pilot balloon may all affect the performance of anaesthetists estimating cuff pressure by palpation. Familiarity is also likely to be a factor: the anaesthetists tested were most familiar with balloons A and B.

Balloon C was inspected for confounding factors. There was increased resistance in the tubing connecting the pilot balloon to the cuff. This was clearly found to be as a result of a restriction of diameter of the connecting tube between the pilot balloon and the tracheal tube shaft produced during manufacture. Other pilot balloons (with their connecting tubes) of the same model were examined and found to have a similar high resistance feel on slow injection of air from a 10 ml-syringe. There was no additional resistance produced where we had grafted the balloon onto the tubing used in our test apparatus. The design of the Kimberly-Clark Microcuff pilot balloon has since changed so that the newer model does not have the same constriction in the connecting tube or resistance to injection of air.

Resistance in the pilot balloon tubing may cause the pressure in the cuff to lag behind the pressure in the pilot balloon. A longer time constant for the system could confuse the operator as to the pressure at the cuff. In this study sufficient time was allowed for the pressure to stabilise before taking readings, so this should tend to produce cuff pressures that were too low rather than too high. However, this could affect the accuracy of inflation of tracheal tube cuffs in clinical practice. This balloon performed poorly in the assessment as well as the inflation tests. In the assessment tests the pressure would have stabilised so the narrow bore connecting tube cannot be the sole reason for its poor performance. Furthermore, a recent National Patient Safety Agency (NPSA) audit [39] recommended that a severed pilot balloon tube may be cannulated using a 23-G needle to allow emergency re-inflation of the tracheal tube cuff.

This study has a number of limitations. First, it is an *in vitro* study. However, numerous studies have demonstrated that estimation of tracheal tube cuff pressure by palpation is also inaccurate *in vivo* and that excessive cuff pressures are generated. Our trachea model is more realistic than those used in previous studies, with the addition of a realistic tracheal compliance and an air leak. An intermittent leak simulating ventilation and allowing the anaesthetists to squeeze a bag may have been even more realistic but technically difficult to standardise.

The addition of the manometer may have slightly altered the feel of the syringe used to inflate the balloons by increasing the volume of tubing in the system, but this is difficult to avoid. Connecting the manometer after inflation leads to a drop in pressure and inaccuracy. The manometer was connected using a thick walled, non-compliant PVC tube, so any change would be due

primarily to the compression volume of the air in the manometer tube. Pilot balloons were of different volumes, but anaesthetists were instructed to judge inflation using air leak or palpation as they would *in vivo*, rather than the volume of air used. The cuffs were inflated from fully deflated. This resulted in an initial negative pressure for some balloons. However, these balloons tended to produce higher rather than lower pressures in general, and this is realistic as tracheal tube cuffs would be fully deflated before insertion. In one case, the final pressure generated after cuff inflation remained negative. This was using a laryngeal mask airway pilot balloon. In contrast to tracheal tubes, it is uncommon to deflate laryngeal mask airway cuffs completely before insertion and the balloon may have been designed accordingly. Anaesthetists took variable lengths of time to inflate cuffs to a satisfactory pressure and for the pressure to stabilise. This calm environment without time pressure may not always be realistic, but should have optimised performance.

For statistical analysis, the mean of the two pressures generated by each anaesthetist for each pilot balloon was taken. This was because these two values are linked and cannot be taken as two separate data points. There was poor agreement between these two values and taking the mean reduces the variability of the readings, which nonetheless remains high. These minor limitations of the inflation test are unlikely to have significantly affected the results. This test should have been more realistic than previous *in vitro* tests, and results are consistent with other studies. The anaesthetists tested commented that the model was realistic. It is reassuring that the results of the inflation test correlate with the results of the palpation test which is not affected by these limitations.

Previous studies have tested different healthcare professionals. Although operating department practitioners or nurses may inflate tracheal tube cuffs more often than anaesthetists themselves, we chose to test anaesthetists as they remain ultimately responsible. Previous studies using anaesthetists have generally produced more acceptable pressures than studies using other healthcare professionals. Three of the pilot balloons used were not designed for use with tracheal tube cuffs; we should stress that we do not seek to denigrate the performance of these devices, they were chosen for comparison simply as they had different physical characteristics to the three tracheal tube pilot balloons and we were interested in examining whether design of the pilot balloon affected performance. Similarly, two of the tracheal tube pilot balloons were used with a cuff to which they were not usually connected, but without this standardisation it would be impossible to conclude anything specific about the pilot balloon.

Checking cuff pressures using a manometer has been shown to reduce the incidence of sore throat following

anaesthesia using laryngeal mask airways [40–43], and is recommended in national guidelines for patients with cuffed tracheostomy tubes [11, 44]. Controlling tracheal tube cuff pressures is likely to reduce tracheal damage. The Lanz tracheal tube (Mallinckrodt Medical) is designed to attenuate increases in cuff pressure during anaesthesia using nitrous oxide and this has been shown to reduce damage to the trachea in dogs [25]. However, another animal study with small numbers and relatively low pressures showed no difference in tracheal wall damage using continuous control of tracheal cuff pressure [45]. Furthermore, automated cuff pressure controllers causing rapid pressure compensation have been shown to worsen tracheal tube sealing [26]. Connection of a manometer and manipulation of cuff pressure could also lead to such pressure drops. This could potentially increase the risk of ventilator-associated pneumonia. Guidelines for the management of ventilator-associated pneumonia recommend maintaining tracheal tube cuff pressure higher than 20 cmH₂O [46].

We suggest that tracheal tube cuffs should be kept at 20–30 cmH₂O in anaesthesia and intensive care. The optimum method of doing this remains to be determined and repeated or prolonged deflation of tracheal tube cuffs should be avoided. Improvements in tracheal tube design are likely to be of benefit and should take into account the design of the pilot balloon.

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Declaration of interest

Dr Bell and Mr Pullen are involved in the development of a new device designed to limit tracheal tube cuff pressure.

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