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APPARATUS

Evaluation of clinical effectiveness of the Frova single-use tracheal tube introducer

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Summary

A prospective observational study design was used to evaluate the clinical effectiveness of the Frova single-use tracheal tube introducer. Data were collected from 203 patients. Consultants and trainee anaesthetists completed 61 (30%) and 142 (70%) forms respectively, when the Frova introducer was used. It was successfully placed in the trachea in 194/203 (96%) of patients with two attempts at placement by the first clinician. The first clinician failed to either pass the Frova introducer or railroad the tube in six (3%) and 10 (5%) of the 203 patients respectively. The success rate by the first clinician was significantly influenced by the laryngeal view obtained ($p < 0.0001$). There was only one failure to place the Frova introducer in the trachea by either the first or second clinician. Airway trauma was detected in 11/203 (5%) patients. In six of these 11 patients blood was detected on tracheal suction; 'distal hold up' was elicited in five of these six. The Frova introducer has a high success rate for tracheal placement but has noteworthy potential to produce airway trauma.

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Tracheal intubation is difficult in 1–4% and impossible in 0.05–0.35% of patients who have seemingly normal airways [1]. Unexpected difficulty associated with tracheal intubation is, consequently, an intermittent and often terrifying problem for all practising anaesthetists. Techniques for dealing with this situation are dictated by the availability of apparatus and the skill to perform the procedures of the selected difficult airway management guidelines. National UK [2] and international [3–5] difficult airway management guidelines suggest the use of a tracheal tube introducer early on in cases of unanticipated difficulty. The Eschmann multiple-use introducer (Reusable guide-'bougie', Smiths Medical International, Hythe, Kent, UK) appears to be the first choice for many anaesthetists in the UK faced with unexpected difficult laryngoscopy [6–8]. However, the recommendations of the Association of Anaesthetists of Great Britain and Ireland on the use of 'single-use intubation aids' has led to a move in clinical practice towards single-use devices [9].

The Portex single-use introducer (Portex Tracheal Tube Introducer, Smiths Medical International) became available in 1997 (a new version of this introducer became available in 2006). The Frova Intubating Introducer (Cook UK Ltd, Letchworth, UK) was brought into clinical practice in 1998. There are both in vitro [10, 11] and in vivo evidence [12] that the original 1997 Portex single-use introducer is less effective than the Eschmann multiple-use introducer. In contrast, the success rate for tracheal placement in a manikin with the Frova single-use introducer (Frova introducer) is similar to [11] or better than [13] the Eschmann multiple use introducer. There do not appear to be any studies that examine the effectiveness of the Frova single-use introducer in patients.

We therefore decided to evaluate prospectively the incidence of successful intubation and overall performance of this device in the clinical setting.

Method

A prospective observational study design was used. The approval of the Local Research Ethics Committee for this study was sought, but it was deemed unnecessary as the

clinical practice was not altered by inclusion in the study. The study was undertaken at Llandough (Cardiff) and the Royal Gwent (Newport) hospitals in South Wales. Both hospitals used the Frova single-use introducer as a first choice. Anaesthetists and operating theatre staff working in the two hospitals were informed of the nature of the study.

A form was available for completion each time a Frova single-use introducer was used. The forms were placed in transparent folders in each anaesthetic room and completed forms were collected regularly from an adjacent folder. The form included patient data, the anaesthetist's grade and years of experience, whether difficult intubation was anticipated and best laryngeal view obtained at laryngoscopy. We also wanted to find out the reason for using the device, whether another method was used before the Frova introducer, what methods, if any, were used to improve the laryngeal view, whether the device was shaped before use, signs of tracheal placement (clicks, distal hold up and coughing), number of attempts needed to insert the device, airway trauma during the placement of the Frova, whether the Frova introducer was successfully placed in the trachea and success with railroading the tube over the Frova. In addition we asked whether initial tracheal intubation with Frova failed, whether a second clinician was involved and whether a second clinician was successful. Cook's modification [14] of the conventional Cormack and Lehane [15] classification of grades of laryngeal view was used (grade 1 – most of cords visible, grade 2a – posterior cords visible, grade 2b – only arytenoids visible, grade 3a – epiglottis visible and liftable, grade 3b – epiglottis visible but closely applied to posterior pharyngeal wall, grade 4 – no part of larynx visible). The completed forms were scrutinised for omissions. When omissions were noted, the clinician was approached in an attempt to gather complete data.

Statistical analyses

Using SPSS (version 11 for Macintosh, SPSS Inc., Chicago, IL) the association between continuous data (i.e. years of anaesthetic experience) and categorical data (e.g. shaping of the Frova introducer) was examined by logistic regression. The Chi-squared test was used to examine the dependence of the shaping of the Frova introducer, and of the success rate for its tracheal placement, on the view during laryngoscopy.

Results

Data were collected from 205 forms. In two of these, there were insufficient responses to enable the data to be included in the analyses; this study therefore involved 203 patients. Patient characteristics and the years of experience of the consultant and trainees are given in Table 1.

Table 1 Characteristics of patients and anaesthetists.

Patients	No. recorded	Mean	SD
Weight; kg	155 (76%)	79	17
Height; cm	99 (49%)	166	11

		Years of experience		
Anaesthetists	Patients anaesthetised	Median	Interquartile range	Range
Consultants	61 (30%)	14.5	13–20	10–30
Trainees	142 (70%)	2	0.5–4.25	0.25–13

Difficult intubation was anticipated in 64 patients (32%). A variety of reasons were cited by anaesthetists for using a Frova introducer, chiefly a poor view of the larynx and difficulty in pushing the tracheal tube towards the larynx (Table 2). Other methods were tried before using the Frova introducer for tracheal intubation in 139 patients (68%): mostly laryngeal manipulation or repositioning (Table 3).

The best views obtained at laryngoscopy, with or without attempts to improve it by external laryngeal

Table 2 Reasons for using the introducer in 203 patients*. Values are number (proportion).

Poor view of larynx	124 (61%)
Difficulty in pushing tracheal tube towards larynx	87 (43%)
Irregular or crowned teeth	13 (6%)
Other	6 (3%)
Restricted neck movement	2
Patient with tracheostomy	1
To reduce number of attempts	1
Distorted anatomy due to tumour	1
Small mouth	1

*There was more than one reason for some patients.

Table 3 Other methods tried to facilitate intubation before using the Frova introducer, in 139 patients*. Values are number (proportion of all 203).

To improve laryngeal view	
Laryngeal manipulation	77 (38%)
Repositioning	117 (58%)
McCoy blade	10 (5%)
Long blade	4 (2%)
To facilitate intubation despite poor view	
Stylet	3 (1.5%)
Laryngeal mask airway	2 (1%)
Fibreoptic scope	1 (0.5%)
None	64 (32%)
Total	203

*In 66 of these patients more than one method was used.

Table 4 Distribution of grades of best laryngeal view* obtained with or without attempts to improve it by external laryngeal manipulation and associated incidence of shaping the Frova. Values are number (proportion).

Best view at laryngoscopy		Shaping the Frova
1	35 (17%)	13/35 (37%)
2a	58 (29%)	20/58 (34%)
2b	56 (28%)	19/56 (34%)
3a	33 (16%)	15/33 (47%)
3b	20 (10%)	7/20 (35%)
4	1 (0.5%)	1/1 (100%)
Total	203	75/203 (37%)

*Grade 1 – most of cords visible, grade 2a – posterior cords visible, grade 2b – arytenoids visible only, grade 3a – epiglottis visible and liftable, grade 3b – epiglottis visible but closely applied to posterior pharyngeal wall, grade 4 – no part of larynx visible.

Table 6 Success and failure rates for the insertion of the Frova introducer and railroading of the tracheal tube into the trachea with first and second clinician. Values are number (proportion).

Success/failure	Frova placement		Railroading tracheal tube	
	1st clinician	2nd clinician	1st clinician	2nd clinician
1st attempt	170 (84%)	3	177 (90%)	8
2nd attempt	24 (12%)	1	8 (4%)	2
3rd attempt	2 (1%)	0	2 (1%)	0
4th attempt	1 (0.5%)	0	0	0
Overall success	197 (97%)	4	187 (95%)	10
Failure	6 (3%)	2†	10 (5%)	0
Total	203	6	197	10

†Intubating laryngeal mask airway was used in one case and the tracheal intubation was performed without the aid of an introducer in the other.

manipulation, and the associated proportion of patients for whom the Frova was shaped before placement (37% overall) are shown in Table 4. Whether the Frova introducer was shaped or not before placement was not significantly influenced by the laryngeal view obtained during laryngoscopy ($\chi^2 = 3.24$ with 5 degrees of freedom (df), $p = 0.66$) or by the years of anaesthetic experience ($p = 0.84$).

The number of attempts by the first clinician at insertion of the Frova introducer in 203 patients and the associated grades of laryngeal view are presented in Table 5. The first-attempt success rate by the first clinician was significantly influenced by the laryngeal view obtained ($p < 0.0001$) (Table 5). The laryngeal view obtained also had a significant effect on the number of attempts required for successful placement of the tracheal tube ($\chi^2 = 37.52$ with 5 df, $p < 0.0001$) (Table 5).

Success rates for insertion of the Frova introducer and railroading the tracheal tube into the trachea are presented in Table 6. A second clinician took over in six patients (3%) for the placement of the Frova introducer and the railroading of the tracheal tube. In one patient (grade 4 laryngeal view) the second clinician used an intubating laryngeal mask airway to facilitate the placement of the tracheal tube; in another patient (grade 2a laryngeal view), the second clinician succeeded in intubating the trachea without the need for an introducer. Thus in only one patient (0.5%) was there failure to place the Frova by the first and second clinician; but in 16 patients (8%) the first clinician failed to place the Frova introducer or to railroad the tracheal tube over it.

The signs of successful tracheal placement elicited during insertion of the Frova introducer in the trachea were mostly 'clicks', with or without distal hold up or cough (Table 7).

The first clinician usually left the laryngoscope in the mouth while railroading the tube over the Frova introducer and/or rotated the tube 90° anticlockwise (Table 8). Anaesthetists with fewer years of anaesthetic experience were more likely to rotate the tube during railroading ($p = 0.015$).

Airway trauma was detected in 11 patients (5%). Details of the evidence of trauma and the associated elicited signs

Table 5 Success and failure rates by the first clinician at insertion of the Frova introducer in 203 patients and associated grades of the best laryngeal view. Values are number (proportion of all attempts).

	Grades of laryngeal view						
Success/failure	**1**	**2a**	**2b**	**3a**	**3b**	**4**	**Total**
1st attempt	34 (97%)	55 (95%)	49 (87%)	21 (64%)	11 (55%)	None	170 (84%)
2nd attempt	1 (3%)	2 (3%)	6 (11%)	8 (27%)	7 (35%)	Fail	24 (12%)
3rd attempt	None	None	None	None	2 (10%)	None	2 (1%)
4th attempt	None	None	1 (2%)	None	None	None	1 (0.5%)
Overall success	35 (100%)	57 (98%)	56 (100%)	29 (88%)	20 (100%)	None	197 (97%)
Failure	None	1 (2%)	None	4 (12%)	None	1 (100%)	6 (3%)
Total	35	58	56	33	20	1	203

Table 7 Signs of successful tracheal placement of the Frova introducer elicited during insertion in the trachea by the first clinician in 197 patients. Values are number (proportion).

No signs elicited	27 (14%)
'Clicks' only	125 (63%)
Distal hold up only	3 (1.5%)
Cough only	7 (3.5%)
'Clicks' + distal hold up	25 (13%)
'Clicks' + cough	8 (4%)
'Clicks' + distal hold up + Cough	2 (1%)

Table 8 Techniques used by first clinician to aid railroading the tracheal tube in the 197 patients in whom the Frova was successfully placed. Values are number (proportion).

Laryngoscope left in mouth	168 (85%)
Tube rotated	146 (74%)
Laryngoscope left in and tube rotated	124 (63%)
Neither	7 (4%)
Total	197

Table 9 Evidence of airway trauma and associated elicited signs of tracheal placement of the introducer.

	n	Totals
Blood on pharyngeal suction		
'Clicks'	4	
No signs	1	5
Blood on tracheal suction		
'Distal hold up'	5	
'Clicks'	1	6
Total		11

of tracheal placement are given in Table 9. One of the patients in whom the 'hold up' sign was elicited suffered surgical emphysema and pneumoperitoneum following use of the Frova.

Discussion

This clinical study shows a high success rate for tracheal placement for the Frova introducer. This device was successfully placed in the trachea in 194/203 (96%) of patients within two attempts at placement by the first clinician (Table 3). Cook reported a 94% (100/106) success rate [14] when using the Eschmann introducer. Cook, an experienced clinician, performed all the intubations in his investigation. The anaesthetists in our study exhibited a wide range of experience. This is likely to give more a realistic impression of 'normal' use. The success rate in another patient study using simulated difficult intubation (grade 3a laryngeal view) with the Eschmann introducer was 96% within two attempts [16]. The Eschmann has been considered to be the gold standard of introducers [11]. There are no patient studies directly comparing the Eschmann and Frova introducers. However, in one study of simulated difficult intubation in a manikin [11], the success rates for tracheal placement with the Frova and Eschmann introducers were (proportion (95% confidence interval, CI)) 65% (CI 50–77%) and 60% (CI 46% to 73%), respectively. In a similar manikin study [13], Whitcombe & Strand claimed significantly higher success rates ($p = 0.0008$) for the Frova introducer than for the Eschmann introducer. They concluded that, in respect of the success at tracheal placement, 'the Frova Intubating Introducer is a viable long-term replacement to the Gum Elastic Bougie'.

The first-attempt success rate for the first clinician decreased consistently as the view at laryngoscopy deteriorated from 1 to 3b (Tables 5, $p < 0.0001$). The six failures by the first clinician to place the Frova were mostly when the view was very poor: four at grade 3a, one at grade 4 and only one at grade 2a. For views of grade 3a or 3b, the success rate by the first clinician was 49/53 (92%) after up to three attempts in our study, whereas Cook [14] reported only 74% (17/23) after three attempts. All failures to place the Eschmann introducer in the trachea in Cook's study were with a grade 3b laryngeal view. Although this difference is not statistically significant ($\chi^2 = 3.34$ with 1 df, $p = 0.07$), it is clearly more likely to be a real difference than not, so it is worth a brief consideration of possible causes. There are three possible explanations for this discrepancy. Firstly, the Frova introducer is 'manufactured using a stiffer material to overcome the excessive flexibility of the Eschmann' [17]. This increased stiffness is reflected in the higher forces exerted by the tip of the Frova introducer when compared to the Eschmann introducer [11]. This added rigidity of the Frova introducer may allow for the epiglottis to be lifted off the posterior pharyngeal wall, explaining high success with a grade 3b laryngeal view. In addition, the success may be influenced by the difference in the angles of the tip of the Frova and Eschmann introducer. Lastly, the ability of anaesthetists to classify laryngeal views correctly using Cormack and Lehane's classification has been questioned [18]. Consequently, this apparent high success of the Frova placement with the grade 3b laryngeal view may be a consequence of incorrect laryngeal view classification. The grade 3b laryngeal view may have been over-diagnosed by anaesthetists taking part in our study. Further clinical evaluation of the Frova introducer may clarify this issue.

Shaping the introducer significantly increases the likelihood of successful placement with a grade 3a laryngeal view in a manikin study [19]. However, only 37% of the anaesthetists in our study shaped the Frova

before attempting to place it in the trachea. Despite this, the overall success rate by the first clinician for tracheal placement for the Frova introducer in our study was high (194/203 (96%) with two attempts) (Table 5). Shaping the introducer prior to placement may not be necessary for successful placement when faced with grade 1 and 2a laryngeal views. This may explain the apparently high proportion of anaesthetists in our study (63%) who decided not to shape the introducer before placement (Table 4). Whether the Frova introducer was shaped or not was not influenced by the years of anaesthetic experience ($p = 0.84$) nor by the grade of the laryngeal view ($p = 0.66$). When faced with grade 2b, 3a and 3b laryngeal views, a large proportion of anaesthetists (62%) still did not shape the Frova introducer before placement (Table 4). It is quite likely that the first attempt success rate with the grade 2b, 3a and 3b laryngeal views (74%) would have been higher if the Frova had been shaped more frequently for such views. We certainly recommend shaping the introducer if difficulty in tracheal placement is encountered.

Anaesthetists taking part in this study reported some difficulties during placement of the Frova introducer in the trachea. These difficulties appear to be associated with the design of the Frova introducer. A number of anaesthetists taking part in the study verbally reported difficulties in advancing the tip of the Frova introducer. This may have been because the tip of the Frova introducer probably hit the anterior tracheal wall at almost a right angle. This problem might be resolved by flexing the head and neck, thus allowing the Frova introducer to advance further into the trachea. This problem has not been observed with the Eschmann introducer [8, 14]. This may be due to the differences both in the design of the angled tip of the two introducers and in flexibility. The angle of the tip of the Frova introducer is 65° and that of the Eschmann introducer is 40°. In addition, the tip of the Eschmann introducer is 5 mm longer.

Difficulties were also reported by the first clinician in railroading the tracheal tube over the Frova introducer in 23 of 197 patients (12%) in whom the Frova had been successfully placed. These difficulties were caused by the blunt end of the tracheal connector inside the tracheal tube impacting on the proximal end of the Frova introducer. The manufacturer, at our suggestion, has made minor changes to the proximal end of the Frova introducer to solve this problem.

In addition, the Frova introducer is a hollow tube designed either to deliver oxygen or to sample carbon dioxide [17]. This design may, however, produce a kink in the Frova introducer when it is shaped before insertion (personal observation, IH). A kink may also interfere with placement and/or railroading. The Frova was not used for oxygenation in any of the patients during the study period and this probably mirrors the current practice in the UK. Further modification to the design of the Frova introducer may be indicated. The optimum design of both angle and length of the tip and the optimum flexibility of introducers remains to be established.

Over the 11 months of this study, 11 of the 203 uses of the Frova introducer (5.5%) were associated with airway trauma, whereas the Eschmann introducer is associated with only very rare instances of airway trauma [20, 21]. In six of our patients the evidence of airway trauma was blood on tracheal suction. It seems that airway/tracheal trauma with the Frova is more likely in the event of distal hold up (five of the six cases) than in the event of just 'clicks' (one of the six). We are not aware of any instances of airway trauma following 'distal hold up' with the Eschmann introducer. We postulate that the higher incidence of trauma on 'distal hold up' with the Frova introducer is because the Frova can exert two to three times greater force at its tip than the Eschmann [11]. A previous recommendation, based on laboratory investigations, stated that the Frova introducer 'should not be advanced beyond 25 cm' [11]. We suggest that, in the absence of 'clicks', the Frova introducer should only be advanced gently and slowly beyond 25 cm, as the 'distal hold up' sign occurs at between 24 and 40 cm in tracheal intubations [22].

It was unfortunately not possible to determine the total number of times the Frova introducer was used during the study period. This may be seen as a shortcoming of the study. The same shortcoming was shared by a previously published clinical evaluation of the Eschmann introducer [8]. The conclusions of the Eschmann study were accepted as a reliable and accurate assessment of the clinical effectiveness of that introducer. Furthermore, the reported success rates for the Frova introducer in our study closely correspond to the published success rates for the Frova introducer in manikin studies [11, 13] thus supporting the reliability of our results.

From the foregoing it is clear that the Frova introducer has a high success rate for tracheal placement. This success rate is comparable and may be even better than the reported success rates for the Eschmann introducer [11, 12, 14]. However, the Frova introducer still does not represent the ideal single-use alternative to the Eschmann introducer. The Frova introducer may have increased potential for airway trauma, especially if the 'distal hold up' sign is elicited to confirm placement. In addition, the proximal end is associated with problems while railroading the tracheal tube over the Frova introducer. The Association of Anaesthetists of Great Britain and Ireland has recommended that single-use items should be used where possible [9]. Comparative

evaluation of the newly introduced single-use tracheal tube introducers needs to be undertaken.

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