Standard versus Flexible tip bougie for Videolaryngoscopy

A randomised comparison between standard and flexible tip bougie (tracheal tube introducers) for tracheal intubation using non channelled videolaryngoscope.

PROTOCOL

IRAS number	**287767**
ClinicalTrials.gov number	NCT04973176
Sponsor	University Hospitals Coventry & Warwickshire NHS Trust
Sponsor reference	*<insert>*
Funder	*<insert if applicable>*
REC reference	*<insert>*
REC approval date	*<insert>*
HRA approval date	*<insert>*
Version number	*V1.0*
Date	14.04.2021
Planned Start date	01.07.2021
Planned End date	30.12.2022
Protocol Amendments	

Amendment Number	Protocol Version	Date of Amendment	Date of Approval

Confidentiality statement

All information contained within this document is regarded as, and must be kept, confidential. No part of this document may be disclosed to any Third Party without the written permission of the Chief Investigator and/or Sponsor.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research, the ICH Good Clinical Practice guidelines and the Sponsor's SOPs.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

…../…./.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date:

14/04/2021

Name: Prof. Cyprian Mendonca

Position: Consultant Anaesthetist

KEY TRIAL CONTACTS

Chief Investigator	Professor Cyprian Mendonca Department of Anaesthesia University Hospital, Coventry, CV2 2DX Contact no: 02476964000 bleep 1865
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Sponsor	University Hospitals Coventry & Warwickshire NHS Trust

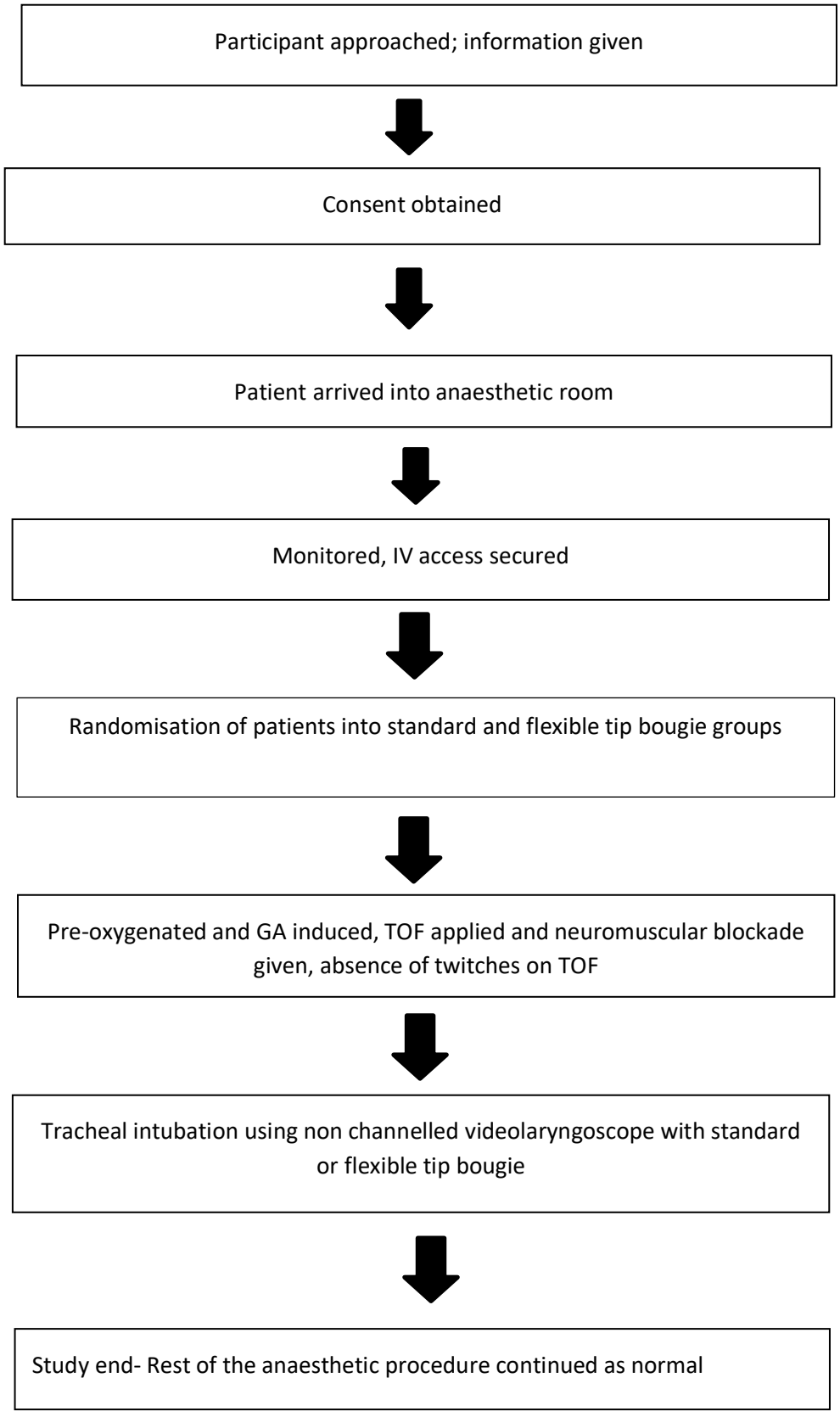
TRIAL SUMMARY

Full study title	A randomised comparison between standard and flexible tip bougie (tracheal tube introducers) for tracheal intubation using non channelled videolaryngoscope	
Short study title	Standard vs flexible tip bougie for videolaryngoscopy	
Trial Design	Randomised control Trial	
Trial Participants	Patients aged 18 and above, presenting for elective surgical procedures where tracheal intubation is indicated	
Planned Sample Size	160	
Follow up duration	3 to 24 hours	
Planned Trial Period	18 months	
	Objectives	**Outcome Measures**
Primary	Ease of tracheal intubation	Modified Intubation Difficulty Scale Score
Secondary	Success rate at first attempt	Laryngoscopy time Intubation time Additional manoeuvres required Bougie impingement Bougie rotation Post op sore throat between 3 -24 hours post op Success of tracheal intubation

Key Words: Intubation; tracheal, airway device; video laryngoscope

STUDY FLOW CHART

Figure 1: Flow of participants through the study



SCHEDULE OF OBSERVATIONS

Table 1: Schedule of Events

Procedure	Screening	Baseline	Pre-Op	Intra-Op	Post-Op
Eligibility assessment	X	X			
Informed consent		X			
Demographic data (DOB, sex, height and weight)		X			
Details regarding operative procedure, Anaesthesia and method of airway management			X		
Airway Assessment			X		
Randomistaion				X	
Laryngoscopy, Tracheal Intubation Laryngoscopy time, intubation time and modified intubation difficulty score				X	
Pot op visit- sore throat					X

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LIST OF ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of Investigational Medicinal Product
DMC	Data Monitoring Committee
EC	European Commission
EU	European Union
EudraCT	European Clinical Trials Database
GCP	Good Clinical Practice
ICF	Informed Consent Form
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SSI	Site Specific Information
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

STUDY PROTOCOL

A RANDOMISED COMPARISON BETWEEN STANDARD AND FLEXIBLE TIP BOUGIE (TRACHEAL TUBE INTRODUCERS) FOR TRACHEAL INTUBATION USING A NON CHANNELLED VIDEOLARYNGOSCOPE.

1. INTRODUCTION

Videolaryngoscopes are devices which aid successful intubation of the trachea. Unlike standard (direct) laryngoscopes, they include a camera at the tip of the blade and display unit to provide an indirect view of the vocal cords (glottis). They are now routinely used for both standard and anticipated difficult tracheal intubation [1] and are recommended for difficult intubation in the national guidelines [2]. Some videolaryngsocopes have channel as a guide to help with the placement of a tracheal tube and some are without channel. The non-channelled videolaryngoscopes with acute-angled blades require a bougie or stylet to facilitate the passage of tracheal tube through the glottis into the trachea. One problem commonly encountered when using standard bougie is the tip of the bougie abutting on the anterior part of glottis and entrance to the windpipe (trachea) and not advancing further into the trachea [3]. This is known as anterior impingement. This can increase the likelihood of repeated intubation attempts, failed intubation and airway trauma. C-Mac is a commonly used non-channelled videolaryngoscope and has been shown to have high first attempt success rate as compared to other videolaryngoscopes [4, 5] and acute angled D-blade require a bougie to facilitate tracheal intubation [6].

The recently introduced flexible tip bougie likely to over comes the problem of anterior impingement due to the ability to flex the tip in the posterior direction once the tip enter the glottis. In a manikin study [7], the paramedics were able to intubate the trachea more efficiently using flexible tip bougie as compared to standard bougie . We are not aware of any study comparing these devices for success of tracheal intubation in patients. Comparing the efficacy of these devices could help inform

anaesthetists decisions in future when faced with a potentially difficult airway and has the potential to update current difficult airway guidelines.

1.1 Background

The recently introduced flexible tip bougie likely to overcome the problem of anterior impingement due to the ability to flex the tip in the posterior direction once the tip enter the glottis. In a manikin study [7], the paramedics were able to intubate the trachea more efficiently using flexible tip bougie as compared to standard bougie. We are not aware of any study comparing these devices for success of tracheal intubation in patients. Comparing the efficacy of these devices could help inform anaesthetists decisions in future when faced with a potentially difficult airway and has the potential to update current difficult airway guidelines.

1.2 Proposed study

We hypothesise that use of the flexible tip bougie will improve first attempt intubation success rates when compared to the standard bougie during laryngoscopy with non-channelled videolaryngoscopes. The intubation success rate is measured using modified intubation difficulty scale score (Appendix1). The score includes the points given to number of attempts at intubation, minor problems noticed during intubation such as bougie impingement, need for bougie rotation, need for tube rotation and percentage of glottic view obtained.

1.3 Study population

Patients aged above 18, presenting for elective surgical procedures and requiring tracheal intubation will be invited to take part in the study.

1.4 Treatment/ Intervention

On arrival to theatre, following standard WHO surgical safety check list, patients will be randomly allocated to have tracheal intubation either using standard bougie or a flexible tip bougie. The rest of the anaesthetic management will remain normal as planned by the lead anaesthetist. During tracheal intubation the data collected will included ease of tracheal intubation using modified intubation difficulty scale [8] and time taken to complete tracheal intubation.

1.5 Pre-clinical data

In a manikin study [7], the paramedics were able to intubate the trachea more efficiently using flexible tip bougie as compared to standard bougie.

1.6 Clinical Data

Both the standard and flexible tip bougies are used in clinical practice at University Hospitals Coventry and Warwickshire NHS Trust.

2. RATIONALE

2.1 Aims and hypothesis

We hypothesise that use of the flexible tip bougie will improve the intubation success rates when compared to the standard bougie during laryngoscopy with non-channelled videolaryngoscopes.

2.2 Justification

The DAS (Difficult Airway Society) guidelines, state that the best intubation effort is the first one. It emphasises on choosing appropriate devices for first attempt, these include laryngoscope and bougie along with optimum position. When using a non-channelled acute angled videolaryngoscope a bougie is essential to facilitate tracheal intubation. The standard bougie consists of a rigid material normally with an acute curve at the distal end (coude tip), which is rigid and fixed. Hence, anterior impingement is a common problem. The commonly used standard bougie is 14 French gauge Frova® airway intubation catheter (William Cook Europe, Bjaeverskov, Denmark). A flexible tip bougie (P3 medical Ltd, Bristol, UK) has a steerable blunt silicon tip and slider tabs which allows tip to be flexed anteriorly to facilitate the passage of the tip through the glottic opening, once advanced tip can be straightened or even retroflexed. Therefore, it can navigate around the curvature of a non-channelled videolaryngoscope more effectively. We are not aware of any study comparing this bougie with standard bougie for tracheal intubation when using videolaryngoscopes. A previous study looking at changing the head and neck position from traditional sniffing to neutral, didn't make any difference in the success

rate [3]. Comparing the efficacy of different bougies during videolaryngoscopy could inform airway practitioners on their choice of bougie in both normal and difficult airway scenarios when using such laryngoscopes.

2.3 Assessment and management of risk

For this study, patients requiring general anaesthesia and tracheal intubation for elective surgical procedures will be recruited. The videolaryngoscope (C-Mac non-channelled videolaryngoscope) and bougies selected for this study are used in routine clinical practice as intubation aids. In the event of any unanticipated difficulty with intubation, the lead anaesthetist will follow the Difficult Airway Society guidelines. The data collection will stop at this point.

The lead anaesthetist is free to choose a different airway equipment to those specified by the study, if they feel that this would be clinically appropriate. We do not anticipate any additional risks to the study participants. During the procedure of airway management, all patients will be closely monitored as specified by Association of Anaesthetists' standards of monitoring during anaesthesia. This includes peripheral oxygen saturation, end tidal oxygen, end-tidal CO_2, ECG and blood pressure.

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

The aim of the study will be to see which of two bougies (an airway adjunct designed to pass through the vocal cords into the trachea in order to facilitate passage of a tracheal tube) is best suited for tracheal intubation (passage of a breathing tube into the trachea) when using a non-channelled videolaryngoscopes. The primary outcome will be ease of tracheal intubation, assed using modified intubation difficulty scale (mIDS) score (Appendix 1). The initial version of this scale was described and validated by Adnet et al [5].

3.2 Secondary objectives

Laryngoscopy time, time to successful tracheal intubation, overall first attempt success rate and visual analogue score for ease of use will be compared for two bougies.

3.3 Primary endpoint/outcome

The reported ease of intubation as measured using the modified intubation difficulty scale score.

3.4 Secondary endpoints/outcomes

- Time to successful tracheal intubation: It is time from when the videolaryngoscope is introduced into the oral cavity until the first capnography waveform is obtained.
- Laryngoscopy time: It is time from when the videolaryngoscope is introduced into the oral cavity to best view of the glottis (vocal cords)
- Overall first attempt success rate: This is the percentage of patients being successful at first attempt. This will be compared for two bougies.
- Anaesthetist's visual analogue score for ease of use of the bougie

4. STUDY DESIGN

Randomised Controlled trial

On arrival to theatre, following standard WHO surgical safety check list, patients will be randomly allocated to have tracheal intubation either using standard bougie or a flexible tip bougie.

5. STUDY SETTING

This will be a single centre study, conducted at University Hospitals Coventry & Warwickshire NHS Trust

6. ELIGIBILITY CRITERIA

Patients scheduled to undergo elective surgical procedures will be assessed for eligibility.

6.1 Inclusion criteria

Patients aged above 18, presenting for elective surgical procedures and requiring general anaesthesia tracheal intubation will be invited to take part in the study.

6.2 Exclusion criteria

- Patients who are do not want to take part or do not give consent
- Patients below 18 years of age
- Patient physical status of ASA 4 and 5,
- Patients deemed to require awake intubation

7. TRIAL PROCEDURES

Suitable patients for the study will be screened from the operating theatre lists. During the preoperative period, one of the research team members will explain the study and provide a patient information sheet. Patients will be given adequate time to read the information and any questions will be answered. If they are satisfied and willing to take part in the study, written consent will be obtained.

7.1 Recruitment

The chief investigator and co-investigators will identify suitable operating lists on the and patients based on the scheduled surgical procedure. Only those patients meeting the inclusion criteria will be approached.

7.1.1 Patient identification

Patients undergoing surgery that requires tracheal intubation are suitable for inclusion in the study. Scheduled operating lists will be screened by the chief investigator and principle investigator and suitable patients will be identified.

During the preoperative assessment one of the research team member will provide a patient information sheet. Patients will be given adequate time to read the information and any questions will be answered. If they are satisfied and willing to take part in the study, written consent will be obtained.

7.1.2 Payment

There is no payment for any participant for taking part in the study

7.2 Consent

Participants will be given adequate time to read and understand the patient information leaflet. Once they have read the information, any questions will be answered. If they agree for the study, they will be asked to complete the consent form. The consent will be obtained by chief investigator, coinvestigator or one of the research team members, supervised by the investigators.

7.3 Randomisation scheme

Sample size: From our previous study using CMAC VL and Frova bougie, the standard deviation was 0.95 and mean mIDS was 1.75. We considered a 30% reduction in mIDS to be clinically relevant. For standardized difference of 0.53, with a power of 0.9 and significance level of 0.05, we need 73 patients in each group. To account for failures and dropouts, we decided to recruit 160 patients in total.

Randomisation for this study will be completed using sealed opaque envelopes. On arrival to the anaesthetic room, sealed envelope will be opened to reveal the group. Based on the group, following induction of general anaesthesia, the chosen bougie will be selected. It would be ensured that both type of bougies readily available in the airway trolley. Once the bougie is successfully placed in the trachea, tracheal intubation is completed as normal.

On arrival in the anaesthetic room, patients will be monitored using peripheral oxygen saturation, end-tidal CO_2, ECG and blood pressure. Both standard and flexible tip bougies will be kept ready for each study patient. Patient will be randomly allocated to one of two groups.

1. Flexible tip bougie
2. Standard bougie

All patients will be pre-oxygenated in a 15 to 20^o head up position, to achieve a fractional ETO_2 of at least 0.8 prior to induction of anaesthesia. General anaesthesia will be induced at the discretion of lead anaesthetist. After the loss of consciousness was achieved, facemask ventilation will be commenced, and anaesthesia will be maintained with a volatile anaesthetic agent (age adjusted minimum alveolar concentration of 1.0) or using total intravenous technique as decided by the lead anaesthetist. Following the confirmation of the onset of neuromuscular blockade

using neuromuscular monitoring, in an optimal head and neck position, laryngoscopy will be performed using the videolaryngoscope as revealed by randomisation. Following laryngoscopy, the chosen bougie will be passed through the glottis and advanced to the trachea. If there was any hold-up immediately after passing the bougie through the vocal cords, it will be gently rotated laterally so that the angle tip faced the lateral wall of trachea. Whilst railroading the tube, if there was any impingement at the level of arytenoids, the tube will be withdrawn slightly, rotated anti-clockwise and then advanced. The correct placement of the tube will be confirmed using end tidal CO_2. Rest of the anaesthetic management will proceed as planned by the lead anaesthetist.

7.4 Blinding

Not Applicable. It will not be possible to blind the investigator the type of device used

7.5 Emergency unblinding

Not applicable

7.6 Baseline data

Base line data includes gender, age, weight, height, BMI & ASA score

Airway assessment includes Mallampati score, thyromental distance, mouth opening, jaw protrusion and neck movement. This is the routine assessment undertaken by the anaesthetists as a part of standard preoperative airway assessment.

7.7 Trial assessments

- Modified intubation difficulty scale score (Appendix 1)
- Time to successful tracheal intubation: It is time from when the videolaryngoscope is introduced into the oral cavity until the first capnography waveform is obtained.
- Laryngoscopy time: It is time from when the videolaryngoscope is introduced into the oral cavity to best view of the glottis (vocal cords).
- First attempt success rate for tracheal intubation
- Anaesthetist's visual analogue score for ease of use of the bougie

7.8 Long term follow-up assessments

Patients will be reviewed in the first 3 to 24 hours whilst they are in the hospital as apart standard postoperative visit. No further follow up is required for this study.

7.9 Storage and analysis of samples
Not applicable for this study. No biological samples required for this study

7.10 End of study definition

This is defined as the date on which the last patient (patient number 160) will be recruited to the study.

8. STATISTICS AND DATA ANALYSIS

8.1 Sample size calculation

From our previous study using CMAC videolaryngoscope and Frova bougie, mean mIDS was 1.75 and SD was 0.95 [5]. We considered a 30% reduction in mIDS to be clinically relevant. For standardized difference of 0.53, with a power of 0.9 and significance level of 0.05, we need 73 patients in each group. To account for failures and dropouts, we plan to recruit 160 patients in total.

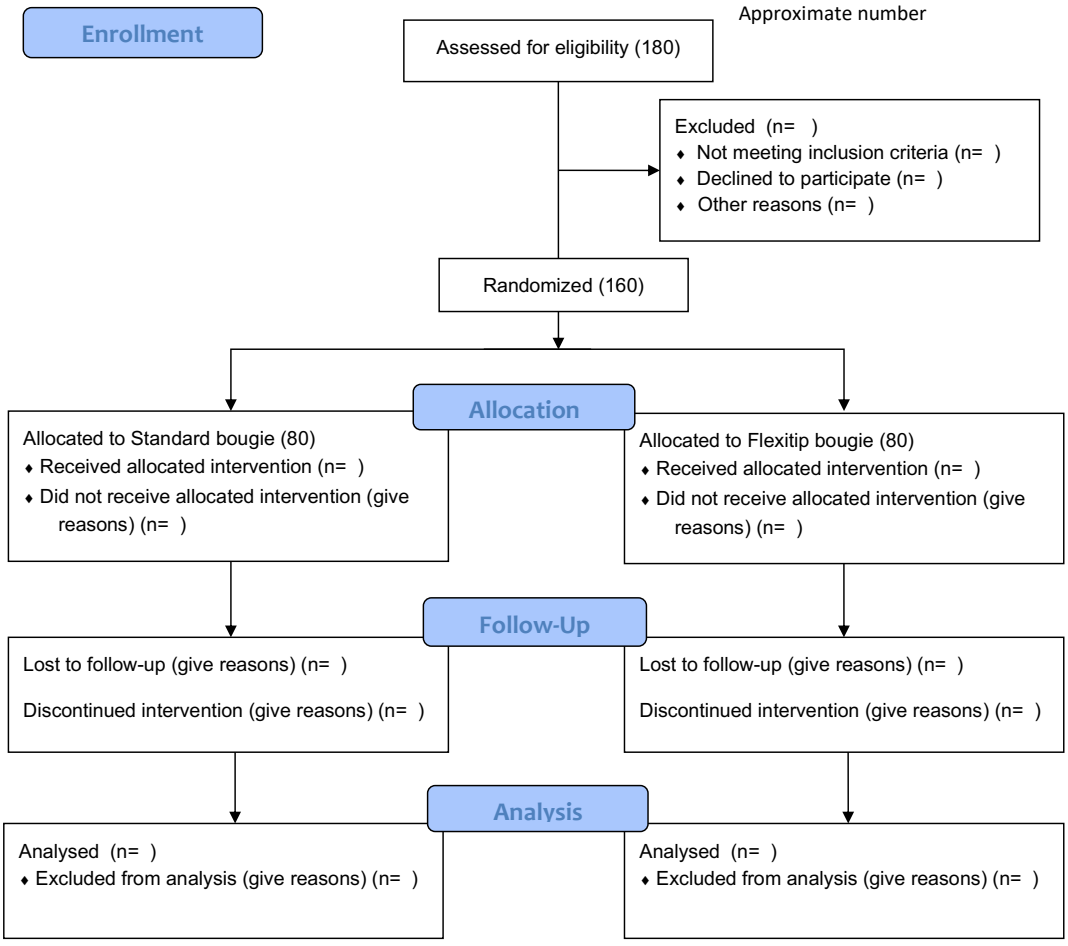
8.2 Planned recruitment rate

We are planning to recruit 160 participants over 18 months. The planned recruitment rate is 4 to 5 participants per week.
Statistical analysis plan

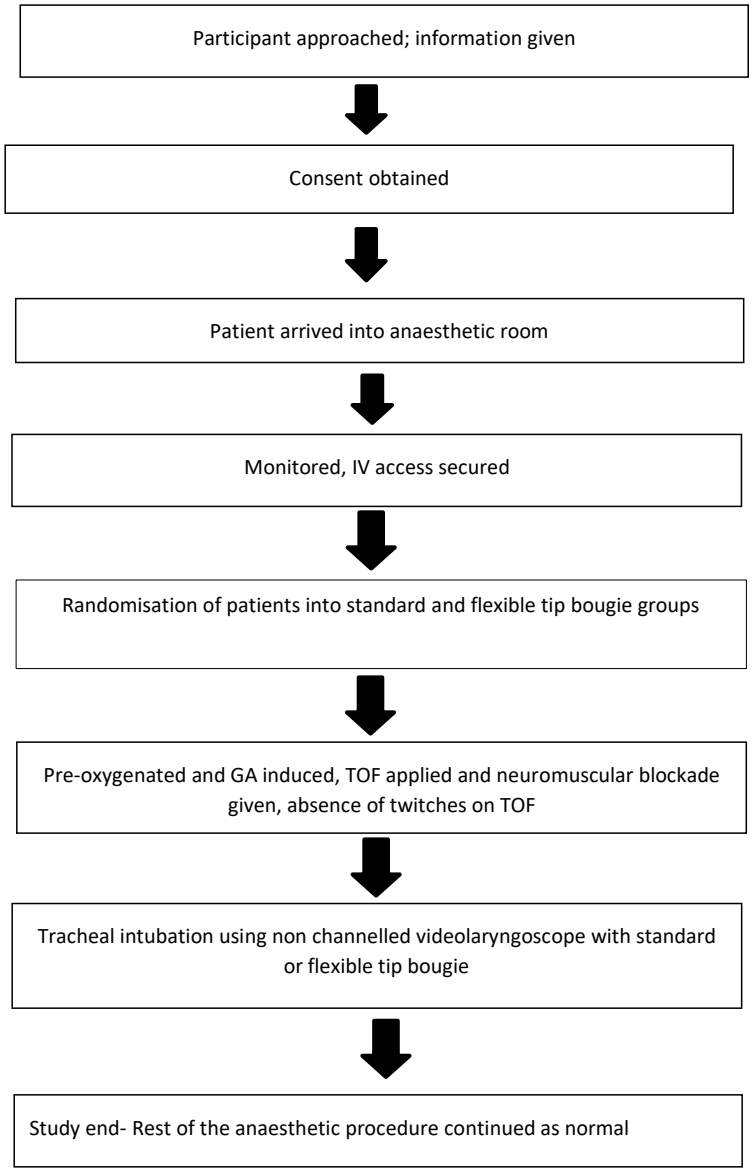
8.3.1 Summary of baseline data and flow of patients

The normally distributed base line data such as age, gender, weight and airway assessment parameters between two groups will be compared using students t test. Statical significance is taken as p value <0.05.

CONSORT Flow Diagram



Flow of participants through the study



8.3.2 Primary outcome analysis

Primary outcome is modified intubation difficulty scale score (mIDS). Non parametric test either Mann-Whitney U test or Kruskal- Wallis test would be used, as appropriate.

8.3.3. Secondary outcome analysis

The sample size is based on primary outcome.

8.4 Subgroup analyses

Not applicable

8.5 Adjusted analysis

Not applicable

8.6 Interim analysis and criteria for the premature termination of the trial

The devices used in this study are currently in clinical use at University Hospitals Coventry & Warwickshire NHS Trust. Therefore, no harm is anticipated as result of randomizing patients to one or other group. There is no plan for interim anlaysis and premature termination.

8.7 Participant population

The participant population would include patients scheduled to undergo elective surgery under general anaesthesia. The study duration very short, lasting one or two minutes. The Base line data is the part of routine airway assessment as a preparation for intraoperative tracheal intubation. During the time of tracheal intubation, the type of bougie used will be chosen randomly. The procedure of tracheal intubation will be evaluated using modified intubation difficulty scale.

8.8 Procedure(s) to account for missing or spurious data

As the study duration is short, we unlikely to miss follow up of patients. All care would be take to record all necessary data during preoperative visit and during

intubation. Very rarely the surgical plan may change, or surgery may be cancelled after recruiting. In total we need 146 patients to detect a significant difference in the modified intubation difficulty scale score. We have planned to recruit 160 in total to overcome any missing data or loss of follow up.

8.9 Other statistical considerations.

There is no plan to deviate from original statistics

8.10 Economic evaluation

Not applicable

9. DATA MANAGEMENT

9.1 Data collection tools and source document identification

CRFs will be completed at the time of data collection

No other data collection is required

9.2 Data handling and record keeping

Consent forms and CRFs will be filed into the investigator site file and the data is then entered at regular interval into the excel sheet on an encrypted NHS computer. The site file is securely kept in the locked filing cabinet in the anaesthetic department office.

9.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

9.4 Archiving

Research data will be stored off site in a secure approved NHS access facility - TNT. Only the research team will have authority to access this data if required via a request to the R&D Archiving Team. The study will be archived for 25 years from the close of the study with a review 1 year before the anticipated destruction date

10. TRIAL OVERSIGHT

10.1 Role and responsibilities of the Sponsor

UHCW has agreed to act as sponsor for this trial and will undertake the responsibilities of sponsor as defined by the Research Governance Framework and ICH Good Clinical Practice. An authorised representative of the Sponsor has approved the final version of this protocol with respect to the trial design, conduct, data analysis and interpretation and plans for publication and dissemination of results. As sponsor, UHCW provides indemnity for this trial and, as such, will be responsible for claims for any non-negligent harm suffered by anyone as a result of participating in this trial. The indemnity is renewed on an annual basis and will continue for the duration of this trial.

10.2 Role and responsibilities of the Funder

This trial has received a small grant of £1000.00 from Guys Airway Management Course-London, towards the R& D support. The design and management of this trial are entirely independent of the funder".

10.3 Trial Management Arrangements

10.3.1 Trial Steering Committee

Name	Affiliation	Expertise
Prof Cyprian Mendonca	Consultant Anaesthetist University Hospitals Coventry & Warwickshire	International expert in difficult airway management and co-author of difficult airway society guidelines in managing unanticipated difficult intubation
Dr Charles Pairaudeau	Consultant Anaesthetist University Hospitals Coventry & Warwickshire	Consultant anaesthetist with special interest in difficult airway management

The TSC will regularly assess the progress of the study and ensure that the investigators will adhere to the protocol.

10.3.2 Trial Co-ordinator / Manager

The Trial coordinator will take the responsibility for overseeing day to day coordination of the trial and reporting regularly to the TSC. The Trial coordinator will co-ordinate the protocol development, patient and trial management documents, setting up and maintaining the Trial Master File, ensure that necessary approvals are in place before the start of the trial, ensure that the data security and quality, ensuring data protection laws are adhered to and archiving all original trial documents including the data forms in line with UHCW NHS Trust policy"

10.3.3 Principal Investigators

Dr Charles Pairadeau is the principal investigator for this study. He will ensure that trail is conducted as set out in the protocol and ensure that the site file contains all necessary documents including CVs and delegation log.

11. MONITORING, AUDIT & INSPECTION

The study will be monitored by the Research & Development department at UHCW as representatives of the Sponsor, to ensure that the study is being conducted as per protocol, adhering to Research Governance and GCP. The approach to, and extent of, monitoring will be specified in a trial monitoring plan determined by the risk assessment undertaken prior to the start of the study.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Ethical approval and research governance

The study will be conducted in compliance the principles of the ICH GCP guidelines and in accordance with all applicable regulatory guidance, including, but not limited to, the Research Governance Framework. Ethical approval for this study will be sought from the Research Ethics Committee combined with Health Research Authority (HRA) approval. No study activities will commence until favourable ethical opinion and HRA approval has been obtained. Progress reports and a final report at the conclusion of the trial will be submitted to the approving REC within the timelines defined by the committee. Confirmation of capacity and capability will be obtained from the R&D department obtained prior to commencement of the study at all participating sites.

12.2 Peer review

The study design was initially discussed in anaesthetic departmental research meeting and approved by the chair of the department. Subsequently study was peer reviewed by Dr Narcis Ungureanu, consultant Anaesthetist, at University Hospitals of Birmingham foundation Trust. Dr Narcis Ungureanu has special interest in airway management and previously been involved videiolaryngoscopy research. As part of small grant application study abstract was submitted to Guy's airway management course grant committee. It was reviewed by Dr Kariem El-Boghdadly, the Editor of Anaesthesia Journal.

12.3 Public and Patient Involvement

The study lay abstract and patient information sheet has been reviewed by the Patient and Public Research Advisory group and the documents been revised as per their guidance.

12.4 Data protection and patient confidentiality

The study will comply with the Data Protection Act 2018 and GDPR. Participants will be assigned a unique identifier upon enrolment into the study to allow pseudonymisation of patient-identifiable of patient-identifiable data. Access to patient identifiable data will be restricted to members of the study co-ordination team who require it for the performance of their role. Electronic data will be stored on password protected encrypted drives and hard copies of study documents will be stored in locked filing cabinets in secure entry-card protected sites.

12.5 Safety reporting

We are not anticipating any adverse events as a result of study. However, any adverse events occurring during the study period will be reported as per the Trust policy using Datix.

13. DISSEMINATION POLICY

The study finding will be first presented as an abstract at national meetings and subsequently published in Anaesthesia peer reviewed journal.

14. REFERENCES

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7. Evrin, T. *et al.* (2019) 'Comparison of Different Intubation Methods in Difficult Airways during Simulated Cardiopulmonary Resuscitation with Continuous Chest Compression: A Randomized Cross-Over Manikin Trial', *Emergency Medicine International*, 2019(August), pp. 1–7. doi: 10.1155/2019/7306204.

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APPENDIX 1

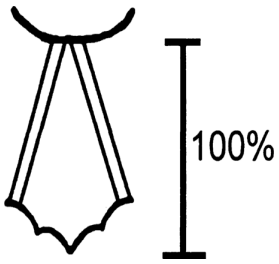
Modified difficult intubation scale score

Parameter	Description		Score
Number of attempts>1	add 1 point for each additional attempt: **N1** (0 if 1 attempt)		
Number of operators>1	add 1 point for each additional operator: **N2**		
Number of alternative intubation techniques, add 1 point for			
Bougie impingement: **N3 =1**	Bougie rotation: **N3=2**		
Subglottic tube impingement: **N3=3**	Tube rotation: **N3=4**		
Other manoeuvre: **N3=5**			
Percentage of Glottis Opening (POGO)	>50%: **N4 =0**	<50%: **N4=1**	
Lifting Force Required	Normal: **N5=0**	Increased: **N5=1**	
External Laryngeal Pressure	Not applied: **N6=0**	Applied: **N6=1**	
Total Score			

Correlation between mIDS and the Degree of Difficulty

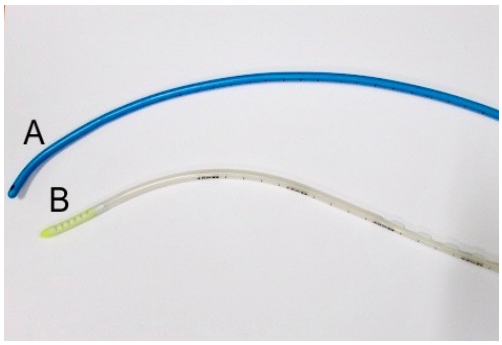
mIDS Score	Degree of Difficulty
mIDS =0	Easy
mIDS =0 < to ≤ 5	Slight difficulty
mIDS = >5	Moderate to Major Difficulty
mIDS = ∞	Impossible intubation

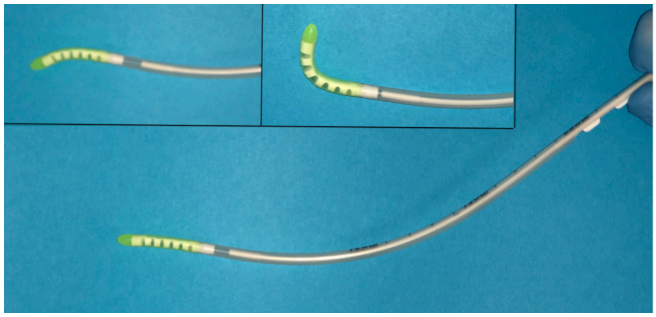
The percentage of glottic opening (POGO) score



The percentage of glottic opening (POGO) score represents the portion of the glottis visualized. It is defined anteriorly by the anterior commissure and posteriorly by the interarytenoid notch. The score ranges from 0% when none of the glottis is seen to 100% when the entire glottis including the anterior commissure is seen.

APPENDIX 2





Photograph showing flexible tip bougie

Video demonstrating flexibility of tip of the flexible tip bougie