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Comparison of the incidence of epistaxis following nasotracheal intubation when using either the fibreoptic laryngoscope technique or the Macintosh laryngoscope technique

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28/09/2007

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28/09/2007

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12/10/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265170229

Study information

Scientific Title
Comparison of the incidence of epistaxis following nasotracheal intubation when using either the fibreoptic laryngoscope technique or the Macintosh laryngoscope technique

Study objectives
1. When performing nasotracheal intubation (passage of breathing tube though the nose, pharynx and larynx into the windpipe) under general anaesthesia, does fibreoptic intubation reduce the incidence of epistaxis (nosebleed) in comparison with traditional intubation using the Macintosh laryngoscope?
2. Secondary research questions/objectives include:
2.1 Does it reduce the severity of epistaxis?
2.2 Does it reduce the number of attempts necessary to pass the tube through the nose?
2.3 Does it reduce the resistance encountered when passing the tube through the nose?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Intubation

Interventions
Patients will be asked the following questions: (1) 20 you have any difficulty breathing through your nose? (2) Can you usually breathe clearly through both nostrils? (3) Can you usually breathe equally through both nostrils or is one nostril clearer than the other7 Only asymptomatic patients who report being able to breathe clearly and equally through both nostrils will be invited to participate in the study.

Xylometazoline (a vasoconstrictor) will be applied to the nasal mucosa approximately thirty minutes and then approximately 5 minutes before the induction of anaesthesia. Anaesthesia will be established with glycopyrrolate, fentanyl, propofol and atracurium and the patients lungs will be ventilated with oxygen and isoflurane until neuromuscular blockade is complete.

Patients will then be randomised into two groups, the Fibreoptic Laryngoscope group or the Macintosh Laryngoscope group, by opening an opaque, sealed envelope. All fibreoptic and Macintosh intubations will be performed by experienced anaesthetists (JES or JLT). In the Fibreoptic group, each nostril will be examined systematically with a videoendoscope (an endoscope attached to a closed circuit television system), and a videotape recording of the procedure will be made following General Medical Council guidelines. Following anterior rhinoscopy (inspection of the front of the nasal cavity), the fibrescope will be passed both underneath and alongside the inferior turbinate in each nostril and any resistance to the passage of the instrument along these pathways will be noted. The presence of any intranasal abnormalities will be documented. The most patent nostril (if any) will be selected for the nasal intubation. If the nostrils are considered to be equally patent, a random selection will he made. The endoscope will then be passed through the pharynx and larynx and into the trachea. The endotracheal tube, which will have been mounted on the fibrescope, will then be advanced over the fibrescope which will guide it into the trachea. Thermosoftened, lubricated tubes, size 7mm or 6.5 mm, for males or females respectively, will be used. The ease of navigability of the tube through the nose (easy, mild resistance, moderate resistance or obstructed - not used) will be noted. If undue resistance to tube advancement is encountered in a nostril that has been selected randomly, the tube and fibrescope will be removed and the other nostril will be used. If undue resistance is still encountered, orotracheal intubation will be performed with a Macintosh laryngoscope and the options for further management of the patient will be discussed with the surgeon. If undue resistance is encountered in a nostril that has been selected as the most patent, the tube and fibrescope will be removed and orotracheal intubation will be performed with a Macintosh laryngoscope. The options for further management will then be discussed with the surgeon. (The inability to intubate both nostrils in a patient with an otherwise normal airway is a recognised problem, but in clinical practice it is a very rare event. It may occur perhaps once in approximately 500-1000 patients. The sequence of events described reflects normal clinical practice and is given in detail for completeness. In the great majority of such cases, the best option available is for the surgeon to perform the patients surgery with the orotracheal tube in study.

Five minutes after successful nasal intubation the severity of the epistaxis will be estimated by a blinded observer (AM or IS) by means of pharyngeal inspection and aspiration of the pharynx using a 1 2F suction catheter with a length of 45cm, attached to suction tubing with an internal diameter of 7mm and a length of 2.5 metre. Epistaxis will be defined as:
1. No epistaxis
2. Mild epistaxis - blood on tube or staining of posterior pharyngeal wall only
3. Moderate epistaxis - blood pooling in the pharynx of sufficient quantity to be aspirated into the suction catheter but not into the suction tubing.
4. Severe - blood pooling in the pharynx, of sufficient quantity to be aspirated into the suction tubing. The patients surgical treatment will then proceed as normal.

The videotape recordings will be analysed later by an otolaryngoiogist (CJ) who will confirm or refute the anaesthetic diagnoses. Will be unaware of the details and the results of the nasal intubations. Nasal abnormalities will be identified and classified as septal deviations (minor, major or impactions), septal spurs, hypertrophied turbinates, polyps, etc. According to the presence or absence of intranasal abnormalities, the nose will be classified as one nostril more

patent than the other (left or right nostril best) or nostrils equally patent. In the Macintosh group, a random, selection of nostril to be intubated will be made. The same type of endotracheal tube (Thermosoftened, lubricated, size 7mm or 6.5mm for males or females respectively) will be advanced through the nose and into the pharynx, where it will be identified by a Macintosh laryngoscope inserted through the mouth. The tube will then be advanced through the larynx into the trachea, with the aid of Magills forceps if necessary. The ease of navigability of the tube through the nose will be assessed as above. If undue resistance to tube advancement is encountered the tube will be removed and the other nostril~ will be used. If undue resistance is still encountered, orotracheal intubation will be performed with a Macintosh laryngoscope and the options for further management will be discussed with the surgeon.

Five minutes after successful nasal intubation, epistaxis will be estimated by a blind observer, as above. The patients surgical treatment will then proceed as normal.

The null hypothesis is that there Is no difference in the incidence of epistaxis between the two groups, The alternative hypothesis is that there is a difference in the incidence of epistaxis between the two groups; that the endoscopic selection of nostril to be intubated followed by fibreoptic intubation has had an effect on the Incidence of epistaxis. In order to assess the effect of fibreoptic intubation, it is essential to have a concurrent comparison, a control group, who receive a standard technique. Without a control group, it is impossible to make an objective evaluation of the effectiveness of the intervention. It is essential to avoid researcher bias in this type of investigation. Therefore, the observer responsible for assessing the degree of epistaxis will be blinded and unaware of which type of intubation has been performed. Participants will be exposed to no increased risk and very little inconvenience. Their tracheas will be intubated by one of the established, accepted, standard methods of nasotracheal intubation - the Macintosh or the fibreoptic technique. It is normal practice for the axillofacial surgeon to first aspirate the pharynx to remove any blood before inserting the throat pack, to prevent contamination of the airway. The surgical and nursing staff involved have been consulted during the design of the investigation and have given their support.

Patients will be invited to consider participating in the study in the pre-clerking clinic approximately one week before surgery. The broad timetable for the study is as follows:
Preparation time - 3 months
Collecting data - 12 to 18 months
Interpreting and analysing findings - 3 months
Final report - at 2 years

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Incidence and severity of epistaxis

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/01/2006

Completion date
04/01/2008

Eligibility

Key inclusion criteria
1. The patients involved will be scheduled for elective surgery on Maxillofacial operating lists. Potential participants will be identified when they attend the surgical pro-clerking clinic, approximately one week before the planned surgery. Suitable patients will be those in whom nasotracheal intubation is essential, ASA classification 1 or 2, with no significant undercurrent illness.
2. A clinical history will be taken and medical examination performed on potential participants. If inclusion criteria are present and exclusion criteria are absent, three questions will be asked:
2.1 Do you have any difficulty breathing through your nose?
2.2 Can you usually breathe clearly through both nostrils?
2.3 Can you usually breathe equally through both nostrils or is one nostril clearer than the other?
3. Asymptomatic patients who report being able to breathe clearly and equally through both nostrils will be invited to consider participating in the clinical investigation. A full explanation will be given and questions answered. The patient will be given a copy of the patient information sheet. S/he will then be allowed to think about the proposal and will then be seen again on the day of operation.
4. Patients in whom nasotracheal intubation is an essential part of their anaesthetic management. Otis not ethical to perform a potentially traumatic nasotracheal intubation unless it is required to facilitate the planned surgery.
5. ASA physical status 1 or 2. Only patients who present no increased anaesthetic risks will be studied
6. Aged 16 and over undergoing elective surgery
7. Asymptomatic patients who report being able to breathe clearly and equally through both nostrils (if one nostril is reported to be clearer, then randomisation of nostril for intubation must not be performed)
8. Able and willing to give informed written consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
250

Key exclusion criteria
1. Morbid obesity - BMI>35 (anaesthetic risk associated with intubation)
2. Oesophageal reflux (anaesthetic risk associated with intubation)
3. Difficult tracheal intubation (anaesthetic risk associated with intubation)
4. History of nasal trauma (probable distorted nasal architecture)
5. History of nasal obstruction or nasal pathology (should have fibreoptic nasendoscopy to

assess nasal cavities)
6. Bleeding diathesis or taking anticoagulant drugs (nasal intubation contra-indicated because of risk of haemorrhage)

Date of first enrolment
04/01/2006

Date of final enrolment
04/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
Birmingham
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
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Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration