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Is the Guedel airway an accurate predictor of optimum laryngeal mask size selection - a pilot study?

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Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 26/10/2015	**Condition category** Surgery	

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
N0265105785

Study information

Scientific Title
Is the Guedel airway an accurate predictor of optimum laryngeal mask size selection - a pilot study?

Study objectives
The Guedel airway is an accurate predictor of optimum LMA size selection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Blinded prospective study

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 below to request a patient information sheet

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

Interventions
Method:
Each individual patient having given written, informed consent and fulfilling the inclusion criteria will be assessed for their appropriate size Guedel airway (GA) during the preoperative visit by anaesthetist investigator No 1. Simply the distance between the angle of the mouth to the tragus and the angle of the mandibular to the gap between the front teeth will be measured. Each patient is accordingly allocated to group A (GA 2), B (GA 3), C (GA 4) until there are 15 patients in each group. On each patient the weight, height, Mallampati score, dental status will be recorded.
In the anaesthetic room anaesthetist investigator No.2 proceeds with a standardised anaesthetic according to protocol. After preoxygenation of 4 minutes each patient will receive J mcg/kg fentanyl followed 2 minutes later by 2-4 mg/kg propofol as induction agent. Having ensured that hand ventilation is possible 0,5-1 mg/kg rocuronium is given.

Anaesthesia is maintained using 1-2% Isoflurane in 100 % oxygen at a fresh gas flow rate of one minute ventilation (100 x weight in kg) using a circle system. Nitrous oxide is to be avoided until all data are collected.
Size 3,4, 5 and 6 LMAs are inserted into each patient by investigator No.2 using the standard technique (8) in random order withdrawing a number sequence from an envelope. Insertion is only attempted if the jaw is relaxed, the eyelash reflex absent and the patient apneic. Only one attempt is permitted for each LMA size. If a LMA proves to large for easy insertion no attempt will be made to insert an even larger size LMA. On the contrary if a LMA seal proves unsatisfactory with an OPL of less than 15 cm H20 no smaller size LMA will be inserted. Investigator No.3 will observe LMA placement and hand the appropriate LMA to investigator No. 2. He will omit an inappropriately large or small LMA. The cuff will be inflated to the recommended intracuff pressure of 60 cms H20 recording the volume of air required to achieve that pressure. The cuff pressure is measured using a hand-held mechanical cuff inflator. Successful placement of the LMA is judged by observation of chest wall excursion and a normal end-tidal carbon dioxide trace during assisted hand ventilation.
A sheath will be placed over the upper part of the anaesthetised patient's face to blind the anaesthetist investigator No. I to the identity of the patient. He opens the patient's mouth as widely as possible and records whether the cuff can be seen or not. He then proceeds to assess the oropharyngeal leak pressure (OLP) using the manometric stability test. It involves the observation of an aneroid manometer dial placed in the expiratory limb of the breathing system. At fresh gas flows (FGF) of one minute ventilation the pressure gauge is expected to rise as the airway pressure increases. As the flow of the air leak equilibrates with the FGF the manometer dial reaches stability and is defined as the OLP (16). We are using the OLP classification of Berry and colleagues (10) whereas OLP is high if >20 cmH20, medium if <20-15 cmH20, low if <15-5 cmH20, fail if <5 cmH20. The airway pressure is not permitted to exceed 40 cmH20. To allow the optimal intracuff volume to contribute to a good airway seal we will withdraw gradually air from the cuff with any LMA that achieves a high OPL (>20cmH20)
until manometric stability is reached at exactly 20 cmH20. One millilitre of air is than reinserted into the cuff and intracuff volume and pressure are recorded. To any LMA cuff producing an OPL less than 20 cmH20 we will add volume gradually not exceeding the recommended maximum volume of 20mls for LMA 3, 30mls for LMA 4, 40 mls for LMA 5 and 50 mls for LMA 6 until the OPL reaches 20 cmH20. After adding one millilitre of air we record the intracuff volume and pressure. This part of the study will give us the minimum effective volume or minimum effective intracuff pressure necessary to achieve an optimal airway seal. The position of each LMA is scored by passing the fibreoptic scope through the LMA tube just proximal to the mask aperture bars and view the cords: score 4, only the vocal cords are seen; score 3, cords and posterior epiglottis are seen; score 2,cords and anterior glottis are seen; score I, cords not seen, but function is adequate; score 0, cords not seen and failure of function (3,18).
Finally to proceed with the planned elective surgery the LMA with the most optimum airway seal is inserted if not already in place. The optimum size LMA chosen from size 3,4,5 and 6 for each individual patient is the LMA that achieves an OLP of >20cmH20 with the lowest minimum effective volume and minimum effective pressure.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/01/2002

Completion date
31/01/2008

Eligibility

Key inclusion criteria
The population from which recruitment is achieved are patients on the elective operating lists of fixed sessions in Urology and General surgery at the University Hospital Birmingham NHS Trust (Queen Elizabeth Hospital and Selly Oak Hospital).

We are planning to recruit 45 patients (50% female/50% male) into each of the three groups (group A: Guedel airway 2, group B: GA 3; group C: GA4). The size of GA is assessed by investigator No.l during the preoperative visit.

Inclusion criteria:
1. ASA 1/2
2. Age > 18 years
3. Indication for using a LMA
4. Listed for elective surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
1. ASA 3/4
2. Age <18 years
3. Contraindication for using a LMA: risk of regurgitation/aspiration (hiatus hernia, heartburn, fasted less than 6 hours, abdominal pathology)
4. Prolonged surgery (>90 min)
5. Pregnancy

6. Obvious anatomical airway abnormalities
7. Patients with Mallampati class 3/4
8. Not fluent in English

Date of first enrolment
31/01/2002

Date of final enrolment
31/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK), NHS R&D Support Funding

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