The Air-Q laryngeal mask airway during anesthesia with controlled ventilation: a clinical trial of efficacy

Published: 28-06-2007
Last updated: 10-05-2024

we would like to evaluate the efficacy of ventilation an intubation using the Air-Q. also, we'll evaluate the patients discomforts after extubation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON31415

Source
ToetsingOnline

Brief title
Air-Q case series

Condition

- Therapeutic procedures and supportive care NEC

Synonym
airway device, breathingtube

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Air-Q, efficacy

Outcome measures

Primary outcome

first attempt succes rate

Secondary outcome

- time to first breath

- Leakpressure

- first attempt succesrate endotracheal intubation

- cuffpressure

- hemodynamic reaction to insertion

- end-tidal CO2 and periferal oxygensaturation

- any episodes of coughing, hiccup, laryngospasm and brochospasm

- presence of blood on the cuff of the Air-Q at extubation

- sore throat, dysphonia and dysphagia after extubation

Study description

Background summary

multiple tools (tubes) were described in literature for securing the patients airway during anesthesia. in general, an endotracheal tube is used. sometimes, when the use of an endotracheal tube is not necessary, a laryngeal mask airway is a propper alternative. laryngeal mask airways are being used frequently, especially in ambulatory surgery, because their use provides some major advantages. when using a laryngeal mask airway, there's no need for muscle relaxants, there's no risk of damaging the vocal cords. furthermore, laryngoscopical endotracheal intubation provoces a stronger raise in bloodpressure and heartrate than a laryngeal mask airway does. over the last decade many types of laryngeal maks airways have been designed, all with their

own strenghts and weaknesses. for example, air leakage is a frequently occuring event with the classical laryngeal mask, and it's not possible to pass an endotracheal tube through it. blokkage of the lumen of the laryngeal mask by the epiglottis does occur, despite bars meant to prevent this from happening. further development of the laryngeal mask airway has lead to the Air-Q. the Air-Q is a modification of the classic laryngeal mask airway, with a differently shaped cuff intended to keep the epiglottis out of the lumen of the tube. this way the protective bars aren't necessary, so there is nothing obstructing the lumen. because of this it is possible to pass an endotracheal tube through the Air-Q. this feature makes the Air-Q an option for intubation when classic intubation using a laryngoscope failes. intubation using the Air-Q is likely to be less stimulating than laryngoscope-aided intubation.

Study objective

we would like to evaluate the efficacy of ventilation an intubation using the Air-Q. also, we'll evaluate the patients discomforts after extubation.

Study design

when a patient wishes to be enrolled in the trial and matches all of the inclusion criteria and doesn't match any of the exclusioncriteria he or she can be included.
heartrate and rythm are monitored (3-lead ecg) as well as bloodpressure (non-invasive) and oxygensaturation.
anesthesia will be induced with propofol 2-3 mg/kg and sufentanil 0.1-0.2 mcg/kg. after disappearence of the cilliary reflex the Air-Q will be inserted. after three failed attempts the patient will be excluded and will receive care as usual. the number of seconds passing from touching the lips with the Air-Q to giving the first effective breath is noted, the number of insertion attempts, as well as heartrate and bloodpressure directly after insertion. the cuff will be filled as described by the manufacturer of the Air-Q. standardized ventilation consists of PCV, 5 cmH2O PEEP, 10-18 cmH2O inspiratory pressure, frequency 14/min, inspiration-expiration rate 1:2, 40% O2. now we will determine leakpressure. after turning the flow to 3 L/min of O2, the expirationvalve will be closed. leakpressure will be determined as the pressure at which equilibrium is reached. to prevent barotrauma, pressure will be limited at 40 cmH2O. if indicated, a musclerelaxant will be administered and the patient will be intubated. again, after three failed attempts the patient will be excluded and will receive care as usual. now, the patient will be mechanically ventilated as described above, untill spontaneous respiration resumes. anesthesia will be maintained with propofol infusion at a rate of 6-12 mg/kg en sufentanil as needed. patients who report severe sore throat (VAS >4) postoperatively will be called every 48 hours untill the pain is gone.

Intervention

an Air-Q will be inserted in all patients.
leakpressures are determined.
when indicated, patients will be intubated through the Air-Q.

Study burden and risks

burden: minimal (3 questions after emergence from anesthesia and every 48 hours untill disappearence of discomforts)
risk: equal to or less than regular treatment

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

S. van Ravestijnkade 378
3071ML Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

S. van Ravestijnkade 378
3071ML Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients undergoing general anesthesia in the ambulatory surgical unit of the ErasmusMC

Exclusion criteria

known or expected difficult intubation
preexistant obstructive airway problems
BMI >30
patients in need of rapid sequence induction

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Air-Q
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-06-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17309.078.07