

**A RANDOMISED CONTROLLED TRIAL ON
ENDOTRACHEAL TUBE-PROSEAL LARYNGEAL MASK
EXCHANGE AND AWAKE EXTUBATION WITH
LIDOCAINE DURING EMERGENCE OF ANAESTHESIA
IN CONTROLLED HYPERTENSIVE PATIENTS
UNDERGOING ELECTIVE SURGERY IN HOSPITAL
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Achievement

This clinical trial has won the second prize in the poster presentation during the Annual Malaysian Society of Anaesthesiology Conference held in Langkawi on the 25th - 27th April 2008.

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May the blessing of our Lord be upon you all.

Abbreviation

ASA	American Society of Anesthesiology
BP	Blood Pressure
cLMA	Classical Laryngeal Mask Airway
DBP	Diastolic Blood Pressure
ETT	Endotracheal Tube
HR	Heart rate
IV	Intravenous
MAC	Minimal Alveolar Concentration
MAP	Mean Arterial Pressure
PLMA	Proseal Laryngeal Mask Airway
RPP	Rate Pressure Product
SBP	Systolic Blood Pressure

Definitions

Hypertension (JNC VII report)

- Systolic blood pressure greater than 140mmHg or Diastolic blood pressure greater than 90mmHg

Controlled hypertension

- Systolic blood pressure less than 140mmHg and Diastolic blood pressure less than 90mmHg

Rate Pressure Product

- Product of systolic arterial blood pressure and heart rate
- Value of more than 12000 is associated with increased risk of myocardial complications

Patients at risk of aspiration (Asai T, 2004).

- Patient factors
 - Emergency surgery
 - Diabetic with gastroparesis
 - Increased intracranial pressure
 - Hiatus hernia
 - Gastrointestinal obstruction
 - Recurrent regurgitation
 - Dyspeptic symptoms
 - Pregnancy

- Operative factors
 - Abdominal surgery

Respiratory complications

- Coughing
- Breath holding
- Airway obstruction
- Laryngospasm
- Desaturation to less than 95%
- Inadequate reversal
- Apnoea (for more than 20 seconds)
- Vomiting
- Aspiration
- Airway trauma – blood stain at the tip of airway device on removal

Difficult intubation

- Mallampati score (Samsoon and Young modification) of 3 and 4
- Thyromental distance less than 6 cm or 4 finger breadths
- Interincisor distance less than 4cm or 3 finger breadths
- Cormack-Lehane score of 3 and 4

Abstrak

Tajuk: Kajian perbandingan antara penukaran tiub trakea (ETT) menggunakan alat pernafasan larings (“Proseal laryngeal mask airway”, PLMA) dan penggunaan lidocaine sebelum extubasi semasa pemulihan bius di kalangan pesakit tekanan darah tinggi yang menjalani pembedahan elektif di Hospital Universiti Sains Malaysia

Objektif: Kajian ini bertujuan untuk membandingkan teknik penukaran tiub penafasan trakea dengan alat pernafasan larings (Proseal) dengan penggunaan lidocaine secara intravena untuk mengurangkan kesan rangsangan terhadap sistem kardiovaskular dan komplikasi sistem pernafasan di kalangan pesakit darah tinggi. Kajian ini juga meneliti kesan pengambilan ubat ‘beta-blocker’ terhadap perubahan hemodinamik pada kedua-dua kumpulan yang dikaji.

Kaedah: Seramai 62 pesakit darah tinggi telah menyertai kajian ini. Cara pembiusan standard diberikan kepada semua pesakit ketika waktu pra-operatif dan intra-operatif. Seramai 31 pesakit di dalam kumpulan 1 telah menjalani extubasi selepas pemberian lidocaine $1 \text{ mg}\cdot\text{kg}^{-1}$ secara intravena 2 minit sebelum extubasi. Manakala 31 lagi pesakit di dalam kumpulan 2 menjalani penukaran ETT kepada PLMA sebelum pemulihan kesan bius. Neostigmine dan glycopyrrolate digunakan sebagai ubat ‘reversal’. Perubahan parameter hemodinamik termasuk tekanan darah sistolik, diastolik dan purata serta denyutan jantung dan ‘rate pressure product’ dicatatkan pada masa pesakit tiba di dewan bedah, pada masa pembuangan ETT atau PLMA, pada minit pertama, kedua, ketiga, kelima dan ke-sepuluh setelah pembuangan alat salur pernafasan. Insiden komplikasi sistem pernafasan juga diteliti. Perubahan hemodinamik telah dianalisa dengan kajian ‘repeated measures ANOVA’ dan

diikuti dengan 'paired dan independent t-test' manakala insiden komplikasi sistem pernafasan dengan 'Chi-square (χ^2) test'. Pesakit yang dirawat dengan beta blocker juga diselidik semula untuk melihat kesannya terhadap perubahan hemodinamik.

Keputusan: Data demografi adalah setara di antara kumpulan. Tidak terdapat sebarang perbezaan yang nyata pada parameter hemodinamik 'baseline' yang diukur pada kesemua kumpulan. Subjek kumpulan 1 telah menunjukkan peningkatan serta merta dan ketara dari segi statistik pada SBP, DBP, MAP, HR dan RPP sementara subjek kumpulan 2 pula cuma menunjukkan peningkatan minimal pada awal pembuangan PLMA. Perbandingan perubahan parameter hemodinamik antara kedua-dua kumpulan menunjukkan perbezaan statistic yang ketara. Penggunaan ubat beta blocker telah mengurangkan ukuran hemodinamik 'baseline' dan tekanan darah dalam masa 10 minute pemantauan. Kesan penurunan tekanan darah adalah minimal. Perbandingan perubahan tekanan darah antara kedua-dua kumpulan tetap ketara dari segi statistic. Perubahan denyutan jantung antara kedua-dua kumpulan adalah minimal. Penurunan denyutan jantung yang berlaku seterusnya menurunkan ukuran indeks RPP. Seramai 93.5% subjek kumpulan ETT-PLMA sedar dari bius dengan lancar dan dengan kadar komplikasi respiratori yang minimal berbanding dengan 87.1% dalam kumpulan lidocaine.

Kesimpulan: Prosedur penukaran ETT-PLMA adalah selamat dan senang dijalankan untuk membolehkan pemulihan dari bius secara lancar. Prosedur ini juga adalah lebih berkesan untuk mengurangkan perubahan ukuran hemodinamik berbanding penggunaan lidocaine 1mg.kg^{-1} di kalangan pesakit darah tinggi. Rawatan jangka panjang ubat beta blocker tidak banyak menambahkan pengurangan tekanan darah sekiranya pesakit telah diberi lidocaine ataupun menjalani penukaran ETT kepada PLMA tetapi rawatan ini dapat memastikan

penurunan dan kestabilan denyutan jantung ke tahap dimana indeks RPP dapat dikurangkan ke tahap yang memuaskan ($<12,000$).

Abstract

Title: A randomised controlled trial on endotracheal tube (ETT)-Proseal laryngeal mask (PLMA) exchange and awake extubation with lidocaine during emergence of anaesthesia in controlled hypertensive patients undergoing elective surgery in Hospital Universiti Sains Malaysia

Objectives: The aim of this study was to compare the use of ETT-PLMA exchange and awake extubation with lidocaine in the attenuation of the cardiovascular response and respiratory complications among hypertensive patients. A substudy of the effects of beta blocker antihypertensive therapy on the haemodynamic changes of both groups will also be explored.

Methodology: A total of 62 controlled hypertensive patients were recruited. Standard anaesthetic management was provided during the preoperative and intraoperative period. Thirty one patients were placed in group 1 where awake extubation was performed after a 2 minutes prior dose of IV Lidocaine 1 mg.kg^{-1} while the other 31 patients were placed in group 2 where a PLMA was inserted in deep plane of anaesthesia replacing ETT before emergence of anaesthesia. Neostigmine and glycopyrrolate were chosen as the choice of reversal. Haemodynamic changes consisting of systolic, diastolic and mean arterial blood pressure, heart rate and rate pressure product were charted on arrival to the operation theatre (baseline), at removal of ETT or PLMA, at 1, 2, 3, 5 and 10 minutes after airway removal. Incidence of respiratory complications was noted. Haemodynamic variables were analysed by repeated measures ANOVA followed by paired and independent t-test while respiratory complication data by Chi-square (χ^2) test. Subset of patients with beta blocker therapy were analysed to assess its haemodynamic effects.

Results: Demographic data were comparable in all groups. There was no difference in the baseline haemodynamic parameters. Group 1 subjects demonstrated an immediate and significant increase in SBP, DBP, MAP, HR and RPP while Group 2 subjects haemodynamic variables showed an initial slight insignificant rise. There was a significant difference in the haemodynamic parameters between group 1 and 2. Presence of beta blocker therapy reduced slightly the baseline haemodynamics and blood pressure changes over the 10 minutes measurement. A significant difference persisted in the BP measurements between group 1 and 2 treated with beta blocker. Measured heart rates were lower and stable resulting in a lower and favourable RPP index. Smooth emergence with minimal minor respiratory complications was noted in 93.5% of ETT-PLMA group subjects as compared to 87.1% in lidocaine group. No major respiratory complication was noted.

Conclusion: ETT-PLMA exchange is a safe and easy procedure that provides a bridge to smoother emergence with a secure airway. It is superior in attenuating the haemodynamic response to emergence of anaesthesia with least haemodynamic variability compared to lidocaine $1\text{mg}\cdot\text{kg}^{-1}$ in hypertensive patients. Treatment with long term beta blocker offer little additional blood pressure lowering effect in the presence of IV Lidocaine and usage of ETT-PLMA for emergence but was able to ensure a lower and stable heart rate resulting in a lower RPP index ($<12,000$) especially in the IV Lidocaine group.

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Chapter 1

Introduction

1 INTRODUCTION

It has become clear as reported in the ASA Closed Claim Study that obvious adverse events related to tracheal extubation accounts for 5% of the respiratory related claims (Caplan R.A. *et al.*, 1990). Tracheal extubation has frequently been associated with tracheal stimulation leading to undesirable haemodynamic changes, raised intraocular and intracranial pressures as well as respiratory complications such as coughing, bucking, laryngeal spasm, airway obstruction and desaturation of which the incidence probably exceeded that associated with tracheal intubation (Asai T *et al.*, 1998). These haemodynamic surges correlate with the increase in plasma catecholamine levels during extubation which understandably leads to the direct stimulation of the cardiovascular system causing increased in the contractility of the myocardium, the afterload and tachycardia hence causing a change in the myocardial oxygen demand and supply relationship (Lowrie A *et al.*, 1992). The effects of haemodynamic changes though short lived and tolerable in most patients, may be detrimental to patients with underlying cardiovascular diseases such as hypertension and ischaemic heart disease, or in patients undergoing intraocular and neuro-surgery. Hypertensive patients often demonstrate an exaggerated cardiovascular response (Fujii Y *et al.*, 1997).

In our current day to day practice in anaesthesia, several methods are utilized to attenuate these detrimental haemodynamic and pressure changes effects. Deep extubation is often practice in patients with minimal risk of aspiration. This method however is commonly associated with other respiratory complications namely laryngospasm or airway obstruction which in turn may stimulate the stressor response. Placing an oropharyngeal airway to maintain airway patency may itself stimulates the gag response. Pharmacological therapy

using lidocaine, beta blockers, calcium channel blockers or opioids in various studies yielded variable results and at times in clinical practice present inconsistent effects (Koga K *et al.*, 1998, Maroof M *et al.*, 1999).

The introduction of laryngeal mask airway (LMA) in the 1980's has brought new perspective in the management of airway in anaesthesia allowing maintenance of anaesthesia without intubation in short procedures and its use has even extended to positive pressure ventilation in patients with normal airway pressure. It provides relative airway protection from pharyngeal secretion though not aspiration and allows a more pleasant emergence from anaesthesia with minimal stimulation of the cardiovascular response and raised intraocular and intracranial pressures (Brimacombe J, 1995, Blanchard N *et al.*, 1997).

Usage of LMA has been suggested as a possible solution to reduce the cardiovascular response associated with tracheal extubation and to minimise respiratory complications that often occurs in deep extubation by exchanging the endotracheal tube with a LMA at end of a surgical procedure while the patient is still in a deep plane of anaesthesia allowing the patient to emerge from anaesthesia with the LMA (George SL and Blogg CE, 1994, Koga K *et al.*, 1998, Dob DP *et al.*, 1999, Asai T and Shingu K, 1999c, Stix MS *et al.*, 2001). Essentially, this provides the security of endotracheal tube during the surgical procedure and the advantages of laryngeal mask airway during emergence. The Proseal Laryngeal Mask Airway (PLMA) is a newer generation of LMA designed with a similar functional profile but a better safety features to reduce the aspiration risk commonly linked to cLMA use.

This randomised controlled study is designed to compare the conventional method of using lidocaine during extubation and the insertion of Proseal LMA in exchange with the

endotracheal tube to attenuate tracheal stimulation and hence prevent the haemodynamic changes and possible respiratory complications in patients with controlled hypertensive disorder.

Chapter 2

Literature Review

2 LITERATURE REVIEW

2.1 Applied Anatomy and Physiology and its relevance in airway instrumentation

The nervous system of the airway has an important role in the maintenance of airway patency and protection of the airway. It is however also the main mediator of the harmful effects of airway instrumentation.

The pharynx receives its sensory and motor nervous supply from the pharyngeal branches of the glossopharyngeal and vagus nerves through the pharyngeal plexus while the larynx is supplied by the superior and recurrent laryngeal nerves of the vagus nerve. The internal branch of superior laryngeal nerve provides the sensation to the larynx down to the vocal cord and the recurrent laryngeal nerve sensate the subglottic region. The complementary sympathetic and parasympathetic supplies arise from the sympathetic trunk and the vagus nerve respectively. The density of sensory innervation is greatest at the laryngeal inlet, especially the laryngeal surface of the epiglottis consistent with its protective function of the distal respiratory tract. The posterior half of the true cord has more touch receptors than the anterior portion.

During airway instrumentation, afferent impulses are transmitted through the glossopharyngeal and vagus nerves to ganglion nodosum and integrated in the brainstem at the tractus solitarius. Sympathetic outflow from the tractus solitarius to the sympathetic trunk leads to undesirable stimulation of adrenergic receptors causing tachycardia, increased contractility and vasoconstriction. This is compounded by further release of adrenaline from the adrenal glands.

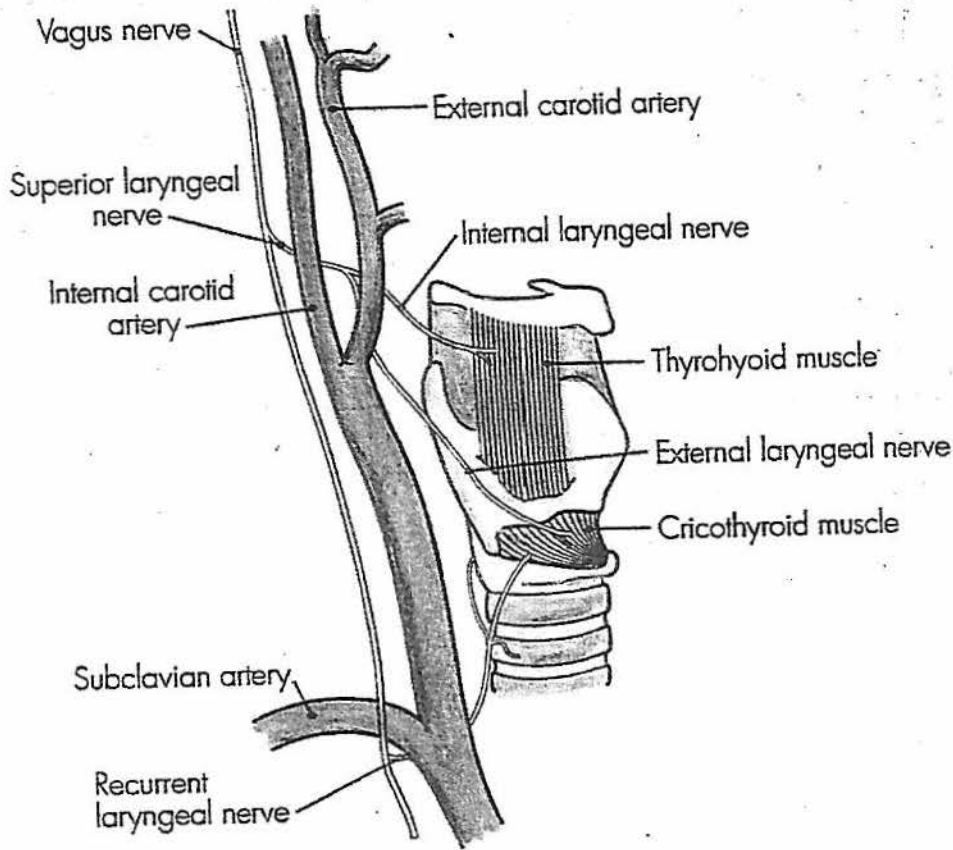


Figure 2.1: Nerve supply of the Larynx

Local airway reflexes occur as a direct response to stimulation of the afferent sensory nerves. Glottic closure reflex or glottic stop reflex is produced by the rapid contraction of the thyroarytenoid muscle in response to superior laryngeal nerve stimulation. Laryngospasm may follow and exaggerates the glottic closure reflex and tends to be prolonged and maintained beyond the cessation of the initial stimulation (Sweeny KD, 1994). These reflexes invariably lead to apnoea desaturation. The cough reflex is believed to be mediated by the same stimulatory pathway. During the compressive phase of a cough, strong activation of the respiratory expiratory muscles cause a massive build up of intrathoracic pressure against a tightly closed glottis which lead to intraocular and intracerebral venous