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COMPARISON OF HEMODYNAMIC PARAMETER WITH LARYNGEAL MASK AIRWAY SUPREME VERSUS CUFFED ENDOTRACHEAL TUBE IN LAPAROSCOPIC CHOLECYSTECTOMY UNDER GENERAL ANAESTHESIA: A RANDOMIZED INTERVENTIONAL STUDY IN SMS MEDICAL COLLEGE AND ATTACHED GROUP OF HOSPITALS, JAIPUR.

Anaesthesiology

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ABSTRACT

Background: Laryngoscopy and tracheal intubation can cause serious cardiovascular responses in patients such as hypertension, tachycardia, and arrhythmias. Alternative airway maintenance techniques may attenuate these hemodynamic stress responses.

Objectives: This study aimed to compare the immediate hemodynamic effects of the insertion of laryngeal mask airway supreme (LMA-S) and classic with laryngoscopy and Endotracheal Intubation (ETT).

Patients and Methods: This study was a prospective, double-blind, and randomized clinical trial conducted on 150 patients aged 18 to 50 years with ASA I (American Society of Anesthesiologists), in the general operating room of Shahid Mohammadi hospital, Hormozgan university of medical sciences, Bandar Abbas, Iran. In the ETT group, endotracheal intubation was performed using the Macintosh laryngoscope; while for the and LMA-S groups, and LMA Supreme was inserted, respectively. The induction and maintenance of anesthesia were similar in all patients. The hemodynamic parameters such as heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were measured before (baseline) and after induction of anesthesia at 4 different time points. The statistical analysis was done and P value less than 0.05 was considered significant.

Results: Participants in all groups were similar in terms of gender, age, weight, height, and Mallampati class. The mean ± SD of SBPs (105.62 ± 12.12, 112.90 ± 12.2, and 112.48 ± 15.14 mm Hg, respectively for ETT, and LMA-S) and DBPs (64.64 ± 10.23, 73.78 ± 9.70, and 71.20 ± 12.27 mm Hg, respectively for ETT, and LMA-S) were significantly lower in the ETT group compared to LMA groups 5 minutes after device insertion ($P < 0.01$ for SBPs and $P < 0.001$ for DBPs); however these values were lower than the baseline values in all groups. There were no differences in the mean SBP and DBPs between the three groups at the other time points. The mean ± SD heart rates in the ETT group, compared to the and LMA-S groups, were considerably higher in the first minute (100.06 ± 18.27, 82.50 ± 10.52, and 82.00 ± 13.60 bpm, respectively for ETT, and LMA-S), third minute (91.04 ± 17.12, 78.84 ± 11.23, and 78.90 ± 13.41 bpm, respectively for ETT, and LMA-S) and fifth minute (85.82 ± 16.01, 75.78 ± 11.73, and 75.04 ± 13.90 bpm, respectively for ETT, and LMA-S) after intubation ($P < 0.001$). There were no significant differences between the and LMA-S groups in terms of hemodynamic parameters.

Conclusions: Maintaining the airway using laryngeal mask airway is associated with less cardiovascular responses

KEYWORDS

Laryngeal Masks; Airway Management; Intubation-Intratracheal; Hemodynamics; Blood Pressure; Heart Rate

INTRODUCTION

Airway management is one of the most important skills in the field of Anaesthesiology, and inability to secure the airway can lead to catastrophic results. The intubating laryngeal mask airway (ILM) is a new airway device that facilitates tracheal intubation without laryngoscopy. (2)

LMA-S was developed in April 2007 by Intavent Orthofix Co. (Maidenhead, UK). It is a disposable airway instrument made of latex-free PVC, adapted for medical use, which has the specifications of LMA-ProSeal (enjoying the privilege of accessing the stomach through the esophageal port) as well as LMA Fastrach (enjoying the privilege of a curved shaft body that allows its easy insertion in the mouth and throat). The oval shape of its anatomic airway tube allows easy insertion without inserting fingers into the patients' mouth. (5)

Hence this study is designed to compare the haemodynamic changes between LMA supreme vs ETT (cuffed) in patients undergoing laparoscopic cholecystectomy under general anaesthesia.

AIM AND OBJECTIVES

AIM:

Comparison of hemodynamic parameter with laryngeal mask airway supreme versus cuffed endotracheal tube in laparoscopic cholecystectomy under general anaesthesia.

PRIMARY OBJECTIVE:

To determine the difference in hemodynamic variables from baseline to 1, 3, 5and 10 minutes after insertion of device in both the groups.

SECONDARY OBJECTIVES:

1. To compare device insertion time, ease of insertion of device, and number of insertions attempts in both groups.
2. To determine difference in percentage of patients who developed side effects (Injury of structures in oral cavity, blood on device, hoarseness, dysphagia, sore throat, postop. cough) if any, in both the groups.

MATERIAL AND METHOD

Study Area:

Study will be conducted in the department of Anaesthesiology in General surgery OT, at SMS Medical College and Hospital, after permission from institution ethics committee and review board.

Study Design: Hospital based randomized intervention study.

Study Period: After approval of the plan from research review board, till the desired number of cases are complete.

Sampling Technique: Simple random technique through opaque sealed envelope method.

Sample Size: A sample of 36 cases in each group in required 95% confidence and 80% power to verify the expected minimum difference of 13.80 (±13.90) in change in Mean Heart Rate from base line to 1 min after induction in both groups. (as per seed article) (5)

Study Universe: Cases undergoing laparoscopic cholecystectomy. (Duration 60-90 min).

PROCEDURE

After taking informed consent and confirming fasting status and PAC, patient will be taken on the operation table. Routine non-invasive monitors will be attached (NIBP, SpO2, ECG). Intravenous line will be secured and IV fluid Ringer lactate infusion will be started.

Patient was premedicated with, Inj Ranitidine 1mg/kg B.w IV, Inj metoclopramide 0.15mg/kg B.w IV, Inj Glycopyrrolate 0.01mg/kg B.w IV 30mins prior to surgery.

The patient was pre -medicated with Inj. midazolam 0.15mg/kg B/W IV, and Inj. Fentanyl 1mcg/Kg IV. Pre induction baseline cardio-respiratory parameters like Heart Rate (HR), Blood Pressure (BP) and oxygen saturation (SpO2) will be recorded.

Anaesthesia was induced with Inj. propofol 2.5mg/kg B.w IV & confirmed by loss of verbal communication and loss of eye-lash reflex and Inj. Succinylcholine 2mg/kg B.w IV will be given as relaxant.

LMAS [size-3 (30-50 kg), size-4 (50-70 kg), size-5 (70-100 kg)] or ETT (cuffed) of appropriate size will be inserted according to group allocation.

Placements of airway was confirmed by presence of good bilateral symmetrical chest movements, square wave form on capnograph, normal end tidal CO2 and stable SpO2 (more than 95%). Airway leak pressure will be measured by closing the adjustable pressure limiting valve (APL) of the circle system at fixed gas flow of 3 lit/ min and pressure at which audible leak will be heard, taken as the leak pressure.

Ease of insertion in term of time taken for insertion and number of attempts will be noted. (Time taken for insertion will be from grasping of the device to observing a square wave capnograph trace) 11 Hemodynamic parameters (Heart rate and Blood Pressure) will be measured at baseline, after insertion at 1,3, 5and 10 minutes.

Anaesthesia will be maintained by using 66% N2O, 33% O2 with 1-2% sevoflurane and Inj Atracurium 0.3mg/kg B.w IV will be given as a bolus dose.

Neuromuscular block will be reversed with Inj. Neostigmine 0.08mg/kg B.w and Inj. Glycopyrolate 0.02mg/kg. The device will be removed .The Structures of oral cavity will be examined for any injuries like lip, dental, tongue injuries, Buccal mucosa and also device will be inspected for blood staining which indicate pharyngolaryngeal injury.

Immediately and 24 hours after surgery patient will be interviewed for any post-operative morbidity like irritation in throat, difficulty in swallowing and any change in voice.

In case of failure to insert the LMA properly as judged by an audible leak or inability to achieve adequate chest expansion, the device will be removed and reinserted. Maximum three attempts will be allowed and if effective ventilation could not be achieved endotracheal intubation will be planned and, proposed surgical procedure will be carried out. That case will be excluded from the study.

RESULT

Patients in all groups were similar in terms of gender, age, weight, and height, but the duration of tracheal intubation in the ETT group was significantly higher than the and LMA-S groups (Table 1).

There were no significant differences between the groups in terms of Mallampati class. The percentage distribution of Mallampati class I/II were as follows: ETT Group, 80/20; Group, 78/22; LMA-S Group, 86/14. The baseline hemodynamic parameters were comparable between the three groups. The mean SBP and DBPs values after anesthesia induction were lower than the baseline values in all groups. There was no difference in the mean SBP and DBP among the study groups at subsequent time points, except in the fifth minute in the LMA groups (LMA-S) in which the mean SBP and DBPs were significantly higher than those of the ETT group. Comparing the LMA groups with the ETT group, the mean heart rate (HR) was significantly higher in the ETT group at the first, third, and fifth minutes after insertion (Table 2, Figures 2-4).

Table 1: Descriptive Statistical Indicators and Duration of Insertion in Studied Groups a

The Group Indicator	Age, y	Weight, kg	Heigh,cm	Duration of Insertio,s
Group 1 (ETT)	27.60 ±7.95	65.30 ± 12.49	168.04 ± 7.47	14.30 ± 6.87
Group 2 (LMA-S)	27.36 ±7.01	65.12 ±10.27	171.12 ± 7.18	7.34 ± 3.33
Average total	27.24 ±8.14	65.22 ±11.57	169.83 ± 7.51	9.73 ± 5.99
P Value	0.87	0.99	0.10	< 0.001b

a The values are presented as (Mean ± SD).

Table 2. Hemodynamic Changes Between the Groups at Five Different Time Points a

Systolic Blood Pressure, mmHg	Group 1 (ETT)	Group 2 (LMA-S)	P Value
Baseline	119.90 ± 10.93	122.66 ± 10.18	0.19
Before insertion	102.88 ± 14.92	108.00 ± 11.41	0.09
After insertion			
First minute	113.26 ± 18.55	110.22 ± 20.20	0.43
Third minute	110.86 ± 14.09	111.54 ± 15.34	0.96
Fifth minute	105.62 ± 12.12	112.48 ± 15.14	< 0.01 b
Diastolic Blood Pressure, mm Hg			
Baseline	76.86 ± 8.83	76.82 ± 7.48	0.82
Before insertion	60.28 ± 12.70	64.28 ± 9.67	0.11
After insertion			
First minute	70.96 ± 15.05	66.96 ± 15.33	0.33
Third minute	67.78 ± 11.21	69.38 ± 13.69	0.28
Fifth minute	64.64 ± 10.23	71.20 ± 12.27	< 0.001 b
Heart Rate, bpm			
Baseline	87.96 ± 61.41	81.76 ± 13.64	0.07
Before insertion	86.02 ± 16.44	83.72 ± 13.50	0.50
After insertion			
First minute	100.06 ± 18.27	82.00 ± 13.60	< 0.001 b
Third minute	91.04 ± 17.12	78.90 ± 13.41	< 0.001 b
Fifth minute	85.82 ± 16.01	75.04 ± 13.90	< 0.001 b

a All values are expressed as mean ± SD.
b P < 0.05 is significant.

DISCUSSION

General Consideration : Direct laryngoscopy and tracheal intubation can cause exaggerated cardiovascular responses such as hypertension and tachycardia. Increase in blood pressure usually starts 5 seconds after laryngoscopy, and culminates in the next 1 to 2 minutes. It returns to the baseline level in the fifth minute. Most patients with normal heart function may tolerate such changes without serious complications while in patients with altered cardiac reserves, these hemodynamic turbulences may be hazardous. Various methods and techniques such as increasing the depth of anesthesia, administration of intravenous opioids, local anesthetics, beta blockers, and tracheal intubation by flexible fiberoptic laryngoscopy have been used to minimize hemodynamic responses, but none of them are ideal (13).

CONCLUSIONS

We did not find any other related study in the literature comparing endotracheal intubation by laryngoscopy with LMA-S and their hemodynamic effects. In our study, changes in SBP, DBP, and HR in the first minute after intubation were equal to 10.08%, 17.71%, and 16.32%, respectively in the ETT group; 1.36%, 6.54%, and -0.48%, respectively in the group and 2.05%, 4.17%, and -2.05%, respectively in the LMA-S group. The amount of increase in SBP and DBP in the first minute was comparable for the LMA groups, but unexpectedly the HR decreased in the LMA groups. If a range of 15% change rate in hemodynamic indexes is considered acceptable (30), no unstable hemodynamic parameters are observed in the LMA groups of our study, where the least changes occurred in the LMA-S group. Therefore, considering the more favorable hemodynamic changes following insertion of LMA compared to intubation with ETT in this study, especially with regard to the changes in the heart rate and lesser duration of insertion, we recommend using LMA, particularly LMA-S as a useful airway instrumentation in patients undergoing surgery, especially those who suffer from ischemic heart disease

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