Original Article

Comparative assessment of ProSeal™ laryngeal mask airway intervention versus standard technique of endotracheal extubation for attenuation of pressor response in controlled hypertensive patients

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ABSTRACT

Background and Aims: Swapping of the endotracheal tube with laryngeal mask airway (LMA) before emergence from anaesthesia is one of the methods employed for attenuation of pressor response at extubation. We decided to compare the placement of ProSeal™ LMA (PLMA) before endotracheal extubation versus conventional endotracheal extubation in controlled hypertensive patients scheduled for elective surgeries under general anaesthesia. **Methods:** Sixty consenting adult patients were randomly allocated to two groups of thirty each; Group E in whom extubation was performed using standard technique and Group *P* in whom PLMA was inserted before endotracheal extubation (Bailey manoeuvre). The primary outcome parameter was heart rate (HR). The secondary outcomes were systolic, diastolic and mean blood pressure (MBP), electrocardiogram, oxygen saturation and end-tidal carbon dioxide. Two-tailed paired Student's *t*-test was used for comparison between the two study groups. The value of $P < 0.05$ was considered as statistically significant. **Results:** The patient characteristics, demographic data and surgical procedures were comparable in the two groups. A statistically significant decrease was observed in HR in Group *P* as compared to Group E. Secondary outcomes such as systolic, diastolic and MBP depicted a statistically insignificant difference. **Conclusion:** Bailey manoeuvre was not effective method to be completely relied upon during extubation when compared to standard extubation.

Key words: Bailey manoeuvre, blood pressure, extubation, heart rate, pressor response, ProSeal laryngeal mask airway

INTRODUCTION

Attenuation of pressor response is one of the most keenly researched subjects in the field of anaesthesiology, the reason being the non-availability of a 'procedure/drug of choice' for the same. Airway instrumentation, i.e., endotracheal extubation, is invariably linked with certain cardiovascular changes such as tachycardia or bradycardia, rise in blood pressure and a plethora of cardiac arrhythmias.[1]

Airway instrumentation leads to sympathoadrenal discharge culminating in undesirable haemodynamic disturbances.[2] The pressor response can lead to various adverse events such as myocardial ischaemia, pulmonary oedema, acute heart failure and cerebrovascular accidents in susceptible individuals.[3] The anaesthetisiologist aims to provide an incident-free extubation process devoid of adverse cardiovascular events. This holds, especially true for patients having prior coronary artery disease and long-standing hypertension. As the morbidity associated with these cardiovascular diseases is on the rise, we thus aimed to establish an efficient method of obtaining a safe

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extubation in this group of patients for day to day anaesthesia practice.

Drugs such as lignocaine,[4] beta-blockers such as esmolol,[5] have been tried and newer options like dexmedetomidine[6] are routinely employed for attenuation of the pressor response.

Literature review advocates the swapping of the endotracheal tube with laryngeal mask airway (LMA) before emergence from anaesthesia (Bailey manoeuvre) as one of the methods for attenuation of pressor response at extubation.[7]

Bailey manoeuvre has also been mentioned for safe extubation in the 'At-risk' algorithm of Difficult Airway Society Extubation Guidelines.[8] ProSeal LMA (PLMA) was introduced in the year 2000 and is widely considered to be an advancement over the previous design. PLMA is a 2nd generation supraglottic airway device with a modified cuff and drainage tube, designed for a better seal with both the respiratory and gastrointestinal tracts, notwithstanding the access to the alimentary tract.

As an overwhelming majority of the available literature review involved the use of Bailey manoeuvre in the American Society of Anesthesiologists (ASA) physical status I patients, we conducted this randomised controlled study on controlled hypertensive patients (ASA II), in whom the attenuation of the pressor response is of utmost importance.

We aimed to compare the use of PLMA intervention before endotracheal extubation versus conventional endotracheal extubation in controlled hypertensive patients scheduled for elective surgeries under general anaesthesia and thus check for the superiority of one over the other for attenuation of pressor response at extubation.

METHODS

After approval by the Hospital Ethics Committee, sixty consenting adult patients aged 18–65 years of either sex of ASA II (controlled hypertensives) posted for elective surgery under general anaesthesia were included in this prospective randomised study.

Joint National Committee 8 defines hypertension as persistent elevation of blood pressure >140/90 mmHg.[9] Controlled hypertensives as per ASA II are patients with a BP <140/90 mmHg on antihypertensive medication.

Patients with a history of pulmonary diseases such as chronic obstructive pulmonary disease, asthma, pregnancy, morbid obesity, diabetes mellitus (HbA1c >6.5%), long duration surgeries (>4 h with major fluid shifts), impaired kidney or liver function, anticipated difficult airway, progressive neurological disease and bleeding diathesis were excluded from the study.

Patients allotted to Group E were ASA II hypertensives posted for elective surgery under general anaesthesia, in whom endotracheal extubation was performed by employing the standard technique of extubation. Patients allotted to Group *P* were ASA II hypertensives posted for elective surgery under general anaesthesia in whom PLMA was inserted before endotracheal extubation (Bailey manoeuvre). In both the study groups, standard extubation criteria were ensued, which incorporated the following convention: Alert and co-operative patient, smooth spontaneous ventilation, sustained head lift, stable haemodynamics.

A complete pre-anaesthetic checkup of patients was performed before their scheduled allotment into the two study groups. Appropriate biochemical, haematological and radiological investigations were done as per hospital protocol. All patients were fasting for a minimum of 6 h before surgery.

Patients in both groups were pre-medicated with tablet alprazolam 0.25 mg the night before surgery and at 6:00 am on the morning of surgery with sips of water. They were instructed to continue their antihypertensive medication as advised routinely.

On shifting the patient to the operation theatre (OT), monitoring devices were attached including 5 lead electrocardiogram (ECG), pulse oximeter, non-invasive blood pressure monitor. An 18-gauge intravenous (iv) infusion line was secured. Injection midazolam 1 mg iv was administered to all patients of the study.

Anaesthesia was induced with injection fentanyl 2 µg/kg and propofol 2 mg/kg, till the loss of response to verbal commands. After giving injection vecuronium bromide 0.1 mg/kg iv, and ventilating the patients with N_2O and O_2 (50:50%) for 3 min, intubation was performed with cuffed oral endotracheal tube of appropriate size for airway management. Patients having unanticipated difficult airway requiring multiple attempts (2 or more) at intubation or laryngoscopy time of more than 15 s were excluded from the study.

Anaesthesia was maintained with sevoflurane (minimum alveolar concentration- [MAC 1]) and nitrous oxide in oxygen (50:50) at flow rate of 2 L/min. The mechanical ventilator was set to achieve an end-tidal carbon dioxide ($ETCO_2$) of 35–40 mmHg. Additional doses of vecuronium bromide if necessary were administered to maintain adequate surgical relaxation. During maintenance of anaesthesia, additional doses of injection fentanyl 1 μg/kg were administered after 90 min of the initial dose, according to haemodynamic variables.

During surgery, all patients received an iv infusion of Ringer lactate as a maintenance dose.[10] Besides this, the 3rd space loss was taken as 3 and 4 ml/kg body weight and blood loss was accounted for as per the type of surgery.

Ten minutes before the end of the surgery, after oropharyngeal suctioning at isoflurane MAC 1 level, the PLMA was inserted behind the endotracheal tube and its cuff inflated in patients belonging to Group P. The endotracheal tube cuff was then deflated and removed. After confirming position of the PLMA by auscultation, capnography and exhaled tidal volume, the patients were ventilated by the same until consciousness was regained in both group of patients and neuromuscular blockade was reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 0.01 mg/kg following which the PLMA and endotracheal tube was removed in the respective groups.

All haemodynamic data were measured on arrival in OT, after reversal (before extubation), after extubation at 1, 3, 6, 8 and 10 min by an independent observer.

The study was conducted in a single-blinded manner, and allocation concealment was performed using sequentially numbered opaque sealed envelopes. Random allocation sequence generation (utilising block randomisation protocol of four blocks, coupled with equal allocation) and enrollment of volunteers in the study protocol was done under the direct supervision of the chief investigator. The block randomisation protocol of four blocks ensured that allocation of patients in both groups was equal after every four patients enrolled.

The parameter monitored as the primary outcome during the study was heart rate (HR). The secondary outcomes were systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), 5 lead ECG, oxygen saturation by pulse oximetry and $ETCO_2$ by capnography.

Data were analysed using Microsoft Excel 2010. Sample size of 60, with thirty patients in both the groups, was determined for primary variable (HR), using the information obtained from a pilot study of 6 patients with mean HR (± standard deviation) of 84.2 beats per min (± 4.2). The estimation was performed using a two-sided test with the power of the study set at 0.9 (corresponding z-value 1.28) and $\alpha = 0.05$ (z value for two-tailed analysis 1.96). The sample size was calculated to be 29.33 rounded off to 30 in each group and a total sample size of 60 was, therefore, taken up for the study. Two-tailed paired Student's *t*-test was employed for comparison between the two study groups. The value of $P < 0.05$ was considered as statistically significant.

RESULTS

The patient characteristics, demographic data and surgical procedures were comparable in the two groups. [Table 1] There was no loss of patients enrolled after randomisation was performed [Figure 1]. No untoward complications were observed in either of the groups.

A statistically significant decline in the HR was observed in Group *P* as compared to Group E [$P = 0.001$, Figure 2].

Overall, there were marginal changes in SBP, DBP and MBP in Group P. On comparing the SBPs of the two groups, we observed statistically insignificant change in both Groups, *P* and E ($P = 0.437$). The DBPs also revealed changes which were not statistically significant in the Groups *P* and E ($P = 0.436$). The MBPs of the two groups, were also statistically insignificant in Groups *P* and E [$P = 0.802$, Figure 3].

DISCUSSION

In this study, we noticed attenuation of HR (primary outcome) with Bailey manoeuvre, but no significant changes in SBP, DBP and MBP. ECG and $ETCO_2$ were largely stable in both the groups.

A safe extubation strategy is one in which haemodynamic pressor response is limited, with minimal discomfort to the patient and an acceptable cost. Catecholamine release during extubation is

Table 1: Demographic characteristics

Study groups	Mean age (in years)	Age (SD)	Gender wise distribution		
			Male	Female	Total (*n*)
Group E	48.62	5.83	15	15	30
Group P	51.73	6.33	14	16	30

SD – Standard deviation

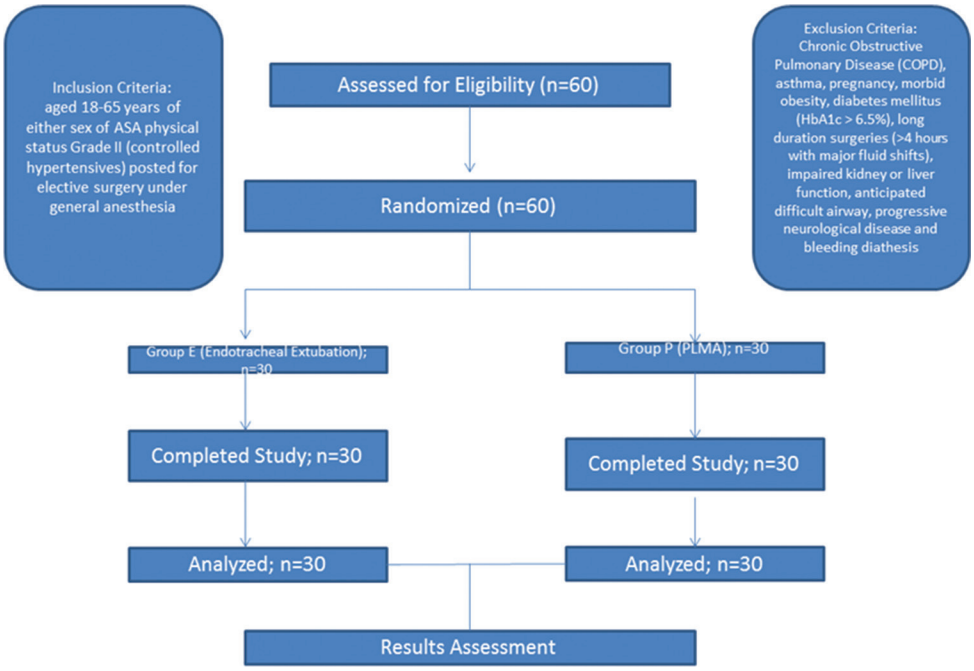

Figure 1: Study flowchart

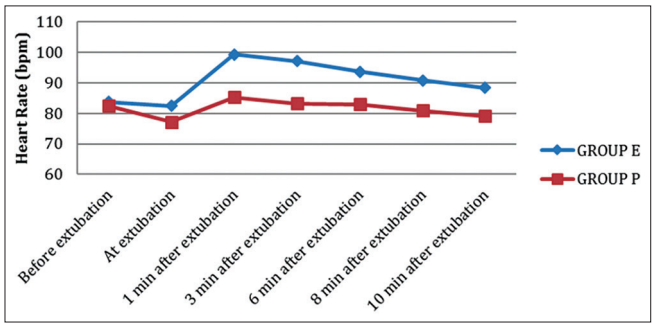

Figure 2: Heart rate changes in the two groups

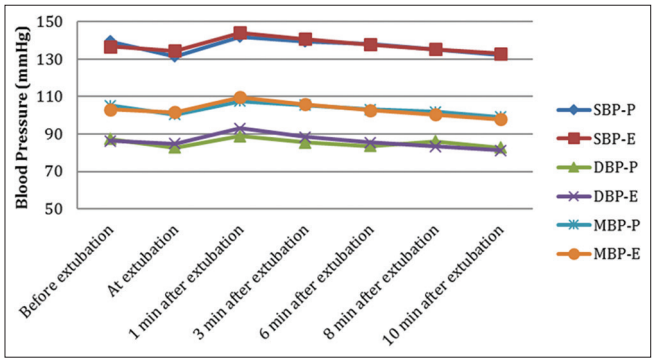

Figure 3: Blood pressure changes in the two groups

thought to be responsible for hypertension and tachycardia associated with the procedure.

The 'Bailey manoeuvre' as a method of attenuation of the haemodynamic response at extubation has been employed widely. Stix *et al*.,[11] in their study confirmed the safety of Bailey manoeuvre as a method for smooth extubation in a wide variety of surgeries for cardiovascular high-risk patients.

Another research[12] revealed that exchange of an endotracheal tube for an LMA under deep plane of anaesthesia in elderly patients posted for upper abdominal surgeries can significantly reduce the pressor responses at extubation. This is in sharp contrast to our study in which we only observed a statistically significant decline in HR [Figure 2] in the group where PLMA (Group P) was used as compared to the other group where endotracheal extubation was performed by the standard technique (Group E). However, a decline in SBP, DBP and MBP did occur in Group *P* as compared to Group E but was considered statistically insignificant. [Figure 3]

From this study, we infer that although Bailey manoeuvre has been regarded as an efficient method for attenuating the pressor response at extubation in previous studies, we observed different results. Our results indicate that Bailey manoeuvre is probably an over-stated method for reducing the haemodynamic response at extubation and one cannot solely rely on this as a foolproof technique.

Studies have been carried out to compare different types of LMAs in attenuating the extubation responses to establish the best device possible. In a study[7]

comparing classic LMA with AMBU LMA as an exchange device to the endotracheal tube before extubation, it was found that AMBU LMA was associated with superior haemodynamic stability as compared to classic LMA.

Studies till now on Bailey manoeuvre have included patients of ASA Grades I and II in totality. However, we have exclusively taken ASA II controlled hypertensive patients in both groups. This could be attributed as the reason for the difference in results that we encountered as compared to previous studies where Bailey manoeuvre proved as an efficient method for attenuating the haemodynamic response at extubation. Owing to these contradictions, a well-structured systematic review and meta-analysis in this subject area may throw light on the actual scenario.

Hence, in the target group of patients where actually attenuation of the pressor response to extubation is most warranted, like the groups in this study, Bailey manoeuvre may not be an efficacious method to be completely relied on.

The limitations of our study included lack of data pertaining to pharyngeal morbidity and the confounding effects of antihypertensive medications; these can be addressed by additional studies in future.

CONCLUSION

Bailey manoeuvre provided an incomplete attenuation of the pressor response on extubation. HR was attenuated, but blood pressure parameters were insufficiently mitigated. Bailey manoeuvre fails to be an efficient method in the target group of controlled hypertensives and thus, cannot be completely relied upon for attenuation of pressor response at extubation.

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Conflicts of interest

There are no conflicts of interest.

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