

"A Prospective Randomized Control Study Comparing Hemodynamic Changes During Traditional Awake Extubation And Exchange Extubation Using Lma Supreme In Controlled Hypertensive Patients"

*Dr A.K. Gupta¹, Dr Sumit Kumar², Dr Sanni Deyol Gautam³

¹Associate Professor, ²Assistant Professor, ³Junior Resident

Department Of Anaesthesiology And Critical Care, Motilal Nehru Medical College, Allahabad, Uttar Pradesh, India

Corresponding Author: *Dr Sumit Kumar

Background And Aims: Patients with arterial hypertension generally exhibit excessive pressor response to stress such as laryngoscopy, intubation, surgical incision and extubation, which can lead to arrhythmias, myocardial ischemia and cerebrovascular accidents. Exchange extubation with LMA Supreme can be used to overcome or blunt the excessive pressor response following extubation. This study was aimed to compare the hemodynamic stress response between traditional awake extubation of the endotracheal tube (ETT) and that following exchange extubation of ETT by using a laryngeal mask airway (LMA Supreme) in terms of Post Extubation Heart Rate (H.R), Systolic Blood Pressure (S.B.P), Diastolic Blood Pressure (D.B.P), Mean Arterial Pressure (MAP), to determine whether this method is easy to perform, the amount of experience needed to perform the exchange well and to calculate the time delay in extubation caused by adopting this method.

Methods: The proposed study was carried out in S.R.N. Hospital associated with M.L.N. Medical College, Allahabad after approval from ethical committee and obtaining written and informed consent from the patient. After complete pre-anesthetic check-up and investigations, controlled hypertensive patients with ASA (American Society of Anaesthesiologists) grade II, between the age of 18 and 65 years, undergoing elective, non-oral surgery were included in the group.

Results: On the basis of observations and statistical comparison following conclusions were made:

- ❖ There was highly significant increase in **pulse rate** in Group A (ETT Group) as compared to LMA SupremeTM group, which was statistically significant till 15 min. of extubation.
- ❖ Statistically significant increase in **SBP** was seen in Group A (ETT Group) which was statistically significant till 10th min. after extubation as compared to group B. Statistically significant increase in SBP in LMA supreme exchange group was not observed.
- ❖ Significant increase in **DBP** was seen in group A (ETT Group) which was statistically significant till 5 min. after extubation ($p < 0.0001$). In group B, there was no significant rise in DBP after extubation till 15 min.
- ❖ Significant increase in **MAP** was seen in group A (ETT Group) in compare to LMA Supreme exchange group, which was statistically significant till 5 min. after extubation ($p < 0.001$). There were no fluctuations in MAP trend in the group B (LMA Supreme exchange group).
- ❖ It took more **time** for extubation in Group B as compared to Group A. ($p = 0.002$).

Conclusion: The comparative study showed LMA supreme exchange group has good results in terms of success of insertion, hemodynamic stability, adequate ventilation and less post-operative airway complication. Hence, it was concluded that LMA Supreme exchange extubation is suitable and a safe alternative to cuffed ETT for airway management in elective controlled hypertensive patients undergoing surgeries under general anaesthesia.

Keywords: Exchange extubation, pressor response, LMA Supreme.

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I. Introduction

"Anesthesia is quite remarkable. Its lost time. And you wake up kind of refreshed." - Michael Keaton
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 intubation and/or extubation, is invariably linked with certain cardiovascular changes such as tachycardia or bradycardia, rise in blood pressure and a plethora of cardiac arrhythmias. Airway instrumentation leads to sympathoadrenal discharge culminating in undesirable hemodynamic disturbances. The pressor response can lead to various adverse events such as myocardial ischemia, pulmonary edema, acute heart

failure and cerebrovascular accidents in susceptible individuals. Drugs such as lignocaine, beta-blockers such as esmolol, have been tried and newer options like dexmedetomidine 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: one of the methods for attenuation of pressor response at extubation. Awake extubation of endotracheal tube (ETT) is associated with complications such as bucking, coughing, bronchospasm, hypertension, tachycardia, myocardial ischemia, arrhythmias, and increased intracranial pressure. Deep extubation of ETT leads to upper airway obstruction and hypoventilation. Replacing the ETT with a laryngeal mask airway (LMA) when the patient is deep and performing an awake extubation of the LMA was shown to decrease the above described respiratory and hemodynamic complications. This method of extubation has been described as an advanced technique which requires training and experience.

II. Material And Methods

The proposed study was carried out in S.R.N. Hospital associated with M.L.N. Medical College, Allahabad after approval from ethical committee and obtaining written and informed consent from the patient. After complete pre-anesthetic check-up and investigation, controlled hypertensive patients with age group between 18 to 65 years, ASA I and ASA II were included. History of clinically significant cardiovascular, pulmonary, hepatic, renal, neurologic, psychiatric, or metabolic disease and obesity (BMI > 30) were excluded from the study. 60 patients were randomized by permuted blocks into two groups-

- Group A: Patients undergoing traditional awake endotracheal extubation and,
- Group B: Patients undergoing exchange extubation with LMA Supreme™.

All patients were orally pre-medicated with ranitidine 150mg and metoclopramide 10mg on the night prior to the surgery. Alprazolam 0.25 mg was given one night prior to the surgery. On the day of the surgery, the patient was brought to the operation theatre, and an intravenous cannula was inserted. The following monitors were then connected: pulse oximeter, electrocardiogram, non invasive blood pressure (NIBP). Patients were pre-oxygenated for 3 minutes with 100% oxygen using face mask. Patients were then given i.v. midazolam 0.01mg/kg to a maximum of 2 mg, glycopyrrolate 0.01mg/kg to a maximum of 0.2mg, tramadol 1 mg/kg and propofol (mixed with 2ml i.v. lignocaine) 1-2 mg/kg. Then succinylcholine 2 mg/kg was given i.v. (fast). Patient was ventilated with bag and mask for 45 seconds and then intubated with ET Tube of appropriate size. Anaesthesia was maintained with 0.6-1% isoflurane in nitrous oxide-oxygen mixture (1:1) with mechanical ventilation. Vecuronium 0.1mg/kg was given as a loading dose and 0.02 mg/kg was repeated every 20 minutes. Tidal volume was set at 7ml/kg of ideal weight and respiratory rate was adjusted to keep end tidal carbon dioxide (etCO₂) between 32 and 40 mmHg. Intra-operatively, Paracetamol infusion 1gm and i.v. Diclofenac 1 mg/kg were given if there were no contraindications. In the endotracheal awake extubation group (Group A), at the end of the surgical procedure, isoflurane and nitrous oxide were discontinued. Neostigmine 0.04-0.08mg/kg i.v. were used for reversing the effects of vecuronium. When the patient spontaneously generated tidal volume of >4ml/kg, etCO₂ < 45 mmHg and was responding to verbal commands, extubation was performed. Supplementary oxygen was then provided with Oxygen Mask at a rate of 6L/min.

In the LMA Group (Group B), at the end of the surgical procedure, nitrous oxide was discontinued and 0.5 mg/kg propofol was given intravenously. After 1 minute, the oropharynx is suctioned and a deflated LMA Supreme is inserted after removing the ETT. LMA Supreme is inflated and connected to the breathing circuit. If we were unable to ventilate through the LMA Supreme, it was repositioned. If still unsuccessful, LMA Supreme insertion was abandoned and mask ventilation was resumed. Following successful insertion of the LMA, isoflurane was discontinued, 100% oxygen is administered at the rate of 6L/min, neuromuscular blockade was reversed with neostigmine and glycopyrrolate and the patient was monitored. When the patient was able to spontaneously maintain the tidal volume of >4ml/kg, and end tidal carbon dioxide (etCO₂) < 45 mmHg and was responding to verbal commands, removal of LMA was performed. In Group B, the heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), was recorded at the following times baseline-

- before induction,
- end of surgery (EOS),
- just after exchange (Ex),
- just after extubation/removal of LMA (E0),
- 5 minutes after extubation/removal of LMA (E5),
- 10 minutes after extubation/removal of LMA (E10) and
- 15 min after extubation/removal of LMA (E15).

Time between placing and extubating the LMA was also recorded.

Statistical Analysis: Statistical analysis was performed using Microsoft Excel 2010 and statistical software plug-ins. Continuous data was analyzed by ANOVA. Data are being represented as mean ± SD. P < 0.05 was considered statistically significant and P < 0.001 was considered statistically highly significant.

Results: A total of 60 patients were selected in the study "a prospective randomized control study comparing hemodynamic changes during traditional awake extubation and exchange extubation using LMA supreme in controlled hypertensive patients" comprising of 30 patients in each groups. There was no protocol deviation and all patients successfully completed the study protocol and were cooperative with subsequent assessment. Hence, all patients were included for data analysis. Surgical procedures were performed uneventfully and there were no surgical or anesthetic complications. Patients of the two groups were statistically comparable regarding mean age, weight, height, gender, ASA physical status, and surgical characteristics.

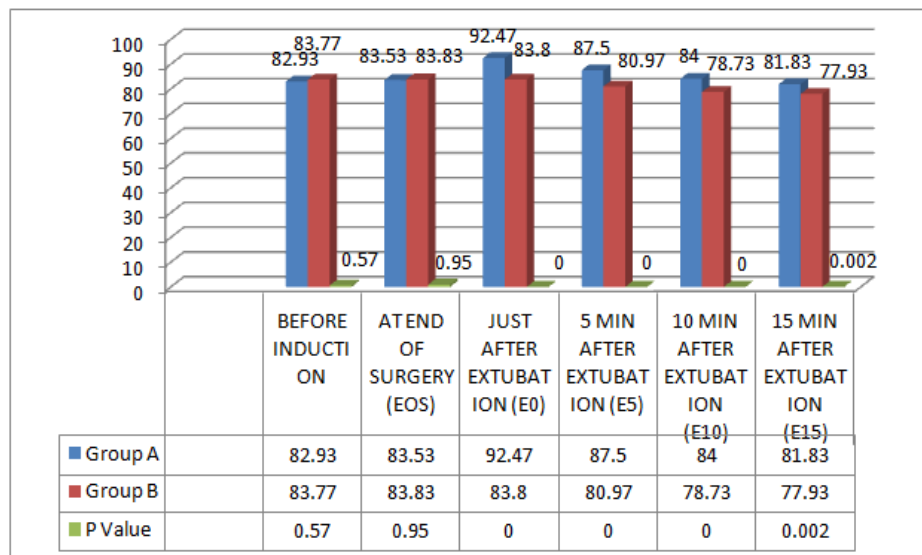
Table -1: Comparison of Pulse Rate Following Tube Exchange.

Pulse rate	GROUP A (N=30)		GROUP B (N=30)		'p' value
	Mean	SD	Mean	SD	
Baseline	82.93	6.7	83.77	4.25	0.57
At end of surgery(EOS)	83.53	6.7	83.83	3.71	0.82
Just after extubation(E0)	92.47	6.72	83.8	3.84	<0.0001
5 min after extubation(E5)	87.5	5.32	80.97	3.06	<0.0001
10 min after extubation(E10)	84.0	5.82	78.73	3.83	<0.0001
15 min after extubation(E15)	81.83	5.87	77.93	3.14	0.002

Note: - p < 0.05 = statistically significant.

p < 0.001 = highly significant.

p < 0.0001 = Very highly significant.



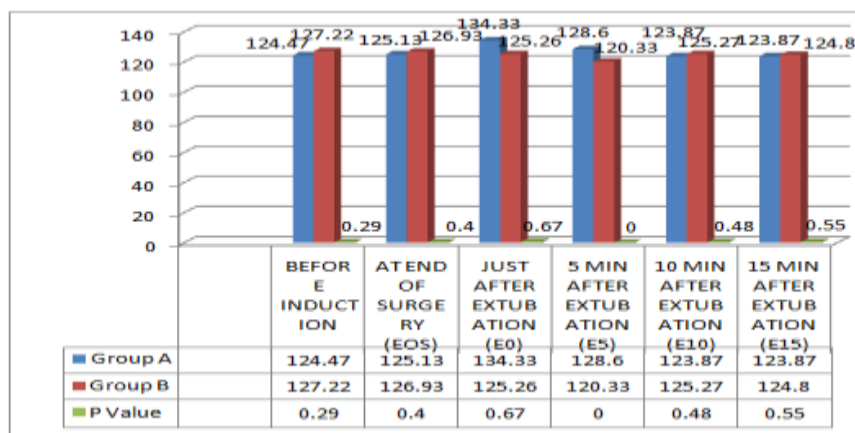
❖ Pulse rate was increased in group A from the baseline values after extubation. Statistically significant increase in HR was noticed in Group A at 0 min, 5th min. which lasted upto 10th min. from after extubation of device in comparison to Group B.

❖ On comparing trends within group, increase in pulse rate was observed just after extubation (E0) persisted till 10 minutes in group A and no significant increase found in group B .

Table -2: Comparison of Systolic blood pressure:

SBP	GROUP A (n=30)		GROUP B (n=30)		'p' value
	Mean	SD	Mean	SD	
Baseline	124.47	10.43	127.2	9.45	0.56
At end of surgery(EOS)	125.13	8.06	126.93	8.41	0.40
Just after extubation (E0)	134.33	10.70	125.27	9.18	0.001
5 min after extubation (E5)	128.6	5.97	120.33	5.83	<0.0001
10 min after extubation (E10)	123.87	7.59	125.27	7.83	<0.0001
15 min after extubation (E15)	123.73	6.80	124.8	7.02	0.46

Note: - P < 0.05 = statistically significant, P < 0.001 = highly significant, p<0.0001 = Very highly significant.



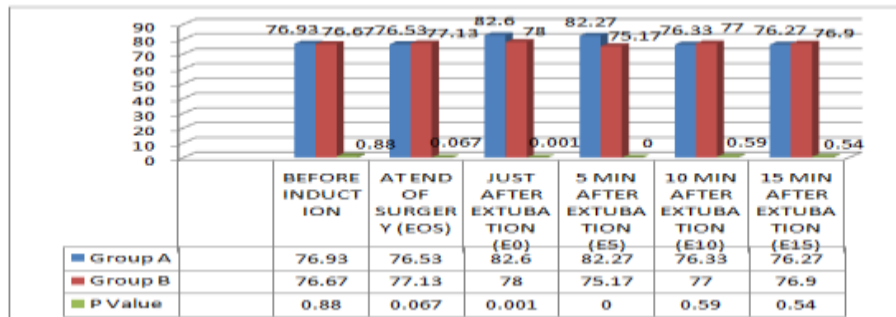
Comparison of Systolic Blood Pressures.

- ❖ Statistically significant increase in SBP was noticed in Group A at 0 min, lasted upto 5th min. (p<0.0001) from insertion of device in comparison to Group B.
- ❖ On comparing trends within groups, statistically significantly higher (p<0.0001) increase in SBP was observed at 1 minute after extubation and persisted till 5 minutes in group A, however, statistically significant increase in SBP in group B was not seen after extubation of the device.

Table -3: Comparison of Diastolic Blood Pressure.

DBP	GROUP A (n=30)		GROUP B (n=30)		'p' value
	Mean	SD	Mean	SD	
Baseline	76.93	7.27	76.67	6.31	0.29
At end of surgery(EOS)	76.53	4.45	77.13	6.16	0.67
Just after extubation(E0)	82.6	4.88	78.0	5.23	0.001
5 min after extubation(E5))	82.27	4.32	75.17	4.58	<0.0001
10 min after extubation(E10)	76.33	4.17	77.0	5.32	0.59
15 min after extubation(E15)	76.27	4.03	76.93	4.12	0.46

Note: P < 0.05 = statistically significant
P < 0.001 = highly significant;
p<0.0001 = Very highly significant.



Comparison of Diastolic Blood Pressures.

On comparing trends within groups, statistically significantly higher ($p < 0.0001$)

- ❖ increase in DBP was observed at 0 minute (E0), and 5 min (E5) after extubation and persisted till end of 5 minutes.
- ❖ In group B, however, statistically significant increase in DBP in was not seen after extubation of device. There was not much fluctuations in DBP after the extubation.

DISCUSSION

The respiratory complications and hemodynamic responses associated with extubation are often not properly taken care of during the conduct of general anesthesia (GA).^[1,2,3]

As anesthetists, we should extubate our patients ensuring both safety and comfort. Smooth extubation becomes more important when the patient has cardiovascular disease or has undergone neurosurgery, ENT surgery or eye surgery. Anesthetists when pressed upon for a smooth extubation, tend to go for a deep extubation of the ETT, which has the theoretical risk of losing the airway, before the patient is fully conscious and requires airway manipulations, albeit external.

Nair and Bailey, Costa e Silva and Brimacombe and Glaisyer et al.^[4,5,6] had suggested that the use of the laryngeal mask after tracheal extubation may minimize the stress response while providing a patent airway during emergence from anesthesia. They inserted the laryngeal mask after extubation; however, there is a small theoretical risk of losing a patent airway, if it is not possible to insert the laryngeal mask after the tracheal tube has been removed. The LMA being situated in the hypopharynx eliminates tracheal stimulation at extubation, makes extubation smooth and comfortable for the patient.

Asai et al. (1998) and **Dob et al. (1999)**^[7,8] improvised on this method by inserting the LMA behind the ETT and then removing the ETT, thereby avoiding the loss of airway.

Exchange extubation has been mentioned in the Difficult Airway Society guidelines for the management of tracheal extubation, where the authors have recommended it as an advanced technique requiring training and experience for extubation for "at risk" extubation.^[9]

An extubation is said to be "at risk" by the authors if the ability to oxygenate is uncertain, the reintubation is potentially difficult, and the patient has cardiovascular, respiratory and neurological co-morbidities.

The first question that comes to the mind of any anesthetist, on hearing about exchange extubation is whether it is feasible?

Stix et al. (2001)^[10] had shown that he could successfully place a LMA in the first attempt in 95% of cases. We were able to place the LMA supreme successfully on the first attempt in 100% of cases. Hence this method of extubation is easy to perform.

Suppiah RK et al. (2016)^[11] conducted a study which showed that hemodynamic response in terms of HR, BP and RPP were significantly lesser in exchange extubation group when compared to awake endotracheal extubation.

Similar results were demonstrated by **Maet et al. (2010)**^[12] and **Ping et al. (2012)**^[13]

Zhonghua Wai Ke Za Zhi (2010)^[14] compared with LMA exchange (LM) group to tracheal tube group (TT), MAP, HR and RPP were significantly higher at T(1), T(2), T(3) than T(0) in group TT ($P < 0.05$). There was no significant difference in the indices mentioned above during extubated intratracheal tube and exchanged for LMA under deep anesthesia in group LM ($P > 0.05$). The incidence rate of glossoptosis in group TT was significantly higher than those in group LM ($P < 0.01$), while complications, such as cough, bucking, breath holding during the recovery stage in group TT were more than those in group LM ($P < 0.05$). Compared with the baseline value, blood glucose and cortisol concentration level were significantly increased in group TT than in group LM ($P < 0.01$). Thus they suggested exchange of tracheal tube for LMA under deep anesthesia during recovery stage can decrease the stress response during the recovery stage and attenuate the harmful response of respiratory tract. It is suitable for the elderly patients with hypertension.

In our study, in Group A there is an increase in the hemodynamic parameters at the time of ETT

removal from the values at the EOS [Table6,7,8,9]. These values are significantly higher than the values documented at the time of exchange extubation in Group B. The heart rate in group A just after end of surgery EOS is 83.53 ± 6.24 and in group B is 83.76 ± 3.84 ($p > 0.05$) which is not significant. At E0 (just after extubation), in group A, the heart rate is 92.47 ± 6.72 and in group B, it is 83.8 ± 3.69 ($p < 0.0001$) which is very highly significant. At E5 (5 min after extubation), the heart rate is 87.5 ± 5.32 in group A and 80.97 ± 3.06 in group B ($p < 0.0001$) which is highly significant. At the end of 15 min after extubation, heart rate in group A is 81.83 ± 5.87 and in group B is 77.93 ± 3.14 ($p < 0.05$), which is significant.

On comparing SBP, DBP, MAP between group A and B, the SBP, DBP and MAP at EOS in group A is 125.13 ± 8.06 , 76.53 ± 4.45 , 92.73 ± 5.27 and in group B is 126.93 ± 8.42 , 77.13 ± 6.16 , 93.62 ± 5.57 ($p > 0.05$) respectively, which is not significant. The SBP, DBP, MAP at E0 in group A is 134.33 ± 10.70 , 82.6 ± 4.88 , 99.84 ± 4.92 and in group B is 124.42 ± 9.06 , 78.0 ± 5.23 , 93.78 respectively. The p values are 0.001, < 0.001 , < 0.001 respectively, which is highly significant. Similarly p values at E5 came out to be highly significant ($p < 0.001$). After this the values became not significant at E10, E 15. So exchange extubation with LMA supreme can be considered as a safe option for those patients in whom hemodynamic stress response of extubation is to be blunted like in hypertensives.

There have been studies on postoperative sore throat after the exchange extubation.

In the study by **Brouillette et al. (2008)**^[15] 8 out of 39 patients in the ETT group had a sore throat in the recovery room and 11 the day after, compared to 3 and 5 in the LMA group. More patients in ETT group complained of hoarseness (29 in the recovery room, 21 the day after) than in the LMA group (7 and 4, respectively). The difference was statistically significant. In the study by **Jain et al. (2013)**^[16] the incidence of a sore throat in both the cLMA exchange group and the Ambu laryngeal mask exchange group recorded 1 h after surgery was 16%. We did not study the incidence of post operative sore throat in our study.

The time taken from end of surgery (EOS) to just after extubation (E0) in group A is 5.3 ± 0.75 min. and in group B is 6.3 ± 1.6 min, which is statistically significant ($p = 0.002$). This shows that time taken for extubation in Group B is a bit more than that in group A.

Our study had shortcomings. There is an obvious bias in the study, as a single anesthetist did all the 30 exchanges. Even though this is a significant limitation, it has a silver lining. It was able to bring out the fact that, a phase of learning is required to have a higher success rate in the first attempt LMA positioning. As the administration of muscle relaxants and depth of anesthesia was left to individual anesthetists doing the case, we could not ensure a uniform depth of anesthesia to all our patients. We were free to maintain isoflurane between 0.6% and 1% and had given muscle relaxants and fentanyl as and when required. A bispectral index and train-of-four monitor would have been useful in ensuring an equal level of depth of anesthesia for all our patients. There was no significant time delay in extubation on opting exchange extubation method.

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