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A Preliminary Feasibility Study on Hemodynamic Changes Following Feyh-Kastenbauer Retractor Insertion During Transoral Robotic Surgeries: Are They Worse Than Endotracheal Intubation?

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Abstract

Transoral Robotic Surgery (TORS) have become increasingly popular for removal of pharyngeal and laryngeal cancers with objective to improve functional and aesthetic outcomes. Feyh-Kastenbauer retractor (FK retractor) is one such routinely used retractors during TORS. The setting up of this retractor has been seen to be accompanied by hemodynamic fluctuations. This prospective observational study was carried in 30 patients undergoing TORS. All patients were administered general anesthesia using pre-defined ana-esthesia protocol. Primary outcome was to compare hemodynamic fluctuations following endotracheal intubation with that after FK retractor insertion. Any requirement of bolus dose of sevoflurane and fentanyl were recorded in response to hemodynamic fluctuations were recorded in secondary outcomes. There was no statistically significant increase in mean heart rate, systolic, diastolic and mean arterial blood pressure from baseline to endotracheal intubation and following retractor insertion (p-0.810, p-0.2, p-0.6, p-0.3 respectively). On subgroup analysis, hypertensive patients reported greater rise in blood pressure following 2 min post FK retractor insertion compared to non-hypertensive patients (p=0.03). Out of 30 patients, 5 patients required bolus dose of sevoflurane. FK retractor insertion had comparable hemodynamic response as endotracheal intubation during Transoral Robotic Surgery. Hypertensive patients showed rise in blood pressure at both endotracheal intubation and at FK retractor insertion.

Keywords: Feyh-Kastenbauer retractor; Transoral Robotic Surgery; Hemodynamic changes

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Introduction

Transoral Robotic Surgery (TORS) have become increasingly popular for the removal of pharyngeal and laryngeal cancers with the objective to improve functional and aesthetic outcomes without worsening survival. The presence of long working arms provides the greatest advantage in reaching to the posterior most part of oral cavity. The main advantage is allowing better surgical access, *via* the mouth, to areas where hands and instruments probably reach with difficulty through the mouth itself [1]. TORS is a relatively new approach to remove cancers from areas of difficult access like the throat, base of tongue and low down in the bottom of the tonsil [1].

Unfortunately, without TORS, the surgery required can be quite invasive, including splitting the mandible (mandibulotomy) to expose the base of tongue. Presently partial laryngectomies are also being performed completely through the mouth with the robot technique. However, having read with all these advantages, TORS is also associated with some potential sequelae. TORS procedure requires placement of complex retractors followed by docking of robotic arms inside the oral cavity [2]. Feyh-Kastenbauer retractor (Gyrus Medical Inc, Tuttlingen, Germany) is one such routinely used retractors during TORS. It allows better exposure of oropharynx using longer tongue blade (Figure 1). The precise placement and setting up of robotic arms inside the oral cavity require a lot of manipulation of retractors and robotic instruments (Figure 2). The setting up of these instruments has been seen to be accompanied by hemodynamic fluctuations which were found to be comparable to those following endotracheal intubation. Through this study, we propose to compare the hemodynamic fluctuations occurring following endotracheal intubation and FK retractor insertion. The study hypothesized that FK retractor insertion is associated with significant increase in blood

pressure as compared to following endotracheal intubation.

Materials and Methods

The present study was conducted in the Department of Anesthesia and Intensive Care in collaboration with the Department of Otolaryngology Head Neck surgery at a tertiary care center in Northern India. The present study is a prospective observational study. The study was approved by the institutional ethics committee with letter no INT/IEC/2020/JPL-52 and was also registered with central Clinical Trials Registry (CTRI) with reference no. CTRI/2020/07/026857. A total of 30 patients were enrolled in the study after receiving a written informed consent. The inclusion criteria were: Patients undergoing TORS for oral cavity pathologies, ASA category I and II and Age 18 to 60 years. Patients with suspected difficult airway were excluded. Patients undergoing robotic assisted ENT surgeries for other than oral cavity cancers and ASA category III and above were also excluded.

All patients were assessed one day prior to surgery and detailed pre-anesthetic check-up was done including preoperative orders were given by a trained anesthetist. The following relevant points were noted from this pre-anesthetic check-up: History of smoking, snoring, parameter of complete airway examination: Mouth Opening (MO), Mallampati Grading (MPG), Thyromental Distance (TMD, Sternomental Distance (SMD) and Dentition. Within the operation theatre all ASA essential monitoring was placed including NIBP, pulse oximetry, ECG and end tidal CO_2 monitoring. Baseline vitals including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation by pulse oximetry were noted. The intravenous assess was secured. A standard induction protocol for general anesthesia was followed which included Inj. Fentanyl 1 μg/kg, Inj. Propofol 2 mg/kg to 2.5 mg/kg, Inj. Atracurium 0.5 mg/kg. This was followed by endotracheal intubation after complete muscle relaxation checked by loss of jaw tone and after bag mask ventilation for 4 min following the administration of muscle relaxation. Following the confirmation of endotracheal tube, the tube was secured and inhalation agent sevoflurane was titrated to maintain MAC between 1.2 to 1.4. The maintenance of anesthesia was done by nitrous 60%, oxygen 40% and sevoflurane titrated to achieve a MAC of 1.2. Ten min following stabilization of MAC at 1.2, the patient was handed over to the surgeons for the insertion of FK retractor. Hemodynamic parameters which included HR, SBP, DBP, MAP was recorded continuously at 1 min interval following endotracheal intubation and thereafter at retractor insertion till the end of the surgical procedure. Other parameters which were recorded included: End tidal CO_2, MAC, end tidal concentration of inhalation agent, SpO_2, and requirement of bolus dose of opioid. The time of retractor insertion and removal and total duration of retractor placement were also recorded.

Hypertension was defined as a Systolic Arterial blood Pressure (SAP) more than 120% of the baseline value or more than 160 mmHg, whereas hypotension was defined as SAP less than 70% of the baseline value or less than 90 mmHg. Tachycardia and bradycardia were defined as HR greater than 120 beats/min and less than 60 beats/min, respectively. The episodes of hypertension, hypotension, tachycardia, and bradycardia was recorded throughout the study. A dysrhythmia was defined as any ventricular or supraventricular premature beat or any sustained rhythm other than sinus. The incidence of dysrhythmia after intubation and following retractor insertion was recorded.

If SBP or DBP is more than 120% of baseline value or more than 160 mmHg for SBP and 100 mmHg for DBP, a bolus dose of inhalation agent-sevoflurane was delivered to increase the MAC to 1.8%. Similarly rise in heart rate greater than 120 beats/min was dealt with bolus dose of fentanyl 0.5 μg/kg.

Outcomes

Primary outcome: To compare the hemodynamic fluctuations i.e., the mean change from baseline in the heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure following endotracheal intubation with that following FK retractor insertion during TORS.

Secondary outcome: Intervention done to decrease the hypertensive response observed during intubation and retractor insertion. The intervention being defined as bolus dose of opioid drug or increasing the depth of anesthesia measured in terms of end tidal concentration of inhalation agent and Minimum Alveolar Concentration (MAC).

Statistical analysis

Data entry and analysis was done with the help of Microsoft Office Excel 2007 and SPSS software version 21. Descriptive analysis was done using frequency, percentages and Mean (± SD). The normality of data was checked by Kolmogorov-Smirnoff test. Statistical analyses of the data for each hemodynamic parameter were performed by appropriate test of significance i.e., t-test and two-way Analysis of Variance with repeated measures (rANOVA). $p<0.05$ was considered as statistically significant.

Results

A total of 40 patients were screened from which 5 patients were excluded due to anticipated difficult airway, 3 patients did not give consent and 2 patients were excluded being ASA III category. The data of 30 patients who underwent TORS was collected and final analysis was done (Figure 3). The demographic details of the patients including age, gender, height, weight, BMI and ASA category are summarized in the Table 1. The variables of the demographic data were normally distributed throughout the study population.

Primary outcome

Heart Rate (HR): The mean heart rate at baseline was 79.04 ± 12.89 at intubation was 88.38 ± 12.19, 1 minute post intubation was 89.29 ± 12.72 and at 10 min was 76.58 ± 15.09. At retractor insertion the HR was 81.58 ± 14.79, at 1 min post-retractor insertion was 82.50 ± 15.88 and at 10 min post retractor insertion was 72.52 ± 12.91. The change in heart rate over time was not statistically significant following endotracheal intubation or FK retractor insertion (Friedman Test: $\chi^2=39.3$, $p=0.810$) (Figure 4). A post- doc analysis was also done to see that at which specific time points the heart rate differed significantly. The Heart Rate (BPM) differed significantly from the baseline at the following time points: 135 min Post RI (p=0.018), 140 min Post RI (p=0.01), 145 min Post RI (p=0.01). These time points correlated to the time of extubation of the patient. Although the maximum change from the baseline time point was observed at the 1 min post-intubation time point but none of the patients had HR>120 (tachycardia) or HR<60 beats per minute (bradycardia).

Systolic blood pressure: The mean SBP at baseline was 129.25 ± 21.67 mmHg which further showed an increase to more than 140 mmHg at 1 min post-intubation (142.88 ± 30.73). Following this a rise in blood pressure was noted 1 min post-retractor insertion, where mean SBP was 140.38 ± 27.3. Though there was rise in mean SBP

Table 1: Demographic details of the patient.

Age(years)*	55.35 ± 14.52.
Gender# (male/female)	27 (91.7%) /3 (8.3%)
Height (cm)*	162.09 ± 7.38
Weight(kg)*	61.88 ± 15.62.
BMI (kg/m^2)*	23.48 ± 5.48
ASA I/II/III#	10 (30%) /20 (70%)
History of Smoking/Non-smoking#	17 (54.2%) /13 (45.8%)
History of Snoring/No snoring #	7 (16.7%) /23 (83.3%)
MO# (>3 FB)	30 (100.0%)
MPG# (II/III)	20 (70.8%) /10 (29.2%)
TMD# (>3 FB)	30 (100.0%)
SMD# (>12 cm)	30 (100.0%)
Dentition# (normal/loose teeth/edentulous)	20 (83.3%) /6 (4.2%) /4 (12.5%)

Data represented as * mean ± SD, # absolute number (%)
MO: Mouth Opening; MPG: Mallampati Grading; TMD: Thyromental Distance; SMD: Sternomental Distance; FB: Finger Breath

Figure 1: Feyh-Kastenbauer (FK) retractor (Gyrus Medical Inc., Tuttlingen, Germany) with tongue blade.

following intubation and retractor insertion, it was less than 120% of baseline and statistically not significant (p-0.2). Further during the surgical period, the change in mean BP was not significant either clinically or statistically. A post hoc analysis was performed and values at three time points i.e., 135 min, 140- and 145-min post retractor insertion were statistically significant. These were time points of extubation and recovery from where such hemodynamic changes can be observed.

Diastolic blood pressure: The diastolic blood pressure followed the similar trend as the systolic blood pressure did, with rise in blood pressure over baseline at 1 min post intubation and 1 min post retractor insertion. The baseline mean DBP was 78 ± 11.85, at 1 min postintubation was 86.79 ± 16.59 and at post 1 min retractor insertion was 84.17 ± 15.49. These variations in the diastolic blood pressure also failed to reach any clinical or statistical significance (p-0.6). The DBP did not show large deviation from the baseline mean DBP at rest of the time points. The data for DBP was normally distributed hence parametric test the repeated measures of ANOVA test was used for statistical inference.

Mean Arterial Blood Pressure (MAP): Clinical variations were

Figure 2: Feyh-Kastenbauer retractor positioned and suspended. The instrument position is depicted in the figure with endoscopic camera in the midline and working arms in a triangular configuration to allow adequate exposure of oral cavity and oropharynx.

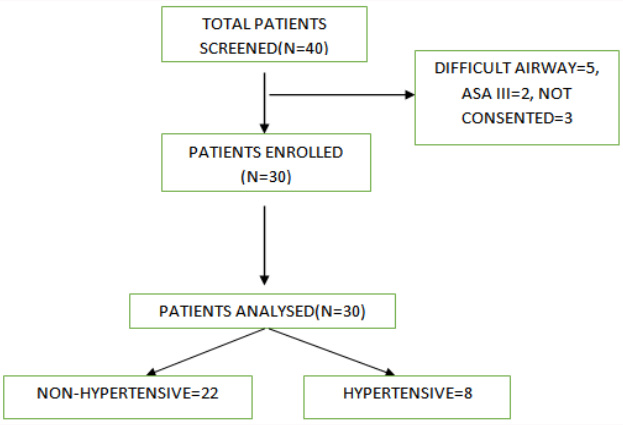

Figure 3: Consort flow diagram of patients recruited.

observed in the MAP over time, changes were observed at time of intubation and at retractor insertion as seen in the both the systolic and diastolic blood pressure measurements. These changes were not found be significant clinically or statistically and did not require any intervention (p-0.3). The post hoc analysis revealed only two values significant, that is at 140- and 145-min post retractor insertion corresponding to the time of extubation and recovery when systolic and diastolic blood pressures were also significantly reduced from the baseline. The variation in the MAP is depicted in Figure 5.

Secondary outcome

Out of 30 patients, 5 patients required administration of bolus dose of sevoflurane to increase the MAC to 1.6 following retractor insertion. None of the patients required additional doses of fentanyl. However no statistically significant increase in MAC was observed throughout the surgery. A rise is seen from a baseline value (starting from the time when delivery of inhalation was initiated) to the time of intubation where maximum end tidal sevoflurane concentration was noted as required during induction. Further during the maintenance phase, the MAC was maintained between 1 to 1.2 with no significant variations in delivery of the inhalation agent even during retractor insertion and following it. The mean MAC increased from a minimum of 0.36 at the Baseline time point to a maximum of 1.18 at the 4 min Post RI time point, and then decreased to 1.00 at the 145 min Post RI time point. This change was also not statistically significant (p=0.188).

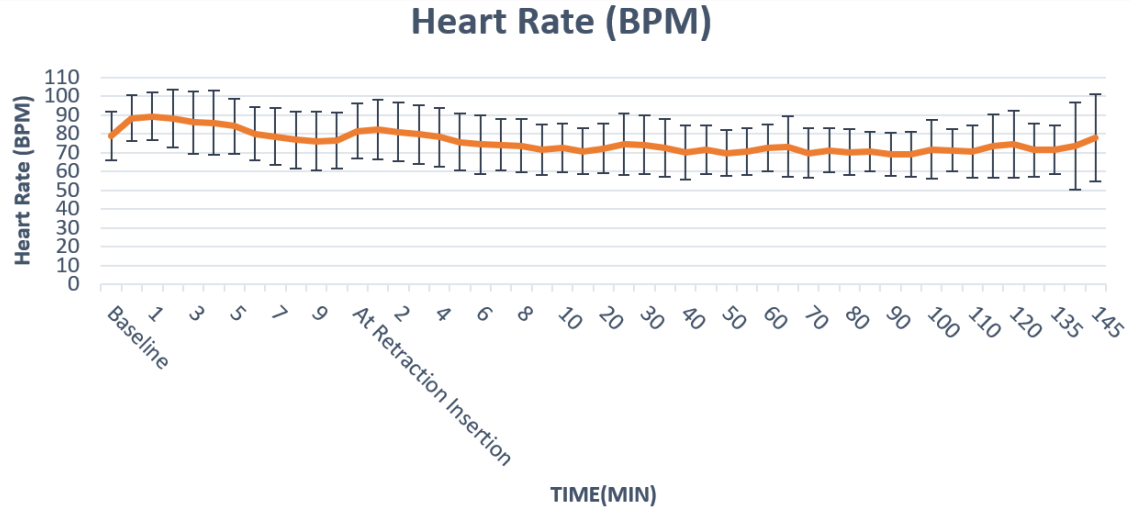

Figure 4: The change in heart rate over time was not statistically significant following endotracheal intubation or FK retractor insertion (Friedman Test: χ^2=39.3, p=0.810).

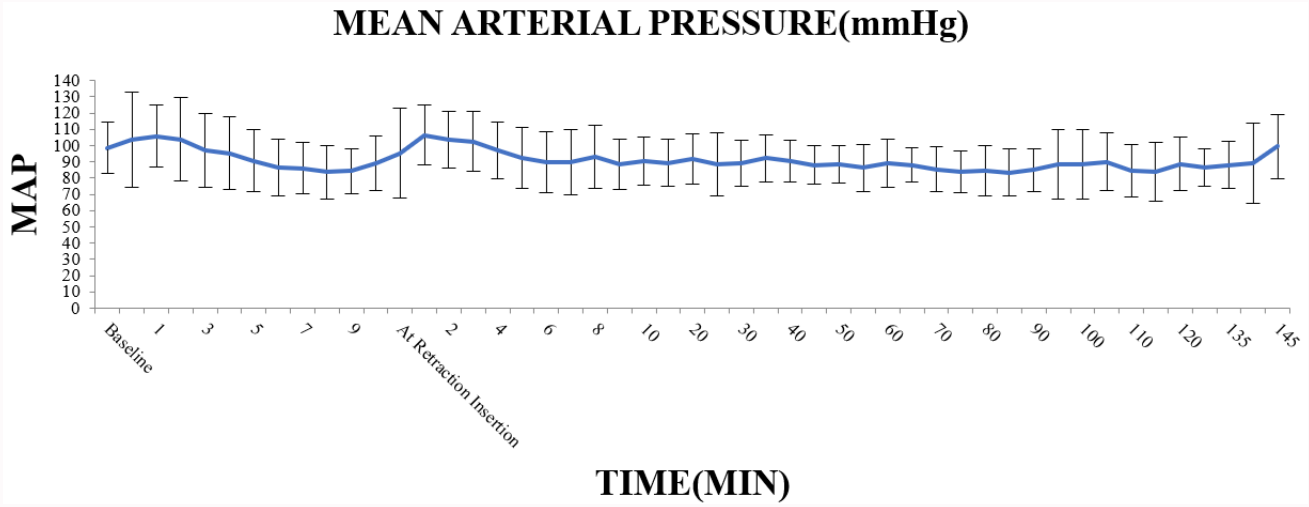

Figure 5: The variation in the MAP was not statistically significant following endotracheal intubation or FK retractor insertion (p-0.3).

On post hoc analysis none of the value both for end tidal sevoflurane and MAC had significant difference from baseline versus intubation and at retractor insertion. Statistically, significant values were found after 125 min of retractor insertion till 145 min (end of procedure). This corresponds to the time when surgery was completed and patients were in the recovery phase of general anesthesia. Figure 5 demonstrates that the variations observed in the end tidal sevoflurane and MAC values.

Hemodynamic changes in hypertensive patients: An intra group analysis comparing hypertensive versus non-hypertensive patients was done, in which out of 30 patients, 8 patients were hypertensive. In Hypertensive group the mean SBP just before intubation (108.62 ± 39.10 mmHg) was significantly lower compared to the non-hypertensive group (147.88 ± 36.51 mmHg, p=0.02). Following retractor insertion at 2 min, the increase in systolic blood pressure was clinically more in hypertensive patients compared to non- hypertensive patients. We also found significant increase in DBP and MAP at 2 min post-retractor insertion (p=0.03) on comparison of hypertensive and non-hypertensive patients. This required administration of bolus dose of sevoflurane to increase MAC to 1.6 in 5 hypertensive patients following 2 min after retractor insertion. Further during points of retractor manipulation and removal, the hypertensive group showed significant increase in heart rate from 20 min post RI to up to 50 min post retractor insertion (Table 2). These hemodynamic fluctuations up to 50 min post-retractor insertion all indicate towards increased sympathetic stimulation in hypertensive group to retractor insertion in comparison to non-hypertensive patients. There was no statistically significant difference in MAC, end tidal CO_2 and end tidal sevoflurane concentrations.

Though all patients successfully underwent surgery and were extubated at the end, one patient had to be re-explored due to bleeding at the surgical site. Another patient experienced delayed extubation, had unequal pupil size and had to be ventilated electively in Intensive care unit for 24 h, following which the patient recovered and was extubated. The non-contrast computed tomography of the patient reported normal. Both these patients were hypertensive and required bolus doses of inhalational agents to maintain the SBP within 120% of baseline.

Discussion

As primary outcome of interest, we observed comparable hemodynamic responses following endotracheal intubation and FK retractor insertion. We also found exaggerated hypertensive response to both endotracheal intubation and FK retractor insertion in hypertensive subgroup. There was also increased requirement of inhalational agents in hypertensive group as compared to normotensive group.

The adverse cardiovascular changes and catecholamine discharge seen during laryngoscopy and tracheal intubation appear in two phases. The effects of laryngoscopy should be distinguished from effects seen while the endotracheal tube is placed through the trachea. Shribman et al. showed the differences between these two events. Even with stable anesthesia, laryngoscopy alone without intubation can cause a supraglottic stimulus. As a result, both Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) increase in contrast to the measurements before induction. However, no significant increase in HR occurs during laryngoscopy. Increase in BP is due to norepinephrine, while increase in HR is due to epinephrine discharge. Infraglottic stimulus caused by placing the endotracheal tube occurs in phase two. In this situation, an extra cardiovascular response and catecholamine discharge occur. Stress response increases at this stage and both SBP and DBP measurements increase by 36% to 40% in contrast to control levels. HR levels increase more than 20% with tracheal intubation in contrast to laryngoscopy [3,4]. Kings et al. [5], in the year 1951 first elucidated by this response to intubation and laryngoscopy. This is a reflex cardiovascular response with afferent pathway mediated vagus which occurs due to stimulation of receptors in the base of tongue and on lifting the epiglottis. This hemodynamic response may not have implications in young ASA category I patients but it needs to be adequately controlled in old patients and higher ASA category where it may have serious implications.

FK retractor comprises of a tongue blade and a suspension arm which helps fixing the retractor to left side of the operation table. Once adequately placed inside the oral cavity, it allows better exposure of surgical field and movement of robotic arms. The precise placement and setting up of robotic arms inside the oral cavity require a lot of manipulation of retractors and robotic instruments. Nevertheless, these manipulations are also associated with significant hemodynamic fluctuations which are found equivalent to those occurring following endotracheal intubation. This study compares the hemodynamic changes following endotracheal intubation with FK retractor insertion during TORS.

The primary aim of our anesthetic management is to maintain the hemodynamic of the patient within in a particular range and avoid large variations within the same. Advances in anesthesia in availability of drugs and various aids for intubation have largely helped us in reducing this hemodynamic response to laryngoscopy and intubation. These methods include deepening plane of anesthesia, use of different laryngoscopy blades and different types of laryngoscopies and use of various drugs before any airway manipulations [6]. Multiple drugs in combination and alone have been used [7-15]. These include anesthetic agents, opioids, beta-blockers, alpha-agonist like clonidine and dexmedetomidine, gabapentin, lignocaine infusions and magnesium sulphate.

In our study, the hemodynamic response to laryngoscopy and intubation has been studied for first 10 min only. After these 10 min, FK retractor was inserted by otorhinologist. We chose 10 min as interval between intubation and FK retractor insertion as maximum sympathetic stimulation following laryngoscopy and intubation occur within 10 min only and subside there after [16]. There were no significant changes in hemodynamic parameters at various time point of intubation, retraction insertion as well as there was no increase in requirement of MAC or opioid in most of the patients. In the intra group analysis of hypertensive patient *vs.* non-hypertensive patients, we found significantly lower blood pressure in hypertensive group compared to non-hypertensive patients, just before intubation. This can be explained by the additive effects of anti-hypertensive agents along with the anesthetic agents, leading to exaggerated fall in blood pressure. Postintubation, we did not any statically significant increase in SBP, though DBP and MAP showed significant increase. This can be explained by enhanced release of catecholamines and increased sensitivity of peripheral blood vessels resulting in increased vasoconstriction and raised DBP and MAP. There was also statistically significant increase in HR 20 min following retractor insertion which persisted till 60 min following retractor insertion in hypertensive patients. Throughout this time, it persisted less than 120 beats/min and did not require any additional dose of fentanyl.

Jeyarajah et al. [17], in their review article on perioperative concerns in patients robotic assisted ENT surgeries advocate the use opioids like fentanyl, remifentanil and beta-blockers to obtund the sustained hemodynamic response to retractor placement. In another recent case series of four case, they described used of fentanyl boluses and beta-blockers to reduce the sympathetic response. While literature search shows scarcity of data on the sympathetic response occurring following FK retractor insertion during TORS, there is no study which directly compares this response with endotracheal intubation. The findings of the present study indicate that if induction of anesthesia, plane of anesthesia and initial opioid dose are given adequately the hemodynamic responses following endotracheal intubation and FK retractor insertion are quite similar. Additional interventions in the form of increase in anesthetic concentration were required in hypertensive patients following retraction insertion. The sympathetic response to the surgical gag insertion lasted for up to 60 min after the retractor insertion in these patients as seen by the hemodynamic alteration. Therefore, it is important to have heightened level of vigilance in hypertensive patients to attenuate their hemodynamic responses. Though statistically not significant, we observed more complications like bleeding, delayed extubation and transient increase in ICP resulting in unequal pupils.

Limitation

As this is only pilot study, due to small sample size it is not powered enough for assessing the primary outcome. However, our study did answer the pragmatics of recruitment and feasibility of larger study. Second, we did not quantify and compare the amount of fentanyl used in hypertensive and non-hypertensive patients. Therefore, we feel more future research on role of opioids in attenuating the hemodynamic response following FK retractor insertion can be planned.

Conclusion

FK retractor insertion had comparable hemodynamic response as endotracheal intubation during Transoral Robotic Surgery. Hypertensive patients showed rise in blood pressure at both endotracheal intubation and at FK retractor insertion requiring

increased requirement of anesthetic agents.

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