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OUTCOME OF PREOPERATIVE SILDENAFIL USE IN PATIENTS UNDERGOING MVR WITH SEVERE PULMONARY ARTERY HYPERTENSION

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Abstract
Endotracheal intubation using conventional laryngoscopy triggers a haemodynamic response, leading to increased heart rate and blood pressure. There are conflicting reports regarding the haemodynamic stress response differences between conventional Macintosh and video laryngoscopes, with limited studies on cardiac surgical patients. This study aimed to compare the haemodynamic stress response and mean intubation time between video and direct laryngoscopy in patients undergoing coronary artery bypass grafting (CABG) at a tertiary care hospital in Karachi. A randomized controlled trial was conducted at the Department of Anaesthesia, National Institute of Cardiovascular Diseases, Karachi, over six months. Data were prospectively collected from 244 patients who met the inclusion criteria, following verbal consent. Quantitative and qualitative data were analyzed, and a post-stratification chi-square test was applied, with a significance threshold of $p \leq 0.05$. Results showed that the mean heart rate was significantly lower in the video laryngoscope group (78.06±6.10) compared to the direct laryngoscope group (84.30±5.14), with a p-value of 0.001. Similarly, the mean arterial pressure was lower in the video laryngoscope group (83.47±2.69) than in the direct laryngoscope group (86±3.58), with a p-value of 0.001. The mean total intubation time was also shorter with video laryngoscopy (22.19±4.33) compared to direct laryngoscopy (24.08±5.91), with a p-value of 0.001. In conclusion, video laryngoscopy offers better haemodynamic stability and ease of intubation than conventional direct laryngoscopy in patients undergoing CABG. These findings suggest that video laryngoscopes may be a superior choice for improving patient safety and procedural efficiency in high-risk cardiac surgeries.

INTRODUCTION

The anesthetic techniques used for cardiovascular surgery are usually based on considerations such as haemodynamic stability, effects on myocardial oxygen supply, and demand and minimizing intubation stress response (Kanchi et al., 2011a). The haemodynamic changes following endotracheal intubation are of great significance and may lead to adverse effects (Colton House et al., 2011). The airway management is of significance for all specialties of medicine and surgery. A better view is assumed to facilitate easier intubations, but this is not entirely confirmed as a good laryngeal view does not guarantee easy or successful endotracheal tube (ETT) insertion (Shribman et al., 1987).

Haemodynamic response increases with the force and duration of laryngoscopy (DOL) (Kanchi et al., 2011b) and can also be affected by prolonged intubation time. (Colton House et al., 2011). Tracheal intubation approaches that minimize oropharyngolaryngeal stimulation might attenuate this stress response (Kahl et al., 2004). Video laryngoscopes do not require alignment of the oral, pharyngeal, and laryngeal axes for visualization of the glottis and tracheal intubation and cause minimal oropharyngolaryngeal stimulation and may hence potentially attenuate the pressor response (Tempe et al., 2016).

Following induction and intubation, the anesthetic course is typically characterized by an initial period of minimal stimulation that is frequently associated with hypotension, followed by periods of intense stimulation, such as skin incision and sternotomy (Basagan-Mogol et al., 2010), that can produce tachycardia and hypertension; anesthetic agents should be used appropriately in anticipation of these events (Moffitt et al., 1968) (Stevanovic et al., 2016). The dissociative agent ketamine is a potent analgesic at sub-anesthetic plasma concentrations, with an elimination half- life of 2.17 h in patients who were not premedicated (Zanos et al., 2018). It elevates arterial blood pressure, pulmonary artery pressure, and heart rate due to sympathetic stimulation (Vaillancourt et al., 2017). Benzodiazepines, the most effective agents for attenuating these cardiovascular effects, cause an increase in plasma ketamine levels and prolong the redistribution and elimination half-lives(Vaillancourt et al., 2017) (Khan et al., 2014).

Coronary artery bypass grafting (CABG) is the most common surgery performed by cardiac surgeons today worldwide (Melly et al., 2018). The key fundamental principles of anesthesia for coronary artery bypass graft (CABG) surgery consist of maintaining haemodynamic stability and minimizing myocardial ischemia (Basagan-Mogol et al., 2010). Kumar Barman et al (2017)study evaluated haemodynamic stress response (heart rate and mean arterial pressure) and total intubation time after intubation with video versus direct laryngoscope and found mean heart rate at 10 min (78.31±8.74 vs 81±10.84), mean arterial pressure at 10 min (84.25±6.38 vs 82.11±5.52) and (22.94±5.56 vs 23.57±5.34) respectively.

The rationale of the study is to compare the haemodynamic stress response and total intubation time after intubation with video versus direct laryngoscope in patients undergoing coronary artery bypass grafting surgery in order to establish the local perspective as there is paucity of local data. This provides me the strong rationale to conduct this study. Furthermore, the results of my study will provide current and local statistics with knowledge as which method is superior to another among patients undergoing elective CABG surgery. Hence outcome of the study could be studied, implemented in the management protocols.

MATERIAL & METHODOLOGY:

Experimental Design, Duration, Sample Size & Sampling Technique: This randomized control trial was conducted at the Department of Anaesthesia, National Institute of Cardiovascular Diseases, Karachi, over a duration of six months, from December 20, 2020, to June 20, 2021, following approval. The study included a total of 244 patients, with 122 patients in each group. The sample size was determined using OpenEpi software with a level of significance of 5%, a power of 90%, and mean arterial pressure at 10 minutes recorded as 84.25±6.38 versus 82.11±5.52 in video versus direct laryngoscope (Kumar Barman et al., 2017). A non-probability consecutive sampling technique was employed for participant selection.

Sample Selection:

The inclusion criteria consisted of patients undergoing coronary artery bypass grafting surgery, those with a Mallampati score of ≤ II, an American Society of Anesthesiologists (ASA) classification of ≤ 2, and individuals of either gender aged between 20 and 60 years. Patients were excluded if they did not provide consent or had a history of type II diabetes mellitus, hypertension, myocardial infarction, or the use of β-blockers, α-blockers, or calcium channel blockers. Additionally, patients with anemia (Hb < 10 g/dl) requiring blood transfusion, thromboembolic disorders, stroke, renal impairment, chronic obstructive pulmonary disease, asthma, chronic liver disease, hypothyroidism, or congestive cardiac failure were also excluded from the study.

Data Collection Procedure:

This study was conducted after approval from the College of Physicians and Surgeons Pakistan. Consenting patients visiting the National Institute of Cardiovascular Diseases, Karachi, and undergoing coronary artery bypass grafting surgery were enrolled in this study who fulfilled the inclusion criteria. A brief history of demographic data (age and gender) was taken from each patient. Each participant's height in meters was measured using wall wall-mounted scale weight to the nearest kilogram was measured using the weighing machine at the time of admission and BMI was calculated at the time of admission to the hospital. Patients were randomly allocated using sealed opaque envelope bearing V= Patients intubated with video laryngoscope and D= Patients were intubated with a direct laryngoscope. Intubation was carried out by attending anesthesiologists who were certified by the National Society of Anesthesiologists to use VLs with over 10 years of experience in the presence of the researcher. After the patient arrived in the operating room, standard monitoring including an electrocardiogram, noninvasive blood pressure, pulse oximeter, and capnometer was performed on all patients after they were premedicated with midazolam 1 mg IV. For both groups, anesthesia induction was provided with propofol at 2–3 mg/kg IV and fentanyl at 1 µcg/kg IV. Rocuronium at 0.6 mg/kg IV will be used for muscle relaxation. Drugs were administered according to predicted body weight. The patients were ventilated with 100% oxygen by a mask in a cramped position and waited for 2 min for adequate muscle relaxation. The patients were intubated in the respective groups using a video laryngoscope and the Macintosh direct laryngoscope or at the end of 2 min. The endotracheal intubation in Group V was done by seeing it from the screen, and in Group D by seeing it directly. For intubation, we used an endotracheal tube with a 7 mm internal diameter for women and an 8 mm internal diameter for men. In addition, in Group V, we placed a stylet in all endotracheal tubes. After taking the patient to the operation table, a multipara monitor was attached and the heart rate (PR), mean arterial pressure (MAP), and oxygen saturation were noted down and will be labeled as baseline readings. All the patients were observed for vital parameters like heart rate and mean arterial pressure at 10 min after intubation. The mean total intubation time was noted in each group as per the operational definition. The findings of quantitative variables (age, height, weight, BMI, heart rate, mean arterial pressure, and total intubation time) and qualitative variables (gender, smoking status, obesity status, and family monthly income status) were entered in Performa attached as an annexure.

Statistical Analysis:

Data was analyzed on SPSS Version 20. Mean and standard deviations were calculated for the quantitative variables like age, height, weight, BMI, heart rate, mean arterial pressure, and total intubation time. Frequencies and percentages were calculated for the qualitative variables like gender, smoking status, obesity status, and family monthly income status. An unpaired t-test was used to compare the mean difference between haemodynamic stress response (heart rate, mean arterial pressure) and total intubation time in both groups. Effect modifiers were controlled through stratification of age, gender, smoking status, obesity status, and socioeconomic status to see the effect of these on the outcome variable (haemodynamic stress response and total intubation time). Post-stratification independent t-test was applied taking a p-value of ≤ 0.05 as statistically significant.

RESULTS:

Video Laryngoscope Group Versus Direct Laryngoscope Group:

Out of 122 patients in the video laryngoscope group, the minimum age of the patient was 20 while the maximum age of the patients was 60 years. Mean age, height, weight, and BMI in our study were 51.29±5.24 years, 151±8.44 cm, 73.7±8.57 kg, and 27.9±4.54 kg/m^2 respectively. Similarly, out of 122 patients in the direct laryngoscope group minimum age of the patient was 20 while the maximum age of the patients was 60 years. Mean age, height, weight, and BMI in our study were 51.25±7.41 years, 149±10.41 cm, 76.9±6.99 kg, and 28.6±5.87 kg/m2 respectively. As shown in Table 1.

Table 1: Descriptive statistics in video laryngoscope group versus direct laryngoscope group

Variable	Mean ± Sd	Standard Deviation	Min-Max
Age Group V (years)	51.29	±5.24	20-60

Age Group D (years)	51.25	±7.41	20-60
Height Group V (cm)	151	±8.44	138-172
Weight Group V (kg)	73.7	±8.57	68-115
Height Group D (cm)	149	±10.41	138-172
Weight Group D (kg)	76.9	±6.99	68-115
BMI Group V (kg/m^2)	27.9	±4.54	23-33
BMI Group D (kg/m^2)	28.6	±5.87	23-33

Demographic Characteristics:

The age distribution showed that in the video laryngoscope group, 23% of patients were aged 20-40 years, while 77% were between 41-60 years as shown in Table 2. In contrast, the direct laryngoscope group had 33.6% of patients in the 20-40 years range and 66.4% in the 41-60 years category as shown in Table 2. Regarding gender, males comprised 43.4% and females 56.6% in the video laryngoscope group, whereas in the direct laryngoscope group, males accounted for 46.7% and females for 53.3%. Smoking status revealed that 13.1% of patients in the video laryngoscope group were smokers, compared to 19.7% in the direct laryngoscope group, with non-smokers making up 86.9% and 80.3%, respectively as shown in Table 2. Obesity was more prevalent in the video laryngoscope group, where 67.2% of patients were obese and 32.8% were not, while in the direct laryngoscope group, 33.6% were obese, and 66.4% were not. In terms of family monthly income, 27.9% of patients in the video laryngoscope group had an income of ≤50,000, while 72.1% had an income above 50,000. In the direct laryngoscope group, 41% had an income of ≤50,000, and 59% earned more than 50,000 as shown in Table 2. These demographic characteristics highlight variations in patient distribution between the two groups.

Table 2: Demographic Characteristics

Variable	Video Laryngoscope Group (n=122)	Direct Laryngoscope Group (n=122)	P-Value
Age Distribution	20-40 years: 28 (23%) 41-60 years: 94 (77%)	20-40 years: 41 (33.6%) 41-60 years: 81 (66.4%)	-
Gender Distribution	Male: 53 (43.4%) Female: 69 (56.6%)	Male: 57 (46.7%) Female: 65 (53.3%)	-
Smoking Status	Yes: 16 (13.1%) No: 106 (86.9%)	Yes: 24 (19.7%) No: 98 (80.3%)	-
Obesity Status	Yes: 82 (67.2%) No: 40 (32.8%)	Yes: 41 (33.6%) No: 81 (66.4%)	-
Family Monthly Income	≤ 50,000: 34 (27.9%) > 50,000: 88 (72.1%)	≤ 50,000: 50 (41%) > 50,000: 72 (59%)	-

Heart Rate:

The mean heart rate was significantly lower in the video laryngoscope group (78.06±6.10) compared to the direct laryngoscope group (84.30±5.14), with a P-value of 0.001as shown in Table 3. When stratified by age, the mean heart rate in the 20-40 years age group was 78.78±6.19 in the video laryngoscope group and 84.19±5.35 in the direct laryngoscope group (P=0.001) as shown in Table 3. Similarly, in the 41-60 years age group, it was 78.14±6.10 and 84.85±5.97, respectively (P=0.001) as shown in Table 3.

Gender-based stratification showed that males in the video laryngoscope group had a mean heart rate of 78.77±6.95, compared to 84.79±5.42 in the direct laryngoscope group (P=0.02). Among females, the mean heart rate was 78.51±6.14 and 84.75±5.86, respectively (P=0.001) as shown in Table 3. Stratification by smoking status revealed that smokers had a mean heart rate of 78.01±6.85 in the video laryngoscope group and 84.58±5.90 in the direct laryngoscope group (P=0.03), while non-smokers had values of 78.92±6.23 and 84.24±5.22, respectively (P=0.001) as shown in Table 3.

Regarding obesity status, the mean heart rate in obese patients was 78.47±6.24 in the video laryngoscope group and 84.85±5.78 in the direct laryngoscope group (P=0.001), while non-obese patients had values of 78.2±6.64 and 84.53±5.33, respectively (P=0.001) as shown in Table 3. Family monthly income stratification showed that patients earning ≤50,000 had a mean heart rate of 78.76±6.36 in the video laryngoscope group and

84.34±5.21 in the direct laryngoscope group (P=0.0001) as shown in Table 3. In the income group earning >50,000, the mean heart rate was 78.17±6.03 and 84.55±5.92, respectively (P=0.001) as shown in Table 3. These findings indicate that across all stratified groups, the video laryngoscope was associated with a significantly lower mean heart rate compared to the direct laryngoscope.

Table 3: Heart Rate

Variable	Video Laryngoscope Group (n=122)	Direct Laryngoscope Group (n=122)	P-Value
Heart Rate (bpm)	78.06 ± 6.10	84.30 ± 5.14	0.001
Heart Rate (by Age)	20-40 years: 78.78 ± 6.19 41-60 years: 78.14 ± 6.10	20-40 years: 84.19 ± 5.35 41-60 years: 84.85 ± 5.97	0.001
Heart Rate (by Gender)	Male: 78.77 ± 6.95 Female: 78.51 ± 6.14	Male: 84.79 ± 5.42 Female: 84.75 ± 5.86	0.02 (M), 0.001 (F)
Heart Rate (by Smoking Status)	Yes: 78.01 ± 6.85 No: 78.92 ± 6.23	Yes: 84.58 ± 5.90 No: 84.24 ± 5.22	0.03 (Yes), 0.001 (No)
Heart Rate (by Obesity Status)	Yes: 78.47 ± 6.24 No: 78.2 ± 6.64	Yes: 84.85 ± 5.78 No: 84.53 ± 5.33	0.001

Mean Arterial Pressure: The mean arterial pressure (MAP) was significantly lower in the video laryngoscope group (83.47±2.69) compared to the direct laryngoscope group (86±3.58) (P=0.001). Age stratification revealed that in the 20-40 years group, MAP was 83.42±2.01 and 86.47±2.14, respectively, while in the 41-60 years group, it was 83.35±2.47 and 86.87±3.09, respectively (P=0.001 for both) as shown Table 4.
Gender-wise analysis showed lower MAP in both males (83.51±2.01 vs. 86.78±3.03) and females (83.47±2.21 vs. 86.87±3.05) in the video laryngoscope group (P=0.001). Among smokers, MAP was 83.87±1.68 vs. 86.48±3.42 (P=0.01), while in non-smokers, it was 83.54±2.16 vs. 86.81±2.92 (P=0.001) as shown in Table 4.
Obesity status analysis indicated that MAP was 83.29±1.97 vs. 86.61±3.39 (P=0.07) in obese patients and 83.71±2.33 vs. 86.19±2.83 (P=0.001) in non-obese patients. Income-based stratification showed that MAP was significantly lower in the video laryngoscope group for both income groups: ≤50,000 (83.51±2.47 vs. 86.84±2.49) and >50,000 (83.47±1.96 vs. 86.89±3.37) (P=0.001) as shown in Table 4. These findings suggest that video laryngoscopy consistently results in lower MAP across different demographic and clinical subgroups.

Table 4: Mean Arterial Pressure

Variable	Video Laryngoscope Group (n=122)	Direct Laryngoscope Group (n=122)	P-Value
Mean Arterial Pressure (mmHg)	83.47 ± 2.69	86.00 ± 3.57	0.001
MAP (by Age)	20-40 years: 83.42 ± 2.01 41-60 years: 83.35 ± 2.47	20-40 years: 86.47 ± 2.14 41-60 years: 86.87 ± 3.09	0.001
MAP (by Gender)	Male: 83.51 ± 2.01 Female: 83.47 ± 2.21	Male: 86.78 ± 3.03 Female: 86.87 ± 3.05	0.001
MAP (by Smoking Status)	Yes: 83.87 ± 1.68 No: 83.54 ± 2.16	Yes: 86.48 ± 3.42 No: 86.81 ± 2.92	0.01 (Yes), 0.001 (No)
MAP (by Obesity Status)	Yes: 83.29 ± 1.97 No: 83.71 ± 2.33	Yes: 86.61 ± 3.39 No: 86.19 ± 2.83	0.07 (Yes), 0.001 (No)
MAP (by Income	≤ 50,000: 83.51 ± 2.47 >	≤ 50,000: 86.84 ± 2.49 >	0.001

Status)	50,000: 83.47 ± 1.96	50,000: 86.89 ± 3.37

Intubation Time: The mean total intubation time was significantly lower in the video laryngoscope group (22.19±4.33) compared to the direct laryngoscope group (24.08±5.91) (P=0.001) as shown in Table 5.

Age-wise stratification showed that in the 20-40 years group, the mean intubation time was 22.92±4.94 vs. 25.25±5.16, while in the 41-60 years group, it was 22.27±4.44 vs. 25.12±5.81 (P=0.001 for both). Gender-based analysis revealed a shorter intubation time in both males (22.40±4.69 vs. 25.20±5.17) and females (22.02±4.03 vs. 25.96±5.10) (P=0.001) As shown in Among smokers, intubation time was 22.12±4.18 vs. 25.9±5.87 (P=0.01), while in non- smokers, it was 22.20±4.21 vs. 25.64±5.76 (P=0.001). Obesity stratification showed shorter intubation times in both obese (22.38±4.43 vs. 25.76±5.75) and non-obese (22.8±4.09 vs. 25.24±5.06) patients (P=0.001) as shown in Table 5.

Income-based analysis indicated that intubation time was lower in the video laryngoscope group for both income groups: ≤50,000 (22.70±4.84 vs. 25.11±5.27) and >50,000 (22.47±4.11 vs. 25.05±5.66) (P=0.001) as shown in Table 5. These results highlight the efficiency of video laryngoscopy in reducing intubation time across various patient subgroups.

Table 5.
Table 5: Intubation Time

Variable	Video Laryngoscope Group (n=122)	Direct Laryngoscope Group (n=122)	P-Value
Total Intubation Time (sec)	22.19 ± 4.33	24.08 ± 5.91	0.001
Intubation Time (by Age)	20-40 years: 22.92 ± 4.94 41-60 years: 22.27 ± 4.44	20-40 years: 25.25 ± 5.16 41-60 years: 25.12 ± 5.81	0.001
Intubation Time (by Gender)	Male: 22.40 ± 4.69 Female: 22.02 ± 4.03	Male: 25.20 ± 5.17 Female: 25.96 ± 5.10	0.001
Intubation Time (by Smoking Status)	Yes: 22.12 ± 4.18 No: 22.20 ± 4.21	Yes: 25.90 ± 5.87 No: 25.64 ± 5.76	0.001
Intubation Time (by Obesity Status)	Yes: 22.38 ± 4.43 No: 22.80 ± 4.09	Yes: 25.76 ± 5.75 No: 25.24 ± 5.06	0.001
Intubation Time (by Income Status)	≤ 50,000: 22.70 ± 4.84 > 50,000: 22.47 ± 4.11	≤ 50,000: 25.11 ± 5.27 > 50,000: 25.05 ± 5.66	0.001

DISCUSSION:

Our study included a total of 244 patients (122 in video and direct laryngoscope group) who met the inclusion and exclusion criteria. The mean heart rate in the video versus direct laryngoscope group was 78.06±6.10 and 84.30±5.14 respectively. P-value was 0.001. Mean arterial pressure in the video versus direct laryngoscope group was 83.47±2.69 and 86±3.58 respectively. P-value was 0.001. The mean total intubation time in the video versus direct laryngoscope group was 22.19±4.33 and 24.08±5.91 respectively. P-value was 0.001.

Thirty patients suffering from coronary artery disease scheduled for elective coronary artery bypass grafting (CABG) were studied. The patients were randomly allocated to undergo either conventional laryngoscopy (group A) or video laryngoscopy (group B). The time taken to perform endotracheal intubation and haemodynamic changes associated with intubation were noted in both the groups at different time points. The duration of laryngoscopy and intubation was significantly longer in group B (video laryngoscopy) when compared to group A patients. However, haemodynamic changes were no different between the groups. There were no events of myocardial ischemia as monitored by surface electrocardiography during the study period in either of the groups. In conclusion, video laryngoscopy did not provide any benefit in terms of haemodynamic response to laryngoscopy and intubation in patients undergoing primary CABG with a Mallam Patti grade of <2.121 (Kanchi et al., 2011a).

Seventy patients were randomized into two groups. Baseline variables including age, weight, Mallam Pati score, and comorbidities were comparable between the two groups. There was a statistically significant elevation in mean heart rate in the Macintosh group at 2nd-min (P = 0.02) and 3rd-min (P = 0.05) postintubation. Similarly, there was a significant increase in mean arterial pressure at 2nd (P = 0.06), 3rd (P = 0.03), and 4th (P = 0.03) in the Macintosh group. The time for laryngoscopy and Intubation Difficulty Scale was significantly better in the Airtraq group (P = 0.001 and 0.001). However, the median time to intubation was longer in the Airtraq group (13 s vs. 11 s, P = 0.05). Laryngoscopy view was better with Airtraq even in patients with Mallam Pati score 3 (ten patients). The incidence of trauma was the same in both groups (Varsha et al., 2019).

Another study included 17 trials with a total of 1,998 patients. The pooled relative risk (RR) of grade 1 laryngoscopy (vs ≥ grade 2) for the Glidescope(®) was 2.0 [95% confidence interval (CI) 1.5 to 2.5]. Significant heterogeneity was partially explained by intubation difficulty using meta-regression analysis (P = 0.003). The pooled RR for no difficult intubations of grade 1 laryngoscopy (vs ≥ grade 2) was 1.5 (95% CI 1.2 to 1.9), and for difficult intubations, it was 3.5 (95% CI 2.3 to 5.5). There was no difference between the Glidescope(®) and the direct laryngoscope regarding successful first-attempt intubation or time to intubation, although there was significant heterogeneity in both of these outcomes. In the two studies examining nonexperts, successful first-attempt intubation (RR 1.8, 95% CI 1.4 to 2.4) and time to intubation (weighted mean difference -43 sec, 95% CI -72 to -14 sec) were improved using the Glidescope(®). Experts did not see these benefits (Griesdale et al., 2012).

CONCLUSION:

In our study, it was confirmed that video laryngoscope intubations resulted in a significantly lesser haemodynamic response and greater ease of intubation compared to direct intubations because of a lower IDS and a shorter laryngoscopy time. Thus, we conclude that video laryngoscope is a superior option to Macintosh in patients with ischemic heart disease planned for CABG surgery in experienced hands. Further studies are required to prove its efficacy and safety in difficult airway scenarios.

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