Section: Anaesthesiology and Critical Care

Original Research Article

A RANDOMIZED CONTROLLED STUDY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS PROPOFOL BASED SEDATION FOR AWAKE FIBRE-OPTIC INTUBATION.

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Abstract

Background: Dexmedetomidine and propofol are commonly used intravenous agents to sedate patients in awake fibreoptic intubation. This study was conducted to compare the efficacy of both agents in terms of haemodynamic stability and sedation in patients with normal airway. **Materials and Methods:** This prospective randomized study was conducted in 78 patients posted for elective surgeries who were randomly divided into two groups of 39 each. Patients in group D received inj dexmedetomidine infusion at the dose of 0.5mcg/kg/hr after a bolus of 1mcg/kg while patient in group P received inj propofol at 1mg/kg bolus followed by 0.5mg/kg/hr until the endotracheal tube was secured. Chi square test was used for analysis of the qualitative data while Unpaired student's t test for the continuous variables. **Result:** Demographic variables were comparable in both the groups. Ramsay sedation score was achieved quickly in group P at 4.64 minutes. Mean arterial pressure, systolic blood pressure and heart rate were significantly lower in group P while diastolic blood pressure was comparable at many intervals. Incidence of bradycardia was higher in group D (n=8/39, p=.005). Time to visualise glottis in group P (2.52±0.11 min) vs group D (2.51±0.13 min) was comparable in both the groups (p=0.656). Overall discomfort score was comparable in both groups [group P vs group D;(1.10±0.30),(1.0±0.39)(p=0.206)]. **Conclusion:** Propofol use is associated with faster onset of sedation but dexmedetomidine provides better haemodynamic stability and optimal sedation required for the procedure. Dexmedetomidine also allays patient discomfort and improves patient tolerance for the procedure.

INTRODUCTION

The flexible Fibreoptic bronchoscope (FOB) is a versatile device at disposal of an anaesthesiologist. It is not just used for difficult intubation but constitutes an integral part of teaching and training.1 Awake fibreoptic intubation(FOI) can be safely performed with adequate local anaesthesia and minimal sedation.2 Previously midazolam, fentanyl, ketamine, propofol, and remifentanil have been used along with local anaesthetics for the desired results.3 Various studies have been conducted to demonstrate the role of dexmedetomidine and propofol in awake FOI for anticipated difficult airway management.4,5. However, this study was conducted in elective surgical patients with uncomplicated airway to compare the efficacy of dexmedetomidine and propofol in awake FOI. The primary objective of this study was to assess the efficacy of dexmedetomidine and propofol in terms of sedation and haemodynamic stability during awake FOI while the secondary objectives included patient satisfaction and adverse effects if any.

MATERIALS AND METHODS

This prospective randomized study was conducted in a tertiary hospital after obtaining the institutional ethics committee's approval and written informed consent from the patients. A total of 78 patients posted for elective surgeries were randomly divided into two groups of 39 each using computer-generated random numbers. Patient and observer were blinded to the infusion used during the

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procedure. Patients aged 18-65 years, belonging to ASA physical status I and II, with normal airway parameters i.e. Mallampatti grade I and II, Thyro-mental distance > 6.5 cm and posted for elective surgeries under general anaesthesia were included in the study. Exclusion criteria comprised of patients with anticipated difficult airway(Mallampatti grade III and IV, Thyro-mental distance < 6.5 cm), pregnancy, known allergy to drugs in the discussion, history of substance abuse such as alcohol or opioids and patients belonging to ASA physical status >II.

During the preoperative visit, an airway and general physical examination was conducted after obtaining a detailed history. Patients were provided with a detailed explanation of the procedure for awake fibreoptic intubation. Institution based protocols were followed for preoperative investigations and fasting guidelines (2 hours for clear liquid and 6 hours for light meal). Patients were premedicated with intravenous (IV) ranitidine 50 mg and IV ondansetron 0.1mg/kg 1hr before the procedure. Intravenous Inj glycopyrrolate 0.2mg was administered 30 minutes before the application of local anaesthetic. Standard ASA monitoring including electrocardiogram, pulse oximetry and non-invasive blood pressure was applied to the patient. The airway was anaesthetised with nebulization of 4% lidocaine 4 ml (168 mg) over 20 min. Xylometazoline nasal drops and lidocaine gel was applied to both nostrils. The tongue and hypopharynx were sprayed with 8 puffs of 10% lidocaine (80 mg). Five minutes before the beginning of respective drug infusions, Inj midazolam 0.03mg/kg and Inj Fentanyl 1mcg/kg were administered intravenously. The fibreoptic bronchoscope's control lever was checked and verified before beginning awake FOI. Patients were given the study drug according to their allocated group. Patients in group D received IV dexmedetomidine at the dose of 0.5mcg/kg/hr after a bolus of 1mcg/kg until the endotracheal tube was secured. Similarly, patients in group P received 0.5mg/kg/hr IV propofol after a bolus dose of 1 mg/kg over 10 minutes, until the endotracheal tube was secured.

Nasotracheal intubation was attempted once Ramsay sedation score (RSS) 3 was achieved. This was considered as level of desired sedation as it ensures optimal sedation without respiratory depression.6 On the visualization of glottic structures, 2-4 ml 2% lignocaine was instilled through the port of the bronchoscope over the vocal cord by spray as you go (SAGO) technique and the fibreoptic bronchoscope was advanced further.7 After the identification of the carina, the endotracheal tube was gently passed into the mid-tracheal position. ET tube's position was confirmed while withdrawing the fibreoptic bronchoscope and reconfirmed using capnography.

Heart rate (HR), mean arterial pressure (MAP), systolic blood pressure (SBP), diastolic blood pressure (DBP) and oxygen saturation (SpO2) were recorded at 0,1,4,7 and 10 minutes. During fiberoptic bronchoscopic intubation haemodynamic parameters and RSS were observed every 30 sec till intubation was achieved. Time to achieve RSS ≥ 3, Fiberoptic endoscopy time(from placement of fiberscopes tip in the patient nose to visualization of carina), intubation time(from visualization of carina to placement of endotracheal tube) and the number of attempts were also noted. Discomfort score[no discomfort(0), mild discomfort but no patient resistance(1), anxious patient with minimal resistance(2), restless patient and severe patient resistance(4)], Endoscopy score[no response(0), grimacing(1), localizing(2), coughing on lignocaine via scope(3), coughing on entering infraglottic space(4), prolonged coughing(5)], Intubation score[no response(0), grimacing(1), localising with one limb at any stage(2), localising with two limbs at any stage(3), coughing on entering trachea(4), prolonged Coughing(5)] and Post-intubation score[cooperative and obeys command(1), uncomfortable with requirement of imminent general anaesthesia(2), others(specific details)(3)] were also assessed. Hypotension (reduction of MAP > 20% from baseline) was treated with IV fluid and/or IV ephedrine 5 mg bolus. Bradycardia (HR <50 beats/min) was treated with IV atropine 0.6 mg and oxygen desaturation (SpO2<92% for >10 s) was treated with oxygen supplementation either through a nasal cannula or oxygen port of bronchoscope.

Statistical analysis: Sample size was calculated to be 35 in each group for equivalence trial with a power of eighty percent and a type-1 error of 0.05. Thirty nine patients were recruited in each group considering 10 % dropout rate. Data were compiled using Microsoft Excel 2016 and analyzed using SPSS software. Chi square test was used for analysis of the qualitative data while Unpaired student's t test for the continuous variables. P value less than 0.05 was considered significant.

RESULTS

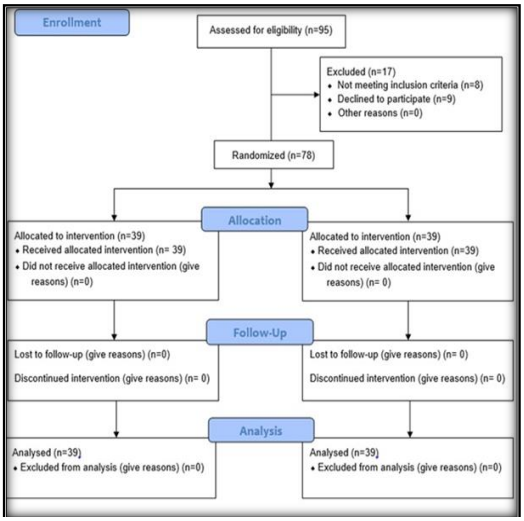

Figure 1: CONSORT diagram of the study

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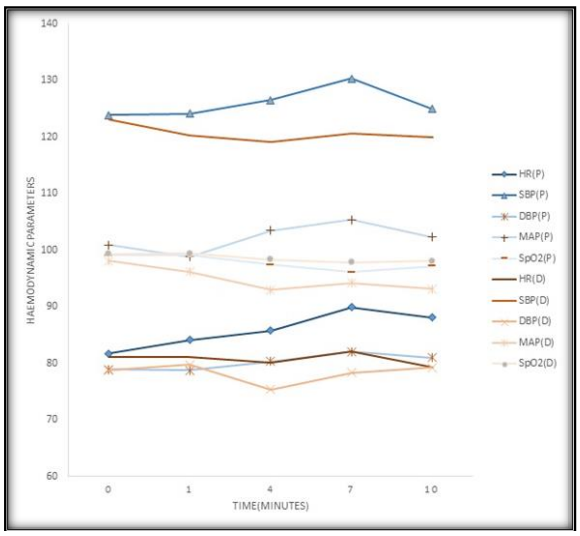

Figure 2: Haemodynamic variables during bolus administration in group P and group D

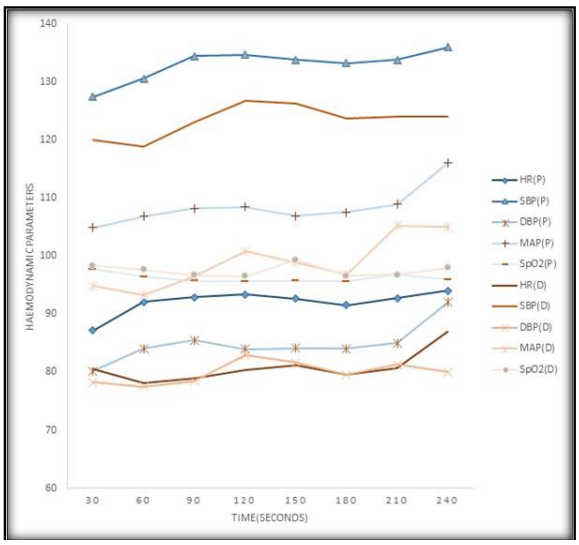

Figure 3: Haemodynamic variables during infusion of drugs in group P and group D

Table 1: Demographic variables in group P and group D

Demographic variables	Group P (n=39)	Group D (n=39)	p value
Age (years)	31.48±9.98	29.97±9.65	0.498
Gender(Male/Female)	22/17	24/15	0.818
Weight(Kg)	60.30±5.33	61.10±5.88	0.533

Table 2: Intraoperative observations in group P and group D

Duration(minutes)	Group P(n=39)	Group D(n=39)	p value
Time to achieve RSS> 3	4.64±0.53	6.23±0.58	<0.0001
Time to visualise glottis	2.52±0.11	2.51±0.13	0.656
Discomfort Score	1.10±0.30	1.0±0.39	0.206
Endoscopy score	1.84±0.43	1.33±0.52	<0.0001
Intubation score	2.05±0.32	1.56±0.59	<0.0001
Post Intubation score	2.0±0.22	1.48±0.75	0.0001

Table 3: Side effects in group P and group D

Adverse Effect	Group P (n=39)	Group D (n=39)	p value
Hypotension	00	01	1.000
Bradycardia	00	08	0.005
Desaturation	09	06	0.566

Demographic data (gender, age and weight) was comparable in both groups [Table 1]. Mean HR, MAP and SBP were comparable at baseline and one minute after the start of bolus dosage but a significant difference was observed up to 10 minutes [Figure 2]. DBP was comparable multiple times during the same period [Figure 2]. Similarly, a statistically significant difference was observed in oxygen saturation between both groups for most periods of observation [Figure 2,3]. Ramsay sedation score was achieved rapidly in group P at 4.64 minutes of bolus dose. It was comparable in both groups at all time intervals except at 210 seconds of the infusion period. Only three cases in Group P and two cases in group D required a rescue bolus dose of 20 mg propofol which was statistically non-significant(p=1.00). Time to visualise glottis was also comparable in both groups [Table 2]. Similarly, intubation time was also comparable with mean time of one minute(p>=1.00, [Table 2]). Endoscopy score, intubation score and post-intubation score were significantly higher in group P as compared to group D but the overall discomfort score was comparable in both groups [Table 2]. Adverse effects such as hypotension and desaturation were also comparable in both groups but a higher incidence of bradycardia was observed in group D(n=8/39) [Table 3].

DISCUSSION

In our study, desired level of sedation was attained faster in group P as compared to group D. Group D provided more haemodynamically stable environment than group P but higher incidence of bradycardia was observed in group D. In both groups, patients expressed similar level of discomfort during the procedure.

Achievement of RSS 3 was faster in group P as compared to group D (p<0.0001) [Table 2]. This can be attributed to the fact that propofol has a faster onset than dexmedetomidine.[8] Previous studies have also reported similar observations where sedation and recovery were faster in the propofol

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group.[9] Despite the faster onset of sedation in the propofol group, the depth of sedation was comparable between both the groups throughout the drug infusion and procedure [Table 3]. Feng et al. reported similar findings based on the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale.[10]

Baseline HR was comparable in both groups but a significant difference was observed at later intervals during both bolus and infusion doses [Figure 2,3]. Similar observations were made by previous studies with lower heart rate in dexmedetomidine group.[11,12] This is due to the sympatholytic properties of dexmedetomidine which are associated with both hypotension and bradycardia.[13] In concordance with the previously conducted research, MAP and SBP reflected downhill trends in our research too which is also associated with sympatholytic action.[11] But unexpectedly an initial increase in SBP was not observed in our study. This may be due to the previously administered premdedication i.e. midazolam and fentanyl which also possess hypotensive properties.[14] In our study, DBP was lower in group D during the whole period of observation but it was still comparable in both the groups at multiple points of observation. This observation was in contrast to findings of the previous studies which have reported a fall in MAP, SBP and DBP at all durations of observations during the procedure.[9,10] Cuff oscillometry may be one of the reasons associated with this variance where potential artifacts are related to cuff volume, compliance, heart rate, and anomalies of local arterial geometry.[15] In response to fibreoptic intubation, SBP and MAP were continuously lower in group D as compared to group P despite similar levels of sedation due to the sympatholytic properties of dexmedetomidine. Chalam K S et al demonstrated a similar increase in SBP in response to intubation.[9]

Oxygen saturation was better maintained in group D as compared to group P. This can be due to the sedative properties of dexmedetomidine which achieves a level of conscious sedation in contrast to propofol which produces deeper sedation. Even during the fiberoptic intubation saturation was higher in group D owing to lower respiratory depression.[13] Similar observations were reported by Hasanin et al in endoscopic procedures where six patients in the propofol group became desaturated but none in the dexmedetomidine group.[16]

Though endoscopy score, intubation score and post-intubation scores were better in group D as compared to group P ($p<0.001$), the mean discomfort score was comparable in both the groups due to sedative and analgesic properties of dexmedetomidine. The findings were consistent with previous studies that reported better tolerance of the procedure in the dexmedetomidine group.[9] The fiberoptic time and intubation time were also comparable in both groups in concordance with previous studies.[10]

There was no significant difference in terms of adverse events such as hypotension and desaturation between both groups ($p=1.000$ and 0.566 respectively) but bradycardia was observed in 8 patients in group D as compared to group P ($p=0.005$) [Table 2]. Bradycardia is one of the most common adverse effects of dexmedetomidine which may require discontinuation of the infusion and pharmacotherapy if associated with haemodynamic compromise.[13] Our findings are consistent with previous studies which have reported similar incidences.[9,10]

Various studies have been previously conducted to compare dexmedetomidine and propofol in difficult intubation scenarios, but our study had distinct advantage of being conducted in patients with uncomplicated airways. By excluding the confounding factor of difficult airway, efficacy of these drugs for awake FOI could be evaluated in ideal scenarios.

Our study still had a few limitations. Ramsay sedation scale could have been complemented with the bispectral index scoring for better objective comparison. Similarly, various scores utilised for assessment such as endoscopy score, intubation score and post-intubation score, need standardisation and external validation for consideration in future research.

CONCLUSION

Propofol use is associated with rapid achievement of sedation for awake FOI but Dexmedetomidine provides better conditions such as haemodynamic stability and optimal sedation required for the procedure. Dexmedetomidine also provides the added advantage of allaying patient discomfort and improving patient tolerance for the procedure. Adequately powered studies focussing on patient comfort and quality of anaesthesia will be required to confirm all these findings.

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