Original Article

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Comparison of Efficacy of Two Different Dose Regimens of Intravenous Dexmedetomidne for Awake Transnasal Fibreoptic Intubation

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Abstract

Background and Objectives: Nasal Fibreoptic intubation (NFI) is the recommended technique in patients with difficult airway like facial defects, limited mouth-opening and cervical instability but it requires the patient to be awake. The usage of an ideal sedative agent and stabilizing the intubating condition was essential for this. In this study we compare efficacy of different doses of dexmedetomidine for conscious sedation facilitating NFI.

Materials and Methods: This is a prospective, blinded-randomized-trial to correlate the effectiveness of different loading and maintenance doses of dexmedetomidine during NFI on 60 patients, 30 in each group, aged between 20 and 60 years with ASA grade I or II enrolled for elective surgery.

All patients received 2 mg Midazolam as premedication before transferring to operating room. Group A patients received Dexmedetomidine 1 mcg/kg I.V bolus slowly over 10 minutes then 0.8 mcg/kg/h as maintenance throughout the procedure. Group B patients received Dexmedetomidine 0.8 mcg/kg I.V. as bolus and 0.2 mcg/kg/h as maintenance dose.

Primary outcomes were assessment of sedation level and comfort of each patient by Total Comfort Scale (TCS). The difference in quantitative measures was done using student 't' test and difference in proportions by 'Chi' square test. $P<0.05$ was considered statistically significant.

Results: With respect to comfort scores and optimal conditions during NFI, Group A people showed significantly lower scores when compared to Group B.

Conclusion: Dexmedetomidine with loading 1µg/kg and higher maintenance dose 0.8µg/kg/h were better for NFI with better patient tolerance, patient comfort, patient satisfaction, good sedation and preserved upper airway with spontaneous breathing.

Key words: Comfort scale; Dexmedetomidine; Fibreoptic intubation.

Key Message: Dexmedetomidine at higher maintenance dose of 0.8 mcg/kg provides better comfort level to the patients and optimal conditions with less side effects during awake trans nasal fibreoptic endotracheal intubation.

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Introduction

Mortality and morbidity in anaesthesia commonly are from difficult airways. It is predicted that one third of all anaesthetic deaths are because of the inability to ventilate and intubate. 3 – 18% of the population are expected to have difficulties during endotracheal intubation during general anaesthesia1.

Intubation with McIntosh laryngoscope can be tough in certain conditions where there are restricted jaw movements, obese individuals with short neck, cervical spine injuries and inadequate mouth opening e.g. - inter-maxillary fixation,Temporomandibular joint trauma, rheumatoid arthritis.

A breakthrough technique for successful Intubation in the above-mentioned patients with difficult airway is the Awake Fibreoptic Intubation (AFOI) which has been in practice since 1960's and gaining wider popularity in managing difficult airways. Nowadays, the Fibreoptic intubation has become the instrument of first choice in difficult intubation cases particularly after the publication of the American society of Anaesthesiologists (ASA) guidelines in Difficult Airway Management2. Further Awake Fibreoptic Intubation is safe with a higher success rate because of the following reasons.

1. Preserved Muscle tone avoids airway collapse and keeps the airway patent.
2. Spontaneous breathing on command can open the obstructed airway passages.
3. Chances of desaturation is minimal in awake state/spontaneous breathing.[3]

Endotracheal Intubation using a Fibreoptic bronchoscope in the Awake State, if performed without proper sedation, can be an extremely unpleasant and discomforting experience for the patient. Numerous drugs have been used for producing conscious sedation such as Benzodiazepines, opioids, propofol which can be either Used alone or in combination.Midazolam administration results in amnesia and sedation. Propofol has fast onset of action and reduced context sensitive half-life with profound amnesia. ***Opioids example:*** Fentanyl and Remifentanil administration results in attenuating hemodynamic response and in reduction of discomfort during the passage of FOB through vocal cords.

All of the above drugs result in favorable intubating conditions, the incidence of oxygen desaturation is high. Therefore, an ideal agent for conscious sedation should ensure Spontaneous ventilation with adequate airway patency, patient Cooperation favorable intubating conditions and stable hemodynamics and should not produce respiratory depression.[4]

Dexmedetomidine when compared to fentanyl had better tolerance to intubation and upper airway obstruction hence it is more effective than fentanyl.

Dexmedetomidine when used at doses of 1 mcg/kg bolus was safe and beneficial even without airway blocks, nerve blocks or topical anaesthesia. Dexmedetomidine on comparison with Midazolam provided better satisfaction and pain score during procedural sedation and less respiratory depression effects. In this study we will be comparing two groups, one with higher maintenance dose of 0.8mcg/kg infusion and the later with lower maintenance dose of 0.2mcg/kg infusion of dexmedetomidine so that the marked reduction in BP and HR which may occur in patients with higher maintenance dose can be reduced.

Aims and Objectives

To administer a bolus of 1 mcg/kg followed by 0.8 mcg/kg intravenous infusion of dexmedetomidine for patients requiring awake trans nasal fibreoptic endotracheal intubation (group A).

To administer a bolus of 0.8mcg/kg followed by 0.2 mcg/kg intravenous infusion of dexmedetomidine for patients requiring awake trans nasal fibreoptic endotracheal intubation (group B).

To compare and document the degree of sedation, adequacy of analgesia and adverse effects if any, between the above two group of patients.

Methods

After obtaining institutional ethical committee approval. 60 patients belonging to ASA I and II, aged between 20 to 60 of both genders posted for elective surgeries under general anaesthesia with anticipated difficult airway were selected. Patients were segregated into two groups of 30 patients each group based on computer generated randomisation after informed written consent. Exclusion criteria included patients suffering from cardio vascular disease (Hypertension, congestive heart failure, coronary artery disease).

- Respiratory disease
- Cerebrovascular insufficiency
- Coagulation defects/bleeding disorder
- Renal/hepatic insufficiency
- Patients with gastro oesophageal reflux, uncontrolled hypertension, ischemic heart diseases and any type of blocks on ECG.

- Patients who are on benzodiazepines or antidepressants or any sedatives.
- Possibility of pregnancy/known pregnancy.
- A thorough preanesthetic check-up was carried out, history was taken and systemic examination done. Vitals were noted including weight of the patient.

Investigations asked prior to surgery include

- Complete hemogram
- Serum electrolytes
- Blood urea and serum creatinine
- Random blood sugar
- Bleeding time and clotting time
- ECG and Chest x-ray
- Urine analysis for sugar, albumin and microscopy
- No other specific investigations were asked

All patients were assessed 1 day before the surgery, investigation reports were checked, anaesthetic procedure explained and informed consent was taken.

Fasting was ensured for 8hours and patients were premedicated with Tab. Alprazolam 0.5mg and Tab. Rantac 150 mg, which were repeated again on the morning of surgery.

Preparation of drug for infusion

Dexmedetomidine 1ml ampule containing 100mcg was diluted with normal saline till 20cc so that the solution contains drug of 5µg per ml.

The drugs were administered using a syringe pump.

Patients were randomly segregated into two groups by computer generated table.

GROUP A: received Dexmedetomidine 1mcg/kg as a bolus dose slowly over 10

minutes then 0.8mcg/kg/hr. as a maintenance dose by a syringe pump.

GROUP B: received Dexmedetomidine 0.8mcg/kg as a bolus dose slowly over 10 minutes then 0.2mcg/kg/hr. as a maintenance dose by a syringe pump.

Inj.Glycopyrrolate 0.2mg I.V given 45min before intubation. Patient was shifted to the operating theatre. Once the patient was shifted to OT their basal HR, NIBP, SPO 2 were noted and monitoring was started. I.V access was obtained with 18G venflon.4% lignocaine 4 ml was used for nebulizing the upper and lower airway.10% Lignocaine oral spray. Xylometazoline nasal drops were instilled.

Flexible fibreoptic bronchoscopy guided tracheal intubation with appropriately sized endotracheal tubes was done. Intubation conditions was evaluated by Total Comfort Score (TCS).

Adverse effects if noted were treated as follows:

Bradycardia with Inj. Atropine 0.6 mg I.V

Hypotension with IV fluids and Inj.Ephedrine 6 mg I.v bolus. Desaturation managed by connecting oxygen cannula through side port of FOB

Total Comfort Score

Levels of comfort and sedation were assessed by Total comfort score which contains seven parameters and each one is rated from a scale of one to five, one being minimum and 5 being maximum.

	1	2	3	4	5
Alertness	Deeply asleep	Lightly asleep	Drowsy	Fully awake	Hyper alert
Calmness	Calm	Slightly anxious	Anxious	Very anxious	Panicky
Respiratory response	No coughing and no spontaneous respiration	Spontaneous respiration	Occasional cough	Coughing regularly	Frequent coughing or choking
Crying	Quiet breathing, no crying	Sobbing or gasping	Moaning	Crying	Screaming
Physical movement	No movement	Frequent slight movement	Vigorous movement limited to extremities	Vigorous movements including torso and head	Occasional slight movement
Muscle movement	Muscles totally relaxed no movement	Reduced muscle tone	Normal muscle tone	Increased muscle tone and flexing of fingers and toes	Extreme muscle rigidity and flexing of fingers and toes
Facial tension	Facial muscle totally relaxed	No facial tension evident	Tension evident through muscle	Facial muscle contorted	Grimacing

Seven parameters which include alertness, calmness, respiratory response, crying, physical movement, muscle movement and facial tension.

Statistical software: The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Sample Size: Sample was estimated based on total comfort scale during pre-oxygenation, during trans-nasal fibreoptic-scopy (FOS), and during endotracheal tube intubation.

In a study conducted by Sharif kamalarafa and Amirabozikryelsayed, During FOS the average variance of total comfort scale was 3.6 with a mean difference of 1.68 with 95% confidence interval, with 80% power to find an effect size of 0.89(14% different in total comfort scores) the required sample size per group is estimated at 30[5]

Results

Table 1: Age distribution of patients studied between two groups.

Age in years	Group A	Group B	Total
20-30	7(23.3%)	8(26.7%)	15(25%)
31-40	4(13.3%)	8(26.7%)	12(20%)
41-50	5(16.7%)	5(16.7%)	10(16.7%)
51-60	14(46.7%)	9(30%)	23(38.3%)
Total	30(100%)	30(100%)	60(100%)
Mean ± SD	44.47±14.16	41.50±13.22	42.98±13.66

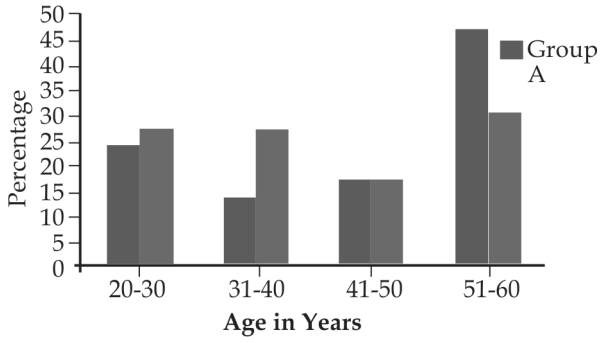

Fig. 1: Bar Diagram Showing Age.

The Mean age of subjects in group A was 44.47±14.16 years and in group B was 41.50±13.22 years. There was no significant difference in mean age between two groups with p value P=0.405. (Fig. 1 & Table 1)

Table 2: Weight (kg) distribution in two groups of patients studied.

Weight (kg)	Group A	Group B	Total
<50	3(10%)	4(13.3%)	7(11.7%)
50-60	10(33.3%)	7(23.3%)	17(28.3%)
61-70	3(10%)	13(43.3%)	16(26.7%)
>70	14(46.7%)	6(20%)	20(33.3%)
Total	30(100%)	30(100%)	60(100%)
Mean ±SD	65.80±12.25	63.27±10.47	64.53±11.37

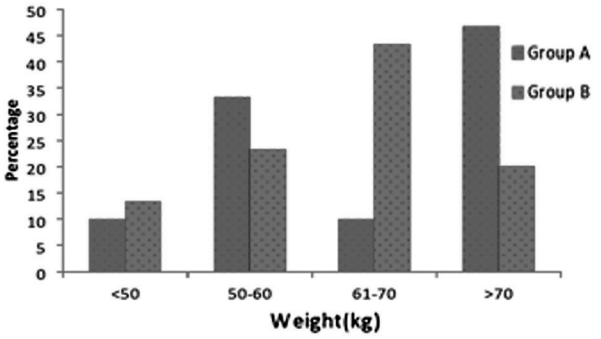

Fig. 2: Bar Diagram Showing Weight Distribution between Two Groups.

Mean weight of subjects in Group A was 65.80±12.25 kgs and in Group B was 63.27±10.47kgs. There was no significant difference in mean weight between two groups.(Figure 2 & Table 2).

Table 3: Gender distribution of patients studied.

Gender	Group A	Group B	Total
Female	12(40%)	12(40%)	24(40%)
Male	18(60%)	18(60%)	36(60%)
Total	30(100%)	30(100%)	60(100%)

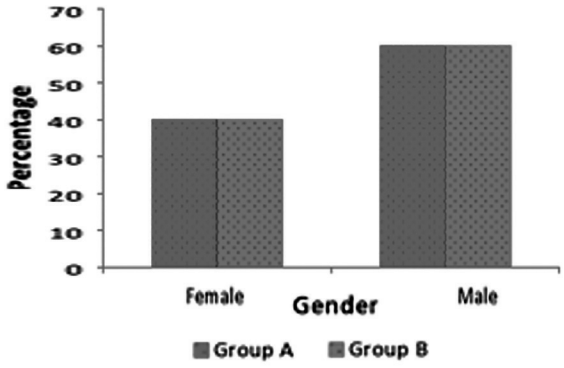

Fig. 3: Bar Diagram Showing Gender Distribution Between Two Groups.

Samples are gender matched with P=1, Chi-Square test. In this study, 40% were females and 60% were males. There was no significant difference in gender between two groups. (Fig. 3 & Table 3).

Table 4: Comparison of vital parameters in two groups of patients studied.

Variable	Group A	Group B	Total	P value
Pulse Rate	80.1±10.87	80.33±11.35	80.22±11.02	0.935
SBP (mm Hg)	120±10.17	116.33±10.66	118.17±10.49	0.178
DBP (mm Hg)	75±9.74	71.33±10.08	73.17±10	0.157
MAP (mm Hg)	89.93±9.42	86.27±9.89	88.1±9.75	0.147
RR	13.57±1.28	13.6±1.57	13.58±1.42	0.928
Spo2%	98.37±1.13	97.83±1.26	98.1±1.22	0.090+

On comparison of vital parameters between two groups Group A has better hemodynamic stability. (Fig. 4 & Table 4)

Variables that were compared areAlertness, Calmness, Respiratory response, Crying, Physical Movement, Muscle Movement and Facial tension. (Fig. 5 & Table 5).

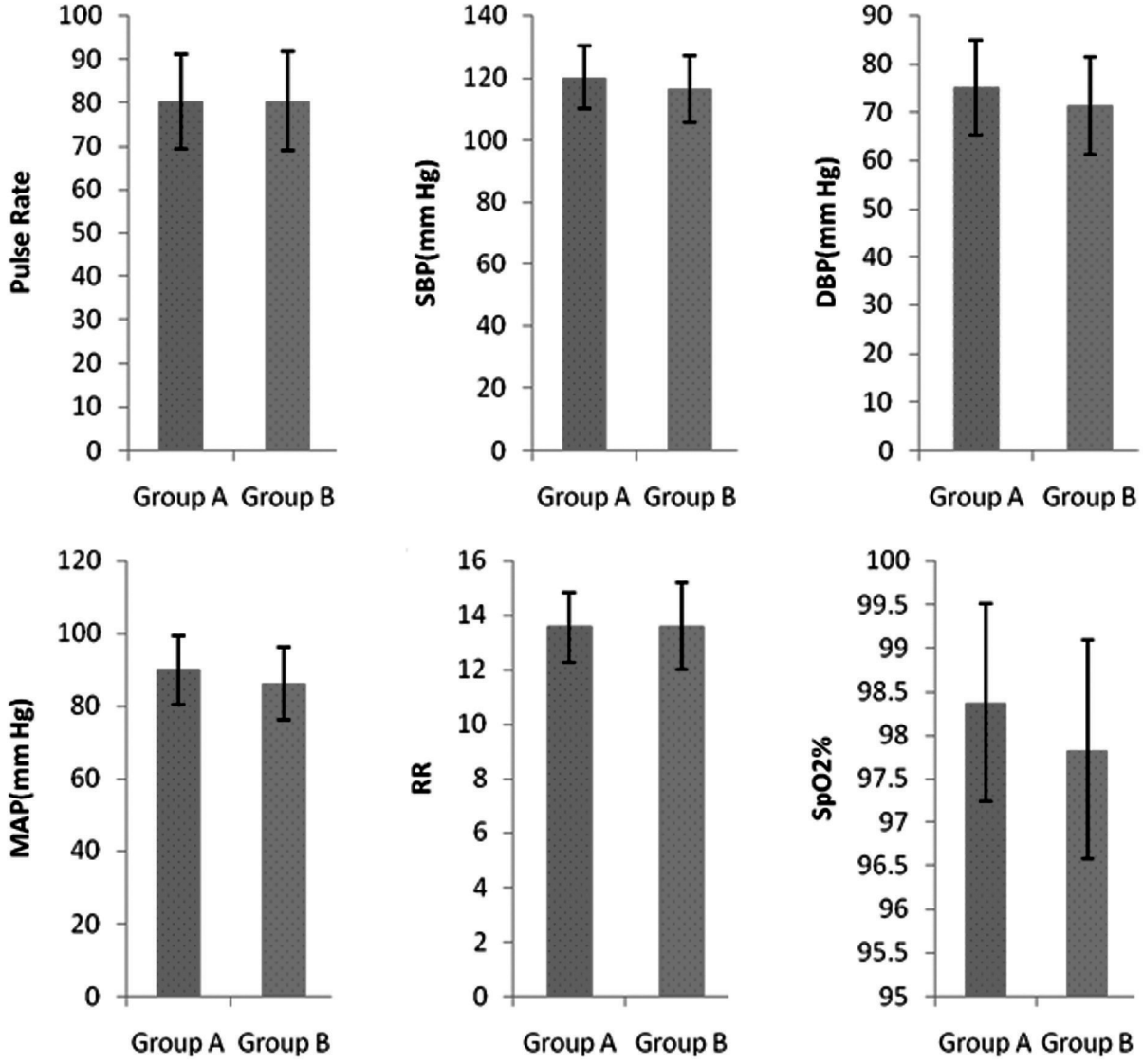

Fig. 4: Bar Diagram Showing Comparision of Vital Parameters between Two Groups.

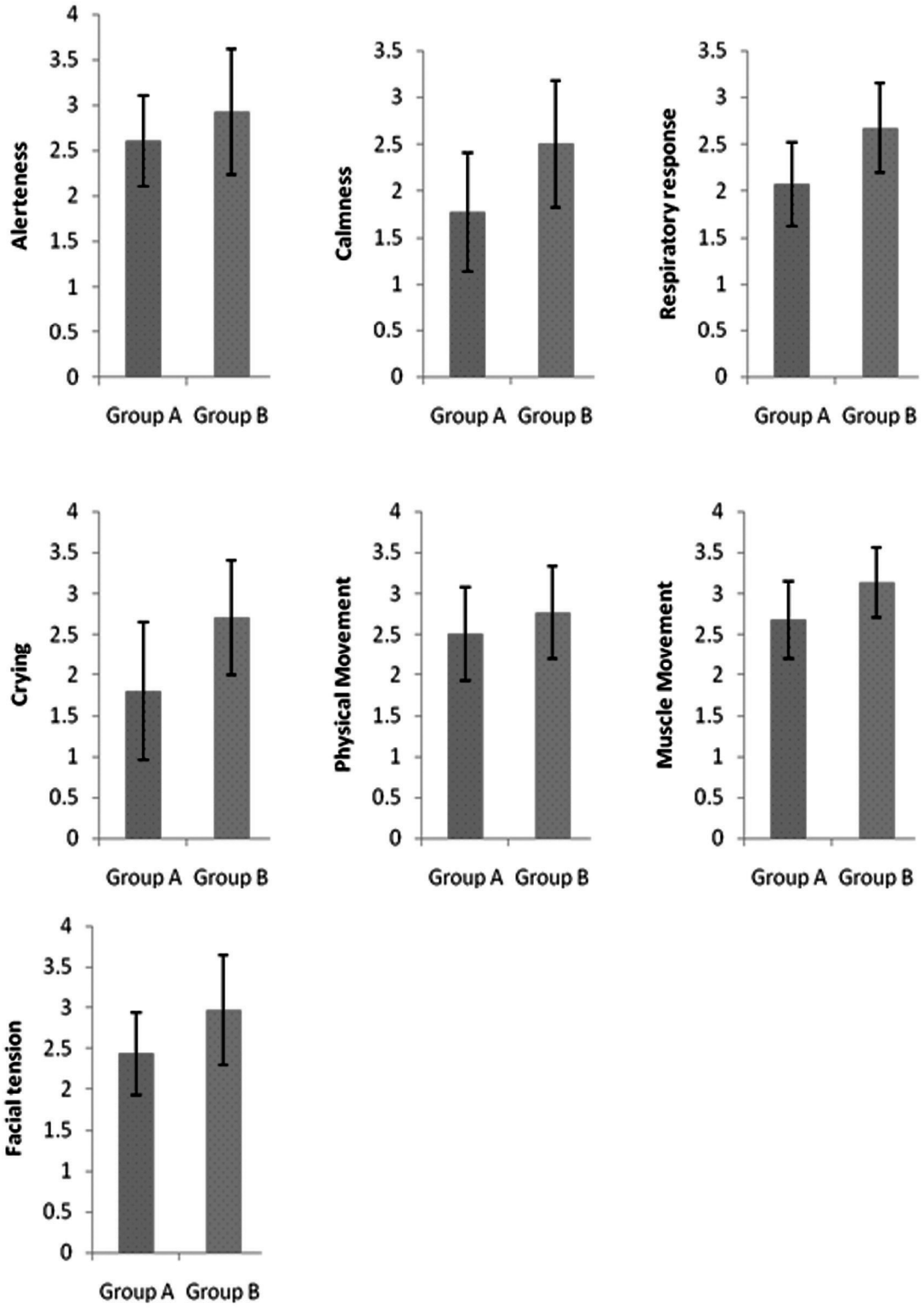

Fig. 5: Bar Diagram Showing Comparision Of Study Variables Between The Two Groups.

Table 5: Comparison of study variables (TCS) in two groups of patients studied.

Variables	Group A	Group B	Total	P value
Alertness	2.60±0.50	2.93±0.69	2.77±0.62	0.036*
Calmness	1.77±0.63	2.50±0.68	2.13±0.75	<0.001**
Respiratory response	2.07±0.45	2.67±0.48	2.37±0.55	<0.001**
Crying	1.80±0.85	2.70±0.70	2.25±0.89	<0.001**
Physical Movement	2.50±0.57	2.77±0.57	2.63±0.58	0.075+
Muscle Movement	2.67±0.48	3.13±0.43	2.90±0.51	<0.001**
Facial tension	2.43±0.50	2.97±0.67	2.70±0.65	0.001**

Table 6: Total Comfort Scores between the two groups.

Total Comfort Score	Group A	Group B	Total
<20	28(93.3%)	14(46.7%)	42(70%)
20-30	2(6.7%)	16(53.3%)	18(30%)
Total	30(100%)	30(100%)	60(100%)

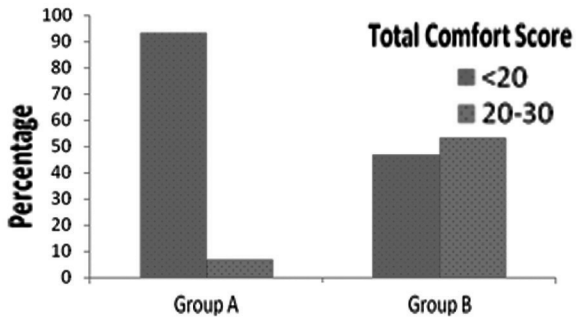

Fig. 6: Bar Diagram Showing Comparision Of Total Comfort Scores Between The Two Groups.

The TCS was scored from 7 to 35 with 7 being minimum and 35 being maximum score and in group A patients the average TCS was 15.84 ± 0.54 and in group B patients the average TCS was 19.67 ± 0.67 with a p value of < 0.001 which was significant using chi square test. (Fig 6 & Table 6)

Significant figures

+ Suggestive significance (P value: 0.05<P<0.10)

* Moderately significant (P value:0.01<P≤ 0.05)

** Strongly significant (P value: P≤0.01)

Discussion

In case of difficult airway scenarios, awake intubation is essential Awake fibreoptic bronchoscope guided intubation is one of the best method to secure airway in a case of anticipated difficult airway. For AFOI, different drugs were used to produce sedation while preserving spontaneous respiration.[6]

Endotracheal intubation in an awake state, if performed without Adequate sedation can be an unpleasant and discomforting experience for the patient. The various drugs used for sedation during AFOI are as

Follows:

1. Benzodiazepine (Midazolam)
2. Propofol
3. Alpha 2 agonists (clonidine &Remifentanil)
4. Ketamine

The above-mentioned drugs can be used alone or in combination with others and in various dosages as per the requirements of the patient, Clinical settings, operative conditions. An ideal sedative regimen for AFOI should provide patient comfort &cooperation, amnesia Anxiolysis, anti-tussive properties/attenuation of airway reflexes Stable hemodynamics and maintenance of a patent airway.[7]

The search for an Ideal sedative regimen for Awake Fibre optic Intubation is being constantly pursued by various clinical studies.[8]

Dexmedetomidine is a highly selective alpha 2 agonist mainly Acting upon the pontine Locus coeruleus nucleus producing sedation. Further, it has Anxiolytic, Analgesic and Anti sialagogue properties. An Important property of Dexmedetomidine is that it produces sedation without respiratory depression; in contrast opioid agonists produce Significant respiratory depression.[9]

This was a comparative two group clinical study carried out at R L Jalappa hospital and research centre, Tamaka, Kolar, during the Academic year from January 2019-June 2020.Sixty patients of age group 20-60 years with ASA grade I, II of both sex undergoing elective surgeries with anticipated difficult airway by general anaesthesia were included. patients were randomly segregated into two groups of 30 each after obtaining informed consent.

In this study we compared two different doses of dexmedetomidine, one with higher maintenance dose and the other with low maintenance dose for sedation during awake trans nasal endotracheal fibreoptic intubation.

GROUP A: received Dexmedetomidine 1mcg/ kg as a bolus dose slowly over 10 minutes then

0.8mcg/kg/hr. as a maintenance dose by a syringe pump.

GROUP B: received Dexmedetomidine 0.8mcg/kg as a bolus dose slowly over 10 minutes then 0.2mcg/kg/hr. as a maintenance dose by a syringe pump.

All patients had been counselled about the procedure and were premedicated with drugs T. Alprazolam 0.5 mg the night before the Surgery, T. Ranitidine 150 mg and T. Ondansetron 4 mg were given 2 Hours before the surgery.Inj.Glycopyrrolate 0.2mg I.V given 45min before intubation. Patient was shifted to the operating theatre. Once the patient was shifted to OT their basal HR, NIBP, SPO2 were noted and monitoring was started. I.V access was obtained with 18G venflon.4% Lignocaine 4 ml was used for nebulizing the upper and lower airway.10% Lignocaine oral spray. Xylometazoline nasal drops were instilled.

Then as per the study and the patient's group, dexmedetomidine loading doses were given before fibreoptic intubation, in group A 1µg/kg over 10 minutes and in group B 0.8µg/kg over 10 minutes.

After this maintenance dose of dexmedetomidine by a syringe pump was commenced in both groups and fibreoptic intubation was started, a well lubricated Fibreoptic bronchoscope preloaded with the appropriate ETT was inserted through the Nasal route and Intubation was successfully performed in all the patients. The infusion is continued till the end of the procedure that is securing the airway by endotracheal tube.

Intubation condition and tolerance to Intubation was assessed by Total Comfort Score (TCS). The Mean Arterial Pressure and the Heart Rate, Oxygen saturation using SpO_2 was monitored throughout the Intubation procedure.

Both the groups were comparable in terms of age, weight, gender and ASA grading in our study. In our study, we observed that there was significant difference in the Total comfort scores among the two groups, in group A the TCS was below 20 in 28 patients out of 30, whereas only 14 patients had a score less than 20 in group with p value <0.001 which was statistically significant. We also observed that TCS above 20 was seen in only 2 patients in group A where as in group B it was seen in 16 patients with a p value of <0.001 which was also statistically significant.

By seeing significant difference in the TCS, we conclude that dexmedetomidine at 1µg/kg bolus with 0.8mcg/kg/hr. Infusion was better at providing optimal sedation and comfort levels for the patient with spontaneous respiratory efforts being preserved; we also didn't observe any significant side effects during the procedure with higher maintenance dose.Peden et al., found that that bradycardia was observed in thePatients of healthy volunteers following dexmedetomidine administration and that can be prevented by administration of Glycopyrrolate before Intubation thereby preventing the side effects of dexmedetomidine.[10]

Bergere et al has observed that Dexmedetomidine in combination with low dose Midazolam is more effective than Midazolam alone for sedation in Awake Fibreoptic Intubation and that Dexmedetomidine at 1ug/kg bolus was safe and of good benefit for patients undergoing Awake Fibreoptic intubation even without airway nerve block or topical Anaesthesia.[11]

Further, Dexmedetomidine has been proved as an effective sedative agent for AFOI in difficult airway scenarios.[12] Venn et al reported unaltered hemodynamics even in higher doses of Dexmedetomidine infusion.[13]

Conclusion

We concluded that dexmedetomidine especially with loading dose 1µg/kg and higher maintenance dose 0.8µg/kg/h was better for fibreoptic intubation with better patient tolerance, patient comfort, patient satisfaction, good sedation and preserved upper airway with spontaneous breathing.

Conflicts of Interest: Nil

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