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# THE COMPARATIVE STUDY TO EVALUATE THE EFFECTIVENESS OF DEXMEDETOMIDINE VERSUS PROPOFOL INTRAVENOUS INFUSION TO FACILITATE AWAKE FIBREOPTIC NASOTRACHEAL INTUBATION.

Anaesthesiology

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## ABSTRACT

Awake fiberoptic intubation (AFOI) is the most valuable technique in the management of difficult airway. This study aimed to compare the effectiveness of dexmedetomidine vs propofol infusion in providing conscious sedation during AFOI

**Method-** Sixty eight patients with anticipated difficult intubation posted for elective surgery were enrolled and randomly allocated into the dexmedetomidine (groupA) (0.4mcg/kg bolus infusion over 10 min, followed by0.12mcg/kg/min) (n = 34) or the propofol (groupB)(0.8mg/kg bolus infusion over 10 min, followed by 0.08 mg/kg/min) (n = 34). Endoscopy and intubation conditions, level of sedation amnesia and patient satisfaction as graded by a scoring system were evaluated as the outcomes.

**Results-**Intubation was successful in all patients.There was statistically significant difference in mean endoscopy score (1.71 vs 2.15 ), mean intubation scores for vocal cord movement (1.29 vs 1.68 ) and the mean postintubation scores (1.68 vs 2.21 ) whereas no statistically significant difference was found in mean endoscopy scores for coughing (1.79 vs 2.15 ) and limb movement (1.53 vs1.82 ) The time taken for endoscopy (116.94 seconds vs 124.32 seconds ) and for the intubation (27.21seconds vs27.06 seconds)were similar in two groups .Patients in the propofol group had a significantly higher level of sedation (OAA/S score 2.76vs4.65). Recall of endoscopy and intubation was(gp A vs gpB;82.4% vs 23.5%). There was no statistically significant difference regarding patient satisfaction between the two groups

**Conclusion.** Dexmedetomidine and propofol both were effective for providing conscious sedation during awake fibreoptic nasotracheal intubation.Dexmedetomidine provided better endoscopy and intubation conditions,similar haemodynamic stability without causing any respiratory distress.

## KEYWORDS

Dexmedetomidine, Propofol, Fibreoptic Nasotracheal Intubation

## INTRODUCTION

Fibreoptic nasotracheal intubation is a useful technique in a situation when the patient's neck can not be manipulated or when it is not possible to visualize the vocal cords because a straight line view can not be established from the mouth to the larynx[1]. Fibreoptic intubation can be performed either awake or under general anaesthesia and it can be performed either as an initial management of a patient known to have difficult airway or as a back up technique after direct laryngoscopy has been unsuccessful[1] Fibreoptic nasal intubation has the advantage over blind nasal intubation of allowing intubation to be performed under direct vision[2] and it also minimizes hemodynamic responses as pharyngeal stimulation of rigid laryngoscopy is avoided.

The difficult airway algorithm devised in 1991 by the American Society of Anaesthesiolosists emphasizes that patients with "difficult airway" should be intubated awake[3]. Awake fibreoptic intubation is aided if the patient achieves a state of 'conscious sedation', that is,the patient receives anxiolysis so optimizing compliance but not so sedated that co-operation is lost[4]. With sedation and topical anaesthesia, fibreoptic nasotracheal intubation makes most patients calm and comfortable yet responsive[4].

Although the skill of endoscopy is obviously important in the setting of awake fibreoptic intubation, success or failure of the technique frequently depends on the adequacy of preparation.These measures include preoperative assessment of the patient,careful explanation of the procedure, preparing the equipment to be used and preparing the patient (antisialogue,sedation and application of topical anaesthesia). If these measures are carried out meticulously, the likelihood of performing a successful and comfortable awake fibreoptic intubation is greatly increased[5].

Many agents have been reported to achieve conscious sedation for intubation including fentanyl, midazolam, ketamine, propofol, remifentanil and dexmedetomidine[6,7,8,9,10,11]. Dexmedetomidine, an alpha-2 adrenoceptor agonist may be a valuable drug for use during awake fibreoptic intubation as it induces sedation and analgesia without depressing respiratory functions[10,12] . Thus dexmedetomidine has many properties that makes it a suitable drug for use in managing patients with difficult airway and it is feasible that when used as a sole agent or as an adjunct dexmedetomidine is efficacious for conscious sedation[10,13,14,15]. There have been numerous reports of propofol,use either alone or in combination to achieve adequate level of sedation for such procedures[11]. The aim of this study was to compare the effectiveness of dexmedetomidine and propofol for providing optimal conditions for fibreoptic intubation while used as sedatives during awake fibreoptic nasotracheal intubation in anticipated difficult intubation cases in terms of endoscopy and intubation conditions,level of sedation, amnesia and patient satisfaction

## Method

This randomized double-blind hospital based interventional study was conducted in the Department of Anesthesiology, S.M.S Medical College and attached group of hospitals, Jaipur with due permission from the institutional ethics committee and research review board. After taking written informed consent we enrolled 68 ASA grade 1-3 patients of age 25 to 75years of either sex requiring awake fibreoptic nasotracheal intubation for elective oral,head and neck cancer surgery,patients with restricted mouth opening <2 fingers(TMJ ankylosis, sub mucous fibrosis etc.),history of previous difficult intubation posted between september 2013 to july 2014. Exclusion criteria were: pregnancy; use of an $\alpha_2$ adrenoreceptor agonist or antagonist within the previous 14 days, known or admitted alcohol or drug misuse , resting heart rate (HR) <60 $min^{-1}$; patients with A-Vblock,heart failure, lack of understanding by the patient of the purpose of the study, and thrombocytopenia or coagulopathy contraindicating nasal intubation .

The sample size was calculated 34 subjects for each group at alpha error 0.05 and power 80%. of each" as per intubation score for vocal cord movement(scores-1) expecting difference of medians to be detected of intubation score for vocal cord movement scores-1 in Dexmedetomidine group and Propofol group 7 with SD 10 as per the seed article[16]. Patients were assigned randomly into two groups of 34 subjects each using pre-sealed opaque envelopes prepared and drawn by an independent observer to receive sedation either with dexmedetomidine (Group A) or propofol(Group B).

All patients were examined before surgery and assessment of difficult airway was carried out based on interincisor gap,thyromental

distance,mallampati grade and head and neck movement.Those with difficult airway were selected for the study. All study subjects were explained about the technique of fibreoptic bronchoscopy and intubation .For the study two experienced anaesthetists,who routinely performed awake fibreoptic intubation clinically managed the study .One anaesthetist performed fibreoptic intubation, while the other anaesthetist controlled the drug infusion. Anaesthetic data and post operative visit were documented by a study Observer. Endoscopy and intubating conditions were graded by the anaesthestist who was preforming the fibreoptic intubation . The intubating anaesthetist, patients and the study Observer were blinded to the study. For the purpose of blinding , Infusion pump and the arm with I V line were kept behind a screen so that it was not visible to the observers. On arrival in the operation theatre baseline parameters oxygen saturation($SpO_2$), Heart rate (HR), Systolic blood pressure(SBP),diastolic blood pressure(DBP) and mean arterial pressure(MAP) were recorded Intravenous lines with 18 / 20 G cannula were secured in a larger vein of forearm. Premedication with Inj. Glycopyrrolate (0.2mg i v) , Inj. Midazolam (1mg i v, if weight of the patient was less than 70 kg and 1.5mg i v, if weight more than 70 kg) were given.The study drug were prepared and administered using an infusion pump. Dexmedetomidine was prepared at the concentration of 2 mcg/ml (100 mcg diluted to 50 ml with normal saline), Propofol was prepared at the concentration of 2mg/ml(100 mg diluted to 50 ml with normal saline)

Dexmedetomidine was given as 0.4mcg/kg bolus infusion over 10 min, followed by0.12mcg/kg/min whereas Propofol was given as 0.8mg/kg bolus infusion over 10 min, followed by 0.08 mg/kg/min. till intubation was successful . While IV bolus was being administered,0.1% xylometazoline nasal drops and 3 to 4 puffs of 10% lignocaine were sprayed in each nostril and then tongue and hypopharynx was sprayed with 6 to 8 puffs of 10% lignocaine and 2ml of 4% ligocaine was injected transtracheally in both the study groups. At the end of bolus infusion,maintenance dose was started and the fibreoptic bronchoscope was introduced. Maintenance drug infusion was continued till intubation was successful Once the glottic structure was identified, another 1ml of 4% lignocaine was sprayed directly on the glottis via the working channel of the fibreoptic scope,and the procedure of fibreoptic intubation was completed. If the patient could not be intubated in the first attempt,or the tube was coughed out or it was not possible to introduce the tube through the glottis, additional rescue dose-1/4$^{th}$ of initial bolus was planned to be given over 2 minutes and the procedure was to be repeated.If there was any episodes of apnoea>60 seconds or a drop in oxygen saturation < 95%, the rescue plan was to decrease infusion rate to half , and to institute bag and mask ventilation with 100% oxygen as necessary .For episodes of apnoea longer than 2 minutes,it was planned to discontinue the infusion and to commence bag and mask ventilation until the patient started to breathe spontaneously.Once the patient started to breathe spontaneously, infusion was restarted at half the initial bolus rate. Following parameters were measured during and after the procedure of fibreoptic intubation :Endoscopy score, Intubation score, Post-intubation score,Endoscopy time,Intubation time, No. of intubation attempts,Hemodynamic parameters,Observers Assessment of Alertness/Sedation scale, Post op interview and satisfaction score Various scores measured during the procedure were;

**Endoscopy score:** Grimacing=1, Localizing=2 , Coughing on lidocaine via scope=3, Coughing on entering infraglottic space=4, Prolonged coughing=5 Intubation score for Vocal Cord Movement: Open =1, Moving=2, Closing=3, Closed=4 .Intubation scores for Coughing and limb movement; None=1, Slight=2, Moderate=3= Severe=4. Endoscopy time was defined as time interval between insertion of fibroscope in the nostril to visualisation of carina and Intubation time was calculated from time of insertion of tracheal tube into nose to confirmation of tracheal intubation by capnography

Soon after the procedure:Post intubation score was assessed and graded as; Co operative=1, Restless,Minimal Resistance=2, Severe Resistance,GA Required=3.Level of sedation was graded by Observers Assessment of Alertness/Sedation Scale(OAA/S) .To assess OAAS scale,the intubation sequence was be separated into five stages: Stage-0(start):10 minutes preceding fibroscope,Stage-1(entry): introduction of fibroscope into nasal cavity,Stage-2(topical):topical anaesthesia of glottis and passage of fibroscope ,Stage-3:passage of ETT through nasal cavity,Stage-4:passage of ETT through trachea .Obsersers Assessment ofAlertness/sedation Scale was; Responds readily to name spoken in normal tone=5, Lethargic response to name spoken in normal tone==4, Responds only after name is called loudly and or repeatedly=3, Responds only after mild shaking or prodding=2, Does not respond to mild shaking or prodding=1.The heart rate, systolic BP,diastolic BP and arterial saturation were recorded every two minutes.Three time points were used for analyzing hemodynamic parameters1.Baseline (before premedication) 2.Infusion (at the end of bolus infusion) 3.intubation (immediately after intubation).

At the 24-h postoperative follow-up visit, patients were interviewed to assess their recall of pre-anesthesia events, administration of topical anesthesia, endoscopy and intubation. Patient satisfaction with the whole procedure was assessed on four grades; Excellent-1,Good-2,Acceptable-3,Poor-4.

Statistical analysis was done by using appropriate standard qualitative and quantitative tests.Paired t-tests was used for comparison of data within the groups and unpaired t-test for comparison of data between the groups.For qualitative data Chi –square test was used.

## Results

A total of 68 patients were enrolled and randomized into Group-A(dexmedetomidine) and GroupB(propfol) and all of them completed the study . Patient's demographic and clinical characteristics did not differ between the groups (Table 1).It was observed that baseline haemodynamic parameters and the arterial saturation were nearly similar in both the groups and no statistically significant difference was present.The mean endoscopy score was 1.71±0.76 and 2.15±0.82 in group A and Group B respectively.The p-value using the Student's t-test was 0.0247 which was stastistically significant.(Table-2) The mean intubation score for vocal cord movement were 1.29 ± 0.46 and 1.68± 0.64 in Group A and Group B respectively( p-value0.006) difference was statistically significant. The mean intubation scores for cough were 1.79±0.59 and 2.15±0.93 respectively in Group A and Group B. The mean intubation scores for Limb movement were 1.53±0.61 and 1.82±0.83 for group A and Group B respectively and the difference was statistically not significant(Table-2) The mean postintubation scores for the Group A and the Group B were 1.68±0.68 and2.21±0.69 respectively.The difference was statistically significant (Table-2) The mean time for endoscopy and intubation in Group A were 116±23.69 seconds and 27.21±6.48 seconds respectively.In Group B the mean time taken for endoscopy and intubation were 124.32±30.49 seconds and 27.06±7.24 seconds respectively.The difference between the two groups was not statistically significant with p-values > 0.05(Table-2)

Level of sedation was assessed using the OAA/S score during five stages of intubation procedure. Significantly lower scores were obtained in Group B as compared to Group A from stage -2 through stage -5 indicating a higher level of sedation (p-value <0.001 using unpaired t-test) with propofol(Table-3)

There was no statistically significant difference regarding the number of intubation attempts between the two groups(table-3). All patients were intubated successfully.There was no statistically significant difference regarding the time taken for endoscopy (116.94 seconds vs 124.32 seconds ) and the time taken for intubation (27.21seconds vs27.06 seconds)

The mean satisfaction score in group A and group B were 1.41±0.50 and 1.54±0.42 respectively.The difference was not significant statistically. In Group A,56% of the subjects recalled endoscopy whereas in Group B the percentage of the subjects recalled endoscopy was 15. The difference was statistically significant(p-value <0.001). In Group A 47% of the subjects recalled inubation while in Group B only 2.9% of the study subjects recalled intubation procedure.The difference was statistically significant (p-value <0.001). Amnesia was present in 18% of the subjects in Group A and 77% of the subjects in the Group B. The difference was statistically significant .(p- value <0.001). Mean arterial pressure and heart rate were not significantly altered during the procedure in both the groups(Figure2,3).There was no incidence of bradycardia in group A ,whereas arterial saturation dropped significantly in group B subjects(Figure-1).

**(Table -1) Demogrphic variables expressed as mean and SD**

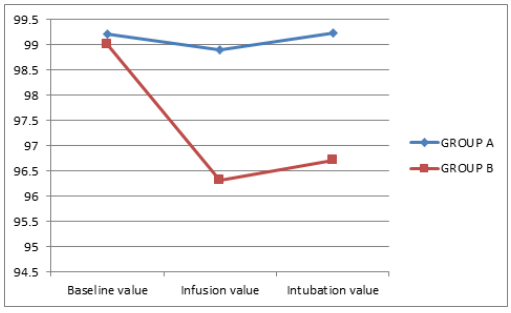
| Characteristics | GroupA(n=34) | GroupB(n=34) | P value |
|---|---|---|---|
| Age(in years) | 40.88±13.88 | 38.09±14.27 | 0.416 |
| Weight (Kg) | 51.7±17.38 | 51.74±8.21 | 0.9877 |
| ASA grade | 1.32±0.47 | 1.35±0.49 | 0.8013 |

**(Table 2) Various scores observed during fibreoptic intubation in patients receiving dexmedetomidine or propofol during awake fibreoptic intubation**

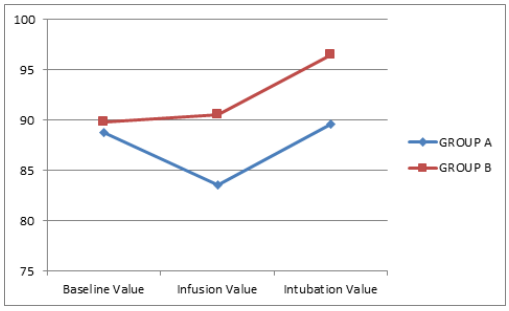
| | | GroupB (propofol) | p value |
|---|---|---|---|
| Endoscopy score | | | |
| 1/2/3/4/5 | 16/12/6/0/0 | 7/17/8/2/0 | |
| mean±SD | 1.71±0.76 | 2.15±0.82 | 0.0247 |
| Intubation score | | | |
| **Vocal cord movement** | | | |
| 1/2/3/4 | 24/10/0/0 | 14/17/3/0 | |
| mean±SD | 1.29±0.46 | 1.68±0.64 | 0.0063 |
| **cough** | | | |
| 1/2/3/4 | 10/21/3/0 | 10/11/11/2 | |
| mean±SD | 1.79±0.59 | 2.15±0.93 | 0.0662 |
| **limb movement** | | | |
| 1/2/3/4 | 18/14/2/0 | 14/13/6/1 | |
| mean±SD | 1.53±0.61 | 1.82±0.83 | 0.1030 |
| Post intubation score | | | |
| 1/2/3 | 15/15/4 | 5/17/12 | |
| mean±SD | 1.68±0.68 | 2.21±0.69 | 0.0022 |
| Endoscopy time(sec) | 116.94±23.69 | 124.32 ±30.49 | 0.2692 |
| Intubation time(sec) | 27.21±6.48 | 27.06±7.24 | 0.9300 |
| No.of Intubation attempts | | | |
| 1/2 | 23/11 | 22/12 | |
| mean±SD | 1.32±0.47 | 1.35±0.49 | 0.8013 |

**(Table-3 ) Various scores observed postintubation**

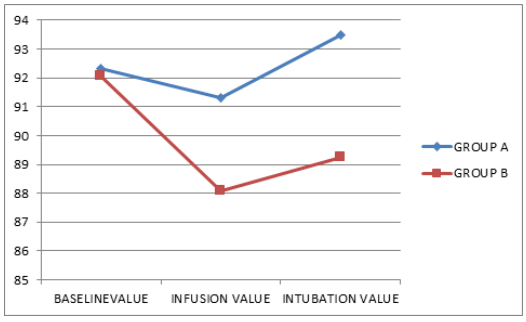
| | GroupA(Dexmedetomidine) | GroupB (propofol) | p value |
|---|---|---|---|
| **OAA/S score** | | | |
| Stage 1 | | | |
| 5/4/3/2/1 | 34/0/0/0/0 | 34/0/0/0/0 | #DIV/0 |
| mean±SD | 5±0.0 | 5±0.0 | 0.0000 |
| Stage 2 | | | |
| 5/4/3/2/1 | 31/3/0/0/0 | 7/17/8/2/0 | |
| mean±SD | 4.91±.29 | 3.85±0.82 | 0.0000 |
| Stage 3 | | | |
| 5/4/3/2/1 | 27/6/1/0/0 | 2/14/16/2/0 | |
| mean±SD | 4.76±0.50 | 3.47±0.71 | 0.0000 |
| Stage 4 | | | |
| 5/4/3/2/1 | 25/7/2/0/0 | 1/7/22/4/0 | |
| mean±SD | 4.88±0.59 | 3.15±0.66 | 0.0000 |
| Stage 5 | | | |
| 5/4/3/2/1 | 24/8/2/0/0 | 1/2/21/8/1 | |
| mean±SD | 4.65±0.60 | 2.76±0.78 | 0.0000 |
| **Satisfaction score** | | | |
| 1/2/3/4 | 20/14/0/0 | 17/14/3/0 | |
| mean±SD | 1.41±0.50 | 1.58±0.62 | 0.0000 |
| **Recall of Endoscopy** | | | |
| Yes/no | 19/15 | 5/29 | |
| Percentage | 55.9/44.1 | 14.7/85.3 | 0.0000 |
| **Recall of Intubation** | | | |
| Yes/no | 16/18 | 1/33 | |
| Percentage | 47.1/52.9 | 2.9/97.1 | 0.00014 |
| **Amnesia** | | | |
| Yes/no | 6/28 | 26/8 | |
| mean±SD | 17.6/82.4 | 76.5/23.5 | 0.0000 |




**(Figure 1) Arterial oxygen saturation changes**




**(Figure-2) Heart rate changes**




**(Figure-3) Mean arterial pressure changes**

## Discussion

Dexmedetomidine has been shown to offer adequate conscious sedation for the fibreoptic intubation of patients with anticipated difficult airway.Abdelmalak et al. reported a series of fibreoptic intubations using dexmedetomidine for sedation in patients with difficult airways caused by a subglottic mass,a thyroid tumour causing tracheal compression,a nasopharyngeal tumour causing obstructive sleep apnoea,and morbid obesity with sleep apnoea[10]..Propofol is widely used in anaesthetic practice to facilitate tracheal intubation and recent developments in propofol delivery using TCI offers reliable techniques for providing safe sedation[11].

Yavacaoglu et al. reported that dexmedetomidine prevented the hemodynamic responses to tracheal intubation more effectively than esmolol during awake fibreoptic intubation[17].Dexmedetomidine offered better endoscopy scores, lower recall of intubation, and greater patient satisfaction, with minor hemodynamic and respiratory side effects when compared with remifentanyl[18]and sufentanil[19].

Lee JH et al[20]. reported that low dose propofol infusion is a useful sedative agent in fiberoptic awake intubation with similar efficacy to midazolam and fentanyl but with more profound sedation and stable hemodynamic profile..Propofol delivery with a TCI system was compared with dexmedetomidine intravenous infusion by J Tsai. et al[16] for awake fibreoptic intubation and they concluded that propofol TCI provided conditions for fibreoptic intubation that were comparable with those provided using dexmedetomidine, but with less favourable patient tolerance and a higher degree of airway obstruction.

In the present study the mean endoscopy scores for Dexmedetomidine group was significantly less as compared to propofol group (p-value 0.0247), showing that the patients in the Dexmedetomidine group experienced a better comfort level during the procedure of fibreoptic endoscopy.It may be attributed to additional analgesic action of dexmedetomidine[10,12].Similar scoring system known as Patient comfort score was used by T Sai et al[16] and K Gupta et al[21] and our results are similar to their study.

Intubation scores in terms of vocal cord movement was better in the dexmedetomidine group, which was significantly less mobile. (p-value 0.006).The difference in intubation scores for coughing and limb movement were not significant statistically.Glycopyrrolate premedication reduces oropharyngeal secretions and thus,topical local anaesthesia solutions are less diluted and remains at the site of application,which is important in preventing cough. A slightly better intubation scores for cough in the dexmedetomidine group may be attributed to its additional analgesic and antisialogogue properties[22,23]. Our results are in accordance with the study of T Sai et al[16] and K Gupta et al[21].

The patients in the Dexmedetomidine group experienced a better tolerance to the procedure of fibreoptic intubation.Most patients in the dexmedetomidine group were co-operative and able to open their eyes to command immediately after nasotracheal intubation.In contrast most patients in the propofol group could not respond to commands and general anaesthesia was required in many of them immediately after nasotracheal intubation.This difference may be attributed to the analgesic, anxiolytic and antisialogogue properties of dexmedetomidine[22,23]. Similar results were obtained in earlier studies[16,21].

Although dexmedetomidine provided significantly better endoscopy and intubation conditions, there was no significant difference between the two groups in terms of time taken for the procedures and our results coincided with earlier studies[16,21]. This may be due to the use of glycopyrrolate premedication to improve the visualisation by reducing oropharyngeal secretions and the effect of local anaesthesia of the airway in minimizing cough and localization. Cattano et al [23] reported first attempt success rate of 38 % with a low dose dexmedetomidine infusion of 0.4mcg/kg. In our study first attempt success rate was comparable in both the groups(67% vs 65%).

In the present study, hemodynamic stability was achieved in most of the patients in both groups. Intravenous infusion of Dexmedetomidine results in a decrease in heart rate especially following rapid infusions[24]. However, significant bradycardia requiring atropine administration (<40beats/minute) was not observed and it could be because of using a slower bolus infusion and a lower dose of 0.4 microgram/kg bodyweight .

The level of sedation in the propofol group was significantly higher as compared to that of the dexmedetomidine group (p-value <0.001).T Sai et al[16] compared the state of entropy to assess the level of sedation and similar higher level of sedation was observed in propofol group. Dexmedetomidine activates the postsynaptic α2-adrenergic receptors in the locus coeruleus, and induces sedation by activation of the endogenous sleep-promoting pathway without the risk of airway obstruction and respiratory depression[12]. Optimum sedation dose for dexmedetomidine for awake fibreoptic intubation has not been established. A loading dose of 0.4 mcg/kg to 1mcg/kg over 10 minutes and beyond has been used to attain sedation[23]. However, respiratory complications with dexmedetomidine have been reported with large and rapid initial loading doses[25]. As a result of lower range of loading dose used, there was no significant airway obstruction or respiratory depression observed with dexmedetomidine group. A wide range of propofol dosage has been used for sedation. The low-dose propofol infusion has been used as an adjunct to local anesthesia for patients undergoing oral, ophthalmologic, and superficial surgeries[26]. However, the infusion rate of propofol may induce a dose related increase in the risk of over sedation and respiratory depression, especially when a large loading dose is used et al[27] used propofol at a lower infusion . Soliman et al used lower dose of 30 mcg/kg/minute for awake fibreoptic intubation and there was no incidence of any respiratory complication. In the present study there was no incidence of arterial hypoxia (drop in arterial saturation <95%) at the dose of 80 mcg/ kg/minute in the propofol group.

Amnesia was present in17.6% of subjects in the dexmedetomidine group and 76% of subjects in the propofol group. This could be due to higher level of sedation with propofol. The percentage of subjects recalling endoscopy and intubation procedure was significantly higher in dexmedetomidine group and this could be explained by higher level of sedation caused by propofol.Eventhough dexmedetomidine provided superior endoscopy and intubation conditions, there was no significant difference with respect to patient satisfaction score and this could be because of higher sedation and amnesia with propofol.

## CONCLUSIONS

Dexmedetomidine and propofol both were effective for providing conscious sedation during awake fibreoptic nasotracheal intubation. With nearly similar hemodynamic stability,dexmedetomidine provided better endoscopy and intubation conditions as compared to propofol without causing any respiratory distress. The level of sedation and amnesia were more with propofol as compared to dexmedetomidine.The level of patient satisfaction was nearly similar in both the groups.

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