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Evaluate the efficacy of dexmedetomidine and fentanyl-midazolam combination on awake fiberoptic intubation in oral cancer surgery

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Abstract
Background: Awake fiberoptic intubation (AFOI) is the principal techniques in the management of difficult airway in oral cancer surgery. The aim of study was to evaluate the efficacy of dexmedetomidine and fentanyl-midazolam combination on awake fiberoptic intubation in oral cancer surgery. An ideal sedation regimen would ensure patient's comfort and co-ordination attenuation of airway reflexes, hemodynamic stability and sedation.
Methods: 60 patients of age group 18-60 years with American Society of Anaesthesiologist I and II posted for oral cancer surgery under general anaesthesia were randomly divided into two groups of 30 each in this prospective randomised and comparative study. Group-D (30 pt): Received an infusion of 1 µg /kg in 100ml Normal saline infusion IV over 10 min. Group-FM (30 pt): Received an infusion of fentanyl 2 µg /kg and midazolam 0.02mg/kg IV in 10ml of normal saline. All Patients were assessed for vocal cord movement, coughing, physical movement, comfort score, Ramsay sedation score, patient satisfaction score, and intubation time and hemodynamics variables.
Results: The demographic characteristics were comparable in two groups (P>0.05).Group-D has more incidence of vocal cord opening than Group-FM. Group-D has less cough score than group-FM. Limb movement scores were more in group-FM than group-D. Group-D were more satisfied than group-FM (P=0.0002). RSS Score was significantly better in Group-D than in Group-FM (P=0.041). Group-D showed significantly reduced hemodynamic response to AFOI than group-FM.
Conclusion: Dexmedetomidine is more effective than fentanyl-midazolam during AFOI, as it provides better intubation condition, hemodynamics stability and sedation.

Keywords: AFOI, dexmedetomidine, fentanyl, midazolam, sedation

Introduction
Difficult airways have a risk to the patients and presents challenges for anaesthesiologists while securing airway during general anaesthesia. Awake Fibreoptic Intubation (AFOI) is used for patients with anticipated difficult intubation and with failed intubation (Due to their anatomy, airway trauma, morbid obesity, head and neck malignancy or unstable cervical spine injuries) [1]. AFOI requires ideal and safe sedation scheme that provides conscious sedation, blunts airway reflexes, patient comfort, patient's co-ordination, hemodynamic stability, amnesia and maintains spontaneous ventilation. Hypoxemia and aspiration are most common issues with AFOI [2]. Many sedative agents with topical anaesthesia and airway blocks were used during AFOI. Dexmedetomidine is specific and selective centrally acting α2 agonist. Opposes the propagation of the pain signals by binding to the presynaptic α2 adrenoceptors, it inhibits the release of norepinephrine. Hypotension and bradycardia produce by activation of the postsynaptic α2 adrenoceptor inhibits the sympathetic activity. Hypnosis, amnesia, analgesia, anxiolysis, sympatholysis and antisialogogue which are desirable effects produced by dexmedetomidine [3]. Fentanyl is synthetic opioids; phenylpiperidine derivative provides analgesia, mild sedation with hemodynamic stability, which is beneficial for AFOI. Respiratory depression, nausea, vomiting and chest wall rigidity associated risk with fentanyl [3-5]. Midazolam is water soluble benzodiazepine. It produces anterograde amnesia, anxiolysis, hypnotic, anti-convulsant, sedative effects. It has undesirable effects which includes nausea, nasal irritation and respiratory depression [6]. In our Study, we compared the efficacy of dexmedetomidine and fentanyl- midazolam combination on awake fibreoptic intubation in oral cancer surgery.

Aim and Objectives

Primary outcomes

Intubation condition

a) Vocal Cord Movement
b) Coughing
c) Patient movement while placement of ETT

- Comfort score
- Patient satisfaction score post-op after operated

1. Excellent
2. Good
3. Fair
4. Poor

Secondary outcomes

Hemodynamics variables like Heart rate, Systolic Blood pressure, Diastolic Blood pressure and saturation were measured.

Materials and Methods

This prospective, comparative and randomized study was conducted after obtaining approval from the institutional Ethical Committee and written Informed consent taken from all 60 adult patients of ASA I-II of either sex, aged 18-60 years having nil mouth opening scheduled to undergo oral cancer surgery under general anesthesia requiring awake fibreoptic Intubation were divided into two groups of 30 each using computer–generated random number. Exclusion criteria included patient's refusal, un co-operative patient, psychiatric patient, pregnant patient, patient on long term opioids or sedatives, known to alcoholic or drugs abusers, drugs allergy, neurological, respiratory, hepatic and renal disorder, heart disease, bleeding disorders, severe bradycardia (baseline heart rate < 60/min), previously operated nostril surgeries and emergency surgeries. All patients were explained about anaesthetic procedure and counselling done. Patients kept fasted for 8hrs prior to surgery. All patients were given tab. lorazepam hydrochloride 1mg at bed time on the previous night of surgery. Other techniques in failed AFOI: retrograde ETT nasal intubation, blind technique and Tracheostomy (T-stomy). On the day of surgery, anaesthesia machine, breathing circuits, resuscitation equipments and T-stomy were checked and kept ready. Patients were shifted to the operating room after confirmation of NPO status. Connected to multi-channel monitor like pulse oximetry (SpO2), electrocardiography (ECG), non-invasive blood pressure (NIBP) was applied and baseline parameters were recorded. Intravenous (I.V) access was secured with 18G cannula and 500 ml of ringer lactate fluid were started. The AFOI was applied on all patients by the same single expert anaesthesiologist. 15 min before the procedure all the patients were premedicated with I.V Inj. glycopyrrolate 0.004 mg/kg, Inj. ondansetron 0.1mg/kg and Inj. ranitidine 1mg/kg. 0.1% Oxymetazoline nasal drops (2 drops in each nostril) were applied to both nostrils, because of vasoconstrictor property; it reduces the risk of bleeding. Both nostrils lubricated with lidocaine 2% jelly, nasopharyngeal airway was inserted for checking nasal patency. Oxygenation at 2-3 L/min was given through opposite nostril via nasal prongs. Airway blocks: 1) Bilateral superior laryngeal nerve block: Inj. xylocard 2%, on each side 2ml is given by 23 gauze needle after negative aspiration at level of thyrohyoid membrane 2-4mm inferior to the cornu of hyoid bone in neck extended position. 2) Recurrent laryngeal nerve block: patient asked to hold the breath during injecting 2% xylocard 3ml in cricothyroid membrane using 23 gauze needle in neck extended position. After that patient asked to take deep breath for spreading the drug over tracheal region. Group-D: Inj. dexmedetomidine 1µg/kg I.V over 10min (in 100ml normal saline). Group-FM: Inj. fentanyl 2µg/kg + Inj. midazolam 0.02mg/kg I.V. Well lubricated 8mm or 7.5mm (in male) & 7.5mm or 7.0mm (in female) internal diameter ET tube mounted over fiberoptic scope. After removing the nasopharyngeal airway, the scope is introduced through the nostril; after visualization of glottis & vocal cord, the scope is passed through the glottis, up to 2-3 cm above the carina. Then the ETT is railroaded over the fibreoptic scope into the trachea; the scope is withdrawn, the cuff is inflated and the tube is fixed after confirming bilateral equal air entry by auscultation and by capnography. Time taken for Insertion of fiberoptic scope to the confirmation of ET Tube Placement by capnography (Intubation Time). Sometimes, while railroading the ETT over scope become difficult, little bit withdrawal and anticlockwise rotation of ETT done. If patient develops severe cough resulting in inability to guide the scope, 2ml of 2% xylocard was injected through the side channel of the scope (such patients were excluded from the study);then general anaesthesia with I.V Inj. thiopentone (5mg/kg) and Inj. Vecuronium (0.1mg/kg); the patient was put on VCV mode of mechanical ventilation. After that surgery was allowed to proceed. At end of surgery, Patients were reversed with Inj. glycopyrrolate 0.008mg/kg I.V + Inj. neostigmine 0.05mg/kg I.V.

Numerical data (like Age, HR, SBP, DBP and Spo2) were analyzed by using unpaired t-test and Categorical data (like Intubation condition, Vocal cord movement, Coughing, Physical movement, Comfort score, Ram say sedation score, Patient satisfaction score) were analyzed with Chi-square test. Probability was considered to be significant if < 0.05 and highly significant if < 0.001.

Results

60 patients scheduled for elective oral cancer surgery under general anesthesia. Patients were divided into two groups: Group-D (dexmedetomidine) and Group-FM (fentanyl-midazolam). There were no clinically significant difference in both groups with respect to demographic characteristics (p>0.05).

Table 1: Demographic profile of both groups.

Descriptive	Group-D (Mean ± SD)	Group-FM (Mean ± SD)	P value
Age(yrs)	37.00 ± 8.45	38.80 ± 8.36	0.4100
Sex (Male: female)	(25:5)	(27:3)	

p>0.05 not significant, p <0.05- significant, p <0.0001- highly significant

VCM ≤ 2 scores (vocal cords were either open or moving in both groups), group-D has more vocal cord movement to AFOI than group-FM (i<0.05). Coughing score favourable in group-D than group-FM (p<0.05). Limb movement was significantly less in group-D as compare to group-FM (p<0.05) which is statistically significant. The patients of Group-D (1.67±0.99) had a lower total comfort scores ≤2 during Intubation as compared to Group-FM (2.73±1.55). These values were statistically significant (p = 0.0012). Group-D showed favourable sedation level (RSS≥2) to

AFOI than group-FM (P=0.041). Group-D patients were more satisfied with AFOI than Group-FM patients (p<0.05). Mean intubation time was lesser in group-D (1.35±0.27) as compare to group-FM (2.17±0.38) (p<0.0001).

HR, SBP, DBP, and Spo2 were measured at before drugs administration, after 10 min drugs administration, immediately after intubations. In Group-D significant decrease in HR during intubation and after intubation as compared to Group-FM. but immediately after intubation and 10 min after drug administration increase in HR in Group-FM.

Table 2: Comparison of mean heart rate at different time interval between both groups.

Hr	Group-D	Group-FM	P Value
	Mean ± S. D	Mean ± S. D	
Berore drug administration	92.53 ± 9.47	93.03 ± 9.68	0.4202
After 10 min drug administration	84.93 ± 8.40	90.17±9.89	0.0156
Immediately after intubation	91.63 ± 8.39	103.13 ± 7.67	<0.0001

p>0.05 not significant, p<0.05- significant, p<0.0001- highly significant

In group-D, SBP were less than group-FM after 10 min drug administration and immediately after intubation, is statistically significant (p<0.05). Mean SBP of Group-D immediately after intubation was (125.47± 7.01) and of Group- FM was (132.20 ± 7.48) and was statistically significant.

Table 3: Comparison of systolic blood pressure at different time interval between both groups

SBP	Group-D	Group-FM	P Value
	Mean± SD	Mean± SD	
Before drug administration	127.53 ± 9.62	123.63 ± 9.49	0.0620
After 10 min drug administration	120.90 ± 6.2	119.97 ± 7.29	0.0430
Immediately after intubation	125.47 ± 7.01	132.20 ± 7.48	0.0003

p>0.05 not significant, p <0.05- significant, p <0.0001- highly significant

Mean DBP of Group-D immediately after intubation was (85.40± 4.8) and of Group-FM was (94.60± 6.6) and was statistically significant (p<0.0001). In group-D, Mean DBP was less than group-FM after 10 min drug administration, immediately after intubation and is statistically significant (p<0.05).

Table 4: Comparison of dystolic blood pressure at different time interval between both groups

DBP	Group-D	Group-FM	P Value
	Mean ±SD	Mean ± SD	
Before drug administration	85.00± 5.6	86.00 ± 5.9	0.2207
After 10 min drug administration	80.90± 4.7	84.37 ± 5.5	0.046
Immediately after intubation	85.40± 4.8	94.60± 6.6	<0.0001

p>0.05 not significant, p<0.05- significant, p<0.0001- highly significant

There were no change in Spo2 values in both group-D and FM.

Table 5: Comparison of saturation level in both groups.

Saturation level	Group-D	Group-FM	P Value
	Mean ± SD	Mean ± SD	
Spo2_before drug administration	99.10 ± 0.84	99.17 ± 0.99	0.3897
Spo2_after 10 min drug administration	99.47 ± 0.63	98.97 ± 1.16	0.0211
Spo2_immediately after intubation	99.47 ± 0.51	99.43 ± 0.5	0.3060

p>0.05 not significant, p <0.05- significant, p <0.0001- highly significant

No Respiratory distress in both groups of patients.

Discussion

The vocal cord visibility was better in group-D as compared to group-FM. 60% patients in group-D had completely relaxed vocal cords as compared to 36.6% patients in group-FM. Partially relaxed vocal cords were observed on 36.6% patients in group-D as compared to 50% patients in group-FM. Closing vocal cords were observed in 13.3% patients in group-FM and 3.3% patients in group-D. None of the patient had completely closed vocal cord. Favourable cough score of ≤2 was found in 29 (99.9%) patients in Group-D as compared to Group -FM 25(83.3%) patients. Unfavourable cough scores of ≥3 was found in 5(16.6%) patients from Group-FM as compared to1 (3.3%) patient from Group-D. Cough score was less in group-D Patients than group-FM Patients which is highly significant (p<0.0001).Physical movement was less in group-D patients (1.53±0.63) than group-FM (2.13±0.73) patients which are highly significant (P<0.0001). Group-D Patients less coughing and limb movement during AFOI as compared to group-FM. In concordance with our study, Chu *et al*. [7] also observed that no respiratory depression and upper airway obstruction in group-D (1µg/kg) as compared to group-FM (1µg/kg). Patient's comfort helps in confirming the position of the tracheal tube during AFOI under general anaesthesia. Comfort score ≤2 is comfortable or react less while doing AFOI. In our study, Patients in group-D had no grimace (17

patients) or had slight grimace (9 patients). This is due to blockage of the sympathetic supply of the upper airway by dexmedetomidine. In concordance with our study Bergese *et al*. [8] noted that Dexmedetomidine (1µg/kg) bolus provides calmness and comfortness without airway nerve block or topical anesthesia for patients undergoing AFOI. Level of sedation was assessed using RSS at different time intervals. In our study, the mean RSS in Group-D as (3.13 ± 0.937) and Group-FM as (3.16 ± 0.949), the comparison between two groups (RSS≥2) were statistically significant ($p<0.05$). Sedation score was higher in group-D as compared to group-FM which was statistically significant ($p<0.015$). In the group-D patients were calmer during the fibreoptic scope and endotracheal tube placement with the help of adequate sedation. Sedation level achieved by our patients was similar to Shimabukuro and Satoh study [9]. Patients were more satisfied with the AFOI in group-D as compared to group-FM; because of better tolerance and higher amnesia level was provided by dexmedetomidine. The mean intubation time was lesser in group-D patients (1.35±0.27) than group- FM patients (2.17±0.38), this was statistically significant ($p<0.0001$). In concordance to our study, Noor Bano *et al*. [10] also found that mean time taken in intubation was much lesser in dexmedetomidine group than clonidine and midazolam group. At various intervals in perioperative period starting from baseline, post induction period, at intubation, after intubation at 1min, 3min, 5min, 7min and 10min; HR, SBP, DBP and SpO_2 were recorded. However, when hemodynamic parameters such as HR, SBP, DBP and SpO2 were compared at various time intervals, they were statistically significant at all intervals of time post induction. There was a significant raised in HR, SBP and DBP in post intubation period [Group-FM as compared to group-D ($p<0.05$)]. This shows that group-D has more favourable hemodynamics than group-FM. Initial HR was similar in both group-D and group-FM. In the post intubation period; there was a significant change of HR in comparison with the baseline value in group-FM ($p< 0.0001$). However, there were no significant changes of HR in the post intubation period in comparison with baseline value in Group-D. Yavascaoglu *et al*. [12] observed that dexmedetomidine more effectively decrease the hemodynamic response to intubation as compared to esmolol. Sayeed *et al*. [13] also reported that statistically significant raised in HR, SBP and DBP at intubation as compared to baseline value in group-FM of patients.

Conclusion

Our study concluded that Dexmedetomidine provides better effectiveness, hemodynamic stability and preservation of patent airway during awake fiberoptic intubation in oral cancer surgery as compared to Fentanyl-Midazolam.

Conflict of Interest

Not available

Financial Support

Not available

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