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Sedation with Dexmedetomidine Infusion versus Superior Laryngeal Nerve Block for Awake Fiberoptic Intubation of Hemimandibulectomy Patients with an Anticipated Difficult Airway: A Randomized Controlled Trial

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Abstract

Background: Dexmedetomidine's analgesic and anxiolytic effects, along with its capacity to produce a sedative effect without respiratory depression, make it a popular choice among anesthesiologists for sedation during awake fiberoptic intubation (AFOI).

Aim of Study: The study aimed to assess the safety and efficacy of dexmedetomidine infusion and superior laryngeal nerve block (SLNB) for conscious sedation during AFOI in hemimandibulectomy patients.

Patients and Methods: This randomized controlled research was performed on 80 cancer cases between the ages of 18 and 60 belonging to the American Society of Anesthesiologists physical status II, III, body mass index 18.5 to 30kg/m^2, hemi-mandibulectomy with an anticipated difficult airway [El-Ganzouri Risk Index >3]. They were divided into two equal groups of patients: Group 1: Received 0.5mcg /kg dexmedetomidine over 10min via syringe pump, after that 0.2-0.7mcg/kg/hour till the end of intubation, and Group 2: Received an airway nerve block through bilateral SLNB and trans-tracheal injection for recurrent laryngeal nerve.

Results: The intubating conditions score was more favorable in Group 1 than in Group 2 with a *p*-value of 0.001. Ramsay sedation score was deeper in Group 1 than in Group 2 with a statistically significant difference (4±0.00 vs. 2.78±0.48, respectively, $p<0.001$). The degree of airway obstruction and the Patient satisfaction score didn't show a significant difference between both groups. Both groups showed Haemodynamic stability throughout the procedure.

Conclusions: Dexmedetomidine provides safe and good intubating conditions required for AFOI compared to SLNB providing an excellent alternative to SLNB in case of anatomical difficulties.

Research and ethics committee approval number: ID: MS-48-2023.

Clinical Trials Registration ID: NCT06651905.

Key Words: *Superior Laryngeal Nerve Block – Sedation – Dexmedetomidine – Awake Fiberoptic Intubation – Hemimandibulectomy.*

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Introduction

AWAKE fiberoptic intubation (AFOI) is recommended for patients with anticipated difficult airways **[1]**. This procedure often requires sedation, anxiolysis, and hemodynamic stability, while also preserving the patient's spontaneous respiration, to enhance comfort during the procedure **[2]**. Intravenous dexmedetomidine, fentanyl, and midazolam are commonly used sedatives during AFOI. These medications are often combined to minimize their individual side effects **[3]**.

Many anesthesiologists prefer dexmedetomidine for sedation during AFOI due to its anxiolytic, analgesic, and sedative effects without causing respiratory depression. However, it may lead to significant bradycardia and hypotension **[4]**.

Airway nerve blocks are commonly used for awake fiberoptic intubation (AFOI) as they provide rapid and effective anesthesia **[1]**. However, these procedures can lead to complications such as nerve damage, intravascular injection, hematomas, or bleeding, which may complicate intubation. Addi-

tionally, the presence of tumors or enlarged lymph nodes can hinder the success of the nerve block **[5,6]**. To achieve optimal airway anesthesia, it is recommended to perform a bilateral block of the superior laryngeal nerve (SLN) and a transtracheal injection for the recurrent laryngeal nerve.

This research aimed to assess SLN block (SLNB) and dexmedetomidine infusion for sedation, in their relative safety and effectiveness for conscious sedation during AFOI in hemimandibulectomy patients.

Patients and Methods

This randomized controlled research was performed on 80 cancer cases between the ages of 18 and 60 belonging to the American Society of Anesthesiologists (ASA) physical status II and III, body mass index (BMI) 18.5 to 24kg/m^2, hemi-mandibulectomy patients with an anticipated difficult airway [ElGanzouri Risk Index (EGRI) >3] who were candidates for AFOI at the National Cancer Institute Cairo University from October 2023 till January 2024. After approval from the Research and Ethics Committee (ID: MS-48-2023), the study began. Each case provided written informed consent. The study was registered at clinical trial .gov (Identifier: NCT06651905).

Exclusion criteria were allergy to drugs studied, neurological or psychiatric disorders, advanced liver or kidney disease, airway distortion, and cervical spine movement abnormality.

Randomization:

Using computer-generated random numbers, two groups of 80 patients were assigned. Each group received 0.5mg of atropine, 1-2mcg/kg of fentanyl, and 2% Lidocaine via nebulization for 10 minutes.

A complete preoperative evaluation was performed. In the airway evaluation, mouth opening, modified Mallampati grading **[7]** thyromental distance, temporomandibular joint TMJ mobility, and dentition were assessed. Complete history-taking, clinical examination, and laboratory investigations such as a complete blood count (CBC), coagulation test, renal and liver function test were performed on all patients.

The AFOI procedure was explained to the patient. Standard fasting protocol and aspiration prophylaxis with ranitidine 150mg was prescribed together with atropine 0.5mg 30 mins before the procedure. Continuous electrocardiogram (ECG), non-invasive blood pressure (NIBP), peripheral arterial oxygen saturation (SpO_2), and capnography monitoring were performed on all patients. Nasal prongs were provided with O_2 at a rate of 6L/min. A nasal pack containing Lidocaine and Adrenaline at a ratio of 1:200,000 was introduced into one nostril.

- Group 1 (DEX group): Received 1mcg/kg dexmedetomidine diluted on 50ml normal saline over 10min via syringe pump, followed by 0.2-0.7mcg/kg/hour till the end of intubation according to hemodynamics.
- Group 2 (SLNB group): Received an airway nerve block through bilateral SLNB and trans-tracheal injection for recurrent laryngeal nerve. Because each group utilized a different technique, the research was considered open label.

Bilateral superior laryngeal nerve block:

To identify the thyroid cartilage and prominent horn of the hyoid bone, the patient was placed in a supine position with their head slightly extended. The hyoid bone and thyroid cartilage were identified then gradually 1ml of 2% lidocaine was injected using a 22-gauge needle at the greater cornu of the hyoid bone on the side of the neck **[8]**. After aspiration to avoid intravascular injection, the same procedure was done on the other side. A 22-gauge intravenous catheter was placed through the cricothyroid membrane and 2ml of 2% Lidocaine was instilled transtracheally until air was aspirated to block the recurrent laryngeal nerve. Local anesthetics were injected then patients were asked to cough to allow its distribution.

- In Group 1: Trial of AFOI was tried after finishing the loading dose of Dexmedetomidine over 10 minutes and accomplishing the desired level of sedation RSS >3.
- In Group 2: AFOI was tried after 10 minutes of performing the block.

For both groups: A lubricated appropriately sized endotracheal tube was placed in the fiberoptic endoscope for both groups. Fiber optic nasotracheal intubation was performed, the scope was manipulated to visualize the vocal cords, and 2ml of 2% lidocaine was sprayed (spray as you go to provide optimal conditions). Then The scope was directed toward the vocal cords and passed between them. After the trachea's carina was identified, the tube was then advanced over the fiberoptic endoscope until 2cm above the carina. After confirmation of the proper position of the tube using capnography, the cuff was inflated and secured into place, and this was followed by induction of general anesthesia and the start of surgery according to the local protocol in the National Cancer Institute. At the end of the surgery, the residual neuromuscular blockade was reversed using neostigmine (0.05mg/kg) and atropine (0.02mg/kg), and extubation was performed after complete recovery of the airway reflexes. Patients were transferred to the post-anesthesia care unit (PACU) where they were monitored for 2 hours before being discharged to the ward.

The intubation score and other parameters were recorded by the observer anesthesiologist during the procedure (from the introduction of scope in the mouth of the patient to the insertion of the endotracheal tube between the vocal cords. In a time range of 10 minutes).

The intubation condition score was assessed as follows: [9]

- Vocal movement (1=open, 2=moving, 3=closing, 4=closed).
- Coughing (1=none, 2=slight, 3=moderate, 4= severe).
- Limb movement (1=none, 2=slight, 3= moderate, 4=severe).

Where Intubation conditions score Excellent=1 when all qualities are 1 (excellent) Good=2 when all qualities are 1 or 2 (excellent or good), Poor = 3 when the presence of a single quality is 3 (listed under 'poor'). The intubation score was the primary outcome. The secondary outcomes were the degree of airway obstruction recorded by an airway obstruction score (1=patent airway, 2=airway obstruction relieved by neck extension, 3=airway obstruction requiring jaw retraction), Haemodynamic changes (HR, MAP) at an interval of 2min until intubation was done followed by every 2min until 6min after intubation. Ramsay sedation score RSS [10], patient satisfaction score (1-excellent, 2-good, 3-reasonable, 4-poor), and adverse effects(including desaturation below 90%, bradycardia below 60, or hypotension below 30% of baseline) were recorded. In case HR or MAP levels elevated above 20% 0.5µg/kg of fentanyl was given.

El-Ganzouri Risk Index (EGRI): [11]

The probability of difficult tracheal intubation can be predicted using this multivariate risk score. An increasingly complex airway was indicated by a greater EGRI score, which ranges from 0 to 12 points. A difficult intubation was indicated by a score of 4 or higher.

Sample size calculation:

As no study addressed the same research question in these cases, the sample size was calculated according to a preliminary analysis of the first 20 patients (10 from each group) as a pilot study. Regarding the primary outcome (intubation score), group 1 (DEX) demonstrated scores of 6.5±2.5 compared to 4.5±2.0 in group 2 (SLNB). A minimum sample size of 72 patients (36 per group) was needed to have a study power of 95% and an alfa error of 0.05. Compensating for drop out 80 patients (40 patients per group) were recruited.

Statistical analysis:

SPSS v26 (IBM Inc., Chicago, IL, USA) was used for our statistical analysis. The data distribution was checked for normality using the Shapiro-Wilks test and histograms. The two groups were compared using an unpaired Student's *t*-test for quantitative parametric variables, which were shown as mean and standard deviation (SD). Quantitative non-parametric data were evaluated using the Mann-Whitney test and reported as median and interquartile range (IQR). The frequency and percentage (%) of qualitative variables were expressed, and the data were analyzed using Fisher's exact test or a Chi-square test. If the two-tailed *p*-value was less than 0.05, it was considered statistically significant.

Results

The eligibility of 106 patients was evaluated; 17 patients did not satisfy the criteria, and 9 patients declined to participate in the investigation. The remaining patients were randomly assigned to two equal groups, each consisting of 40 patients. Statistical analysis was performed on all assigned patients after they were followed-up. (Fig. 1).

The demographic data, including Age, Sex, weight, height, BMI, and ASA were presented in (Table 1), and all were comparable between the groups.

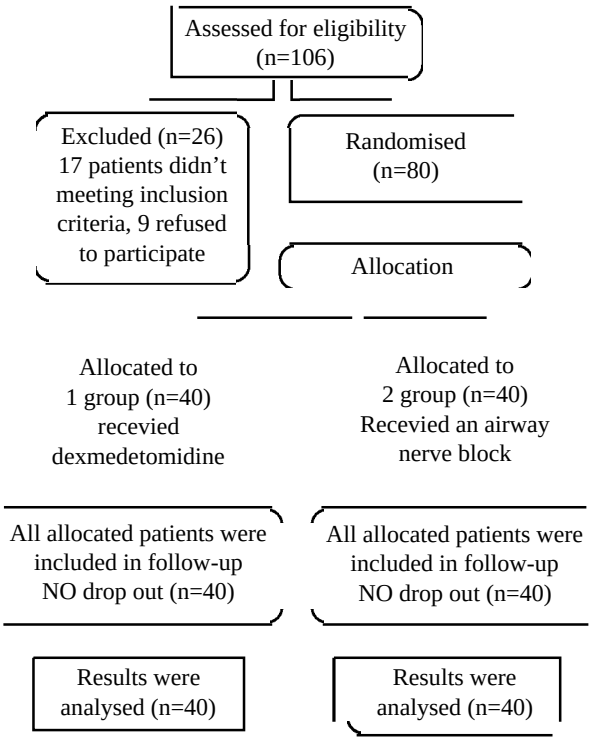

Fig. (1): CONSORT flowchart of the enrolled patients.

Table (1): Basic clinical and demographic characteristics of patients.

	Group 1 (n=40)	Group 2 (n=40)	*p*-value
Age (years)	44.9±12.1	47.2±8.7	0.351
Sex:			
Male	27 (67.5%)	21 (52.5%)	0.171
Female	13 (32.5%)	19 (47.5%)	
Weight (Kg)	72.6±6.9	73.3±7.4	0.688
Height (cm)	169.3±5.2	170.8±3.7	0.142
BMI (kg/m^2)	25.3±2.3	25.1±2.5	0.688
ASA physical status:			
2	29 (72.5%)	34 (85%)	0.172
3	11 (27.5%)	6 (15%)	

- Data are presented as mean ± SD or frequency (%) or median (IQR).
* Significant *p*-value <0.05.
Group 1: Dexmedetomidine. Group 2: Airway nerve block.
ASA: American Society of Anesthesiologists. BMI: Body mass index.

Group 1 (DEX) had more favorable intubation scores for vocal cord opening and cough than Group 2 (SNLB) with statistically significant differences (*p*-value 0.001, 0.005 respectively). However, the scores for limb movement did not differ significantly between groups. Better overall Intubation conditions were in Group 1 with Excellent and good scores in 11, 19 patients while only 2,5 patients in Group 2 respectively. A higher number of patients showed a poor score of intubation conditions in Group 2 than in Group 1 (33 Versus 10 patients). This difference in intubation conditions scores was statistically significant (*p*-value <0.001*). (Table 2).

The time of intubation and degree of airway obstruction were insignificantly different between both groups. (Table 2).

Table (2): Clinical data and degree of airway obstruction.

	Group 1 (n=40)	Group 2 (n=40)	*p*-value
Intubation time in minutes	5.50 (5.0-6.75)	5.0 (4.0-6.0)	0.186
Vocal cord movement:			
Open	27 (67.5%)	6 (15%)	0.001*
Moving	13 (32.5%)	8 (20%)	
Closing	0 (0%)	11 (27.5%)	
Closed	0 (0%)	15 (37.5%)	
Cough:			
None	21(52.5%)	12 (30%)	0.005*
Slight	13 (32.5%)	7 (17.5%)	
Moderate	4 (10%)	12 (30%)	
Severe	2 (5%)	9 (22.5%)	
Limb movement:			
Slight	8 (20%)	11 (27.5%)	0.611
Moderate	5 (12.5%)	7 (17.5%)	
Severe	4 (10%)	5 (12.5%)	
Degree of airway obstruction:			
Absent	8 (20%)	7 (17.5%)	0.895
Requiring neck extension	15 (37.5%)	17 (42.5%)	
Requiring jaw thrust	17 (42.5%)	16 (40%)	
Intubation conditions score:			
Excellent	11 (27.5%)	2 (5.0%)	0.001*
Good	19 (47.5%)	5 (12.5%)	
Poor	10 (25%)	33 (82.5%)	
Patient satisfaction score:			
1	20 (50 %)	12 (30%)	0.172
2	8 (20 %)	16 (40%)	
3	9 (22.5%)	8 (20%)	

- Data are presented as mean ± SD or frequency (%) or median (IQR).
* Significant *p*-value <0.05, Group 1: Dexmedetomidine, Group 2: Airway nerve block, ASA: American Society of Anesthesiologists, BMI: Body mass index.

Sedation was deeper in Group 1, as reported by Ramsay sedation score RSS than in Group 2 with a statistically significant difference (4±0.00 vs. 2.78±0.48, respectively, $p<0.001$). (Fig. 3).

But this deeper sedation didn't affect Patient satisfaction which showed insignificant differences between both groups. (Fig. 2).

When comparing the two groups at different MAP and HR time points, no statistically significant difference was found (Fig. 2). No adverse effects were reported in either group of the study.

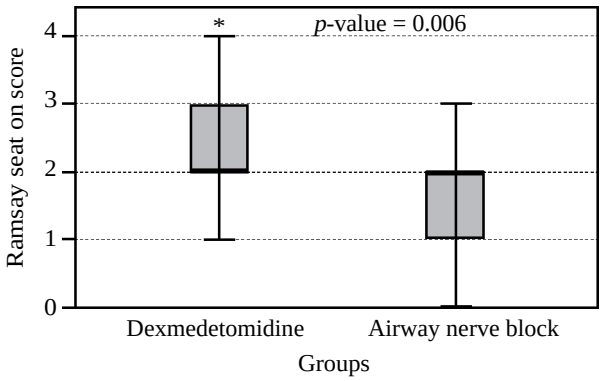

Fig. (2): Boxplot showing Ramsay sedation score among patients.

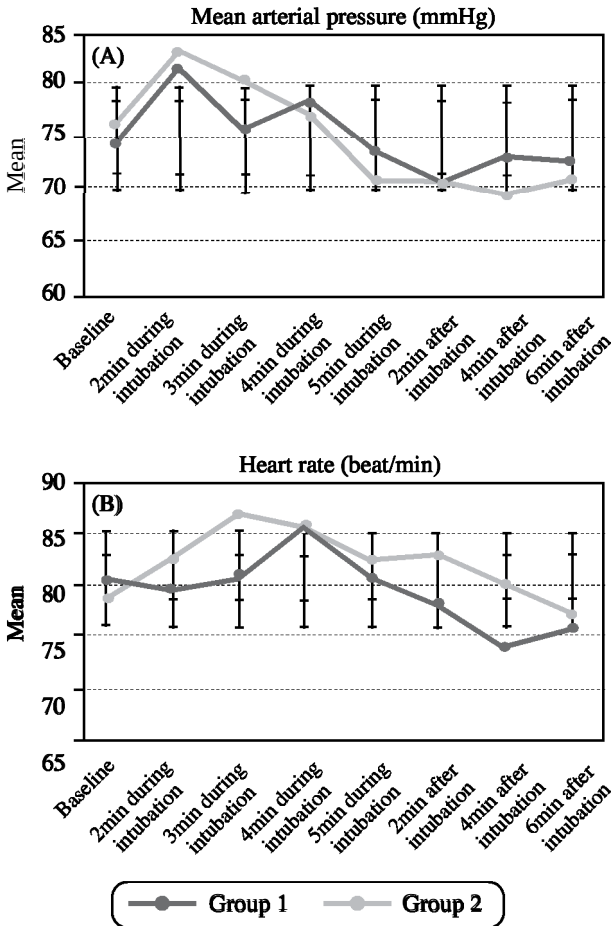

Fig. (3): (A) Mean arterial pressure and (B) Heart rate measurement over time points.

Discussion

The main finding in our study is that Dexmedetomidine conscious sedation provided more favorable intubating conditions to AFOI compared to Airway nerve block.

The ASA algorithm for managing difficult airways emphasizes awake intubation as the primary option in anticipated difficult airway situations *[1]*. The AFOI technique is considered the gold standard for managing anticipated difficult airways, as recommended by the ASA *[1]*. However, selecting the optimal approach for AFOI whether to use airway nerve blocks or conscious sedation remains a significant challenge in practice.

Anesthesia of the airway through superior laryngeal nerve block and recurrent laryngeal nerve block offers comfort and suitable conditions for the awake fiberoptic intubation technique by abolishing cough and gag reflexes *[12]*. Unfortunately the anatomic variations that occur with oncological tumors, and lymph node metastasis interfere with the success of the nerve block.

Dexmedetomidine is a centrally acting α2 receptor agonist that causes amnesia, analgesia, sympatholsis, and antisailoguge. It induces sedation in a physiologic way that mimics normal sleep by acting on the postsynaptic α2 receptors in the Locus ceruleus. This unique sedation allows patients to be sleepy but easily arousable and responsive. All these advantages provide optimum conditions for AFOI *[13]*.

The higher intubating conditions in our study, open vocal cords and absence of cough, in Group1 (DEX) compared to Group 2 (SLNB) is likely explained by the sedative effects of Dexmedetomidine. This sedation promotes smoother and more controlled airway management as the patient remains calm and relaxed during the procedure. This sedation is evidenced by the higher RSS score recorded in Group 1 compared to Group 2.

In agreement with our study, Mondal et al. *[14]* reported a cough score <2 in 28 out of 30 patients in group A (dexmedetomidine) compared to 3 only out of 30 patients in group B (fentanyl). This difference was statistically significant.

However, Alessandri et al. *[15]* reported better cough score in airway nerve block group compared to local anaesthetic nebulizer with remifentanil infusion. This disagreement may be attributed to the potent sedative effect of dexmedetomidine over remifentanil.

Regarding sedation scores, in agreement with our results, Mondal et al. *[14]* illustrated higher RSS in dexmedetomidine group compared to fentanyl group. Also Gupta et al. *[16]* who showed that, when comparing Dex to propofol sedation for AFOI, DEX group accomplished the desired level of sedation faster and even with less propofol dose.

Despite the good sedative effect of Dexetomidine, Group 1 showed comparable results to Group 2 concerning airway obstruction during the procedure. This declares the safety of using Dexetomidine in AFOI.

Concerning Intubation time, we noticed no difference between groups. In agreement Gupta et al. *[16]* showed in both groups, the intubation time was not significantly different.

Both groups demonstrated hemodynamic stability throughout the procedure regarding heart rate (HR) and arterial blood pressure. This finding aligns with Alessandri et al. *[15]*, who reported that the measurements of mean arterial blood pressure and HR were comparable in both study groups during the techniques. In contrast, Gupta et al. *[15]* found that the dexmedetomidine group had a significantly lower HR. This reduction may be attributed to the synergistic effects of using propofol alongside dexmedetomidine, as observed in Gupta et al.'s study.

This study had some limitations. First, being an unblinded study due to the presence of 2 different techniques. Furthermore, being a single-centered study.

Conclusions:

Dexmedetomidine infusion for conscious sedation, provides adequate Intubation conditions (in term of vocal cord movement and cough reflex) required for AFOI compared to SLNB, providing an excellent alternative to SLNB in case of anatomical difficulties.

Acknowledgment: There is none to be declared.

Conflict of interests: None to be declared.

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مقارنة بين التهدئة باستخدام عقار الديكساميد يتوميدين عن طريق الحقن الوريدى وحقن العصب العلوى الحنجرى لإجراء إدخال الانبوبة الحنجرية للمريض المستيقظ عن طريق منظار الألياف الضوئية المرن : دارسة مقارنة عشوائية

إن التأثيرات المسكنة والمضادة للقلق للديكسميديتوميدين، بالإضافة إلى قدرته على إحداث تأثير مهدئ دون تثبيط تنفسى، تجعله خيارًا شائعًا بين أطباء التخدير للتخدير أثناء التنبيب بالألياف البصرية (AFOI) فى حالة اليقظة.

الطرق: أُجريت هذه الدراسة العشوائية المُحكمة على ٨٠ حالة سرطان خضعوا لاستئصال نصف الفك السفلى مع توقع صعوبة في مجرى الهواء. تم تقسيم المرضى إلى مجموعتين متساويتين: المجموعة الأولى: تلقت ٠,٥ ميكروغرام/كغ من ديكسميديتوميدين على مدى ١٠ دقائق عبر مضخة حقنة، ثم ٠,٢–٠,٧ ميكروغرام/كغ/ساعة حتى نهاية التنبيب، والمجموعة الثانية: تلقت حصارًا عصبيًا فى مجرى الهواء من خلال SLNB ثنائى الاتجاه وحقنًا عبر القصبة الهوائية للعصب الحنجرى الراجع.

كانت درجة ظروف التنبيب أكثر ملاءمة فى المجموعة الأولى منها فى المجموعة الثانية بقيمة احتمالية ٠,٠٠١. أظهرت كلتا المجموعتين استقرارًا فى الديناميكية الدموية طوال الإجراء.

يوفر ديكسميديتوميدين ظروف التنبيب الآمنة والجيدة المطلوبة لـ AFOI مقارنةً بـ SLNB مما يوفر بديلاً ممتازًا لـ SLNB فى حالة الصعوبات التشريحية.