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Research Article

Dexmedetomidine vs midazolam sedation in middle ear surgery under local anesthesia: Effect on surgical field and patient satisfaction

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KEYWORDS

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Abstract *Background:* A relatively bloodless microscopic field is essential to facilitate surgical exposure in Simple Middle Ear Surgery (SMES). Our aim was to compare dexmedetomidine with midazolam in reducing bleeding in SMES performed under local anesthesia.

Methods: In this prospective, double-blind, comparative study, 54 patients undergoing SMES randomly received intravenous sedative infusion of either: Dexmedetomidine (Group D) or midazolam (Group M) titrated to a bispectral index reading of 70–80. Pain on local anesthesia injection was assessed by a verbal rating scale. Using a 3-grades score, the surgeon assessed the quality of surgical bleeding. Mean Arterial Pressure (MAP) and Heart Rate (HR) were assessed. Time parameters recorded include: time to reach adequate sedation, surgery duration, sedation recovery and

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postanesthesia care unit discharge. Patient satisfaction, visual analog scale for intraoperative pain, and number of patients required rescue fentanyl were recorded. Adverse effects were also recorded. *Results:* Surgical field bleeding score was significantly better in group D compared to group M (Grade I: 18 vs 4, Grade II: 9 vs 19, Grade III: 0 vs 4, respectively) $p < 0.001$. Intraoperative MAP and HR in group D were lower than their baseline values and the corresponding values in group M. Group M patients were earlier to reach adequate sedation level than those of group D, but they felt more pain either on local anesthetic injection or during operation. Rescue fentanyl was needed only for group M patients. Patient satisfaction was higher in group D. Time of surgery was longer in group M. Both groups were similar in sedation recovery and ward discharge times, as well as, incidence of side effects.

Conclusion: Compared to midazolam sedation in SMES performed under local anesthesia, Dexmedetomidine was associated with a near bloodless microscopic surgical field, shorter surgery time, greater patient satisfaction, and lower pain scores with no adverse effects.

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1. Introduction

Simple Middle Ear Surgeries (SMESs) can be performed under either local or general anesthesia. Many advantages has been reported with the local anesthetic techniques, as early recovery, less postoperative pain, and of great importance the surgeon ability to test hearing while in surgery. Despite these advantages, most of SMES are still done under general anesthesia due to special concerns; some are related to patients' anxiety which is augmented in some by their hearing loss, limiting their ability to cooperate. Other concerns are related to surgeon comfortability with the hypotensive general anesthetic techniques, and the fear of sudden patient movement during operation [1]. Yung found that most common discomforts that faced the patients of SMES under local anesthesia were noise during surgery and anxiety, followed by dizziness, backache, claustrophobia, and earache [2].

Dexmedetomidine (Dex); is a highly selective α -2 adrenoreceptor agonist, which posses both sedative and analgesic actions [3]. Unlike midazolam, Dex does not depress ventilatory drive and has shorter elimination half life of 2 h (vs 3–4 h for midazolam) [4]. By attenuating sympathetic activity, it inhibits norepinephrine release and provide a modest reduction in arterial blood pressure and heart rate [5]; these effects could be advantageous in some surgeries in which a near-bloodless field is required to facilitate surgical view and dissection. Dex has been proved as effective adjunct to general anesthesia to provide deliberate hypotension in many studies [6–8]. Dex was used to provide sedation for septoplasty under local anesthesia and proved to reduce surgical bleeding and gained more patient satisfaction compared to general anesthetic technique [9]. For sedation in SMES under local anesthesia, Dex resulted in high surgeon and patient satisfaction with the method of sedation, but the degree of bleeding in the surgical field was not evaluated [7].

So we designed this study to compare the use of Dex as opposed to midazolam when used to provide sedation for SMES, as regards their efficacy to provide a near-bloodless microscopic surgical field (primary outcome), hemodynamic and respiratory effects, patient satisfaction, and recovery characteristics (secondary outcome).

2. Methods

Fifty four adult patients (ASA I–II) scheduled for SMES under local anesthesia, were enrolled in this double blind, randomized, comparative clinical trial. Patients were of both sexes and between 18 and 55 years of age. After gaining the ethics committee approval from Ain Shams University Hospitals, the study was conducted in the period from October 2010 to August 2011.

Exclusion criteria: Refusal to local anesthesia, impaired mental status, known allergy to local anesthetics or any of the study drugs, coagulation disorders, history of cardiac arrhythmias, sleep apnea, treatment with beta blockers, chronic use of analgesics, sedatives, alcohol or drug abuse. Patients were excluded also if operations were redo, the expected surgery time was more than 2 h, or development of intraoperative severe pain that mandated the conversion to general anesthesia.

Using the sealed envelope technique, patients were randomized to receive intravenous continuous infusion of either Dex (Group D) or midazolam (Group M). The study scenario was explained in details in the preoperative visit after which a written informed consent was obtained from each patient. We recommended 8 h fasting, no premedications, and urine voiding within 2 h before operation time.

When the patient arrived to operating room, the operation site was checked for hair shaving behind the ear, intravenous 18 G cannula was inserted peripherally and a lactated ringer solution was started at 4 mL/kg/h. A standard monitoring was applied (non-invasive blood pressure, ECG, pulse oximeter), and a nasal catheter was inserted into one patient nostril for expired carbon dioxide (CO₂) monitoring. Bispectral index (BIS) monitoring system (BIS VIEW, Aspect Medical Systems, Inc., Norwood, USA) was used for monitoring the level of sedation.

2.1. Sedation protocol

As the recommended initial sedation bolus of Dex should be given over 10 min [10], while that of midazolam over

Table 1 Observer's Assessment of Alertness/Sedation scale (OAA/S) scale.

Score	Responsiveness	Speech	Facial expression	Eyes
5	Responds readily to name spoken in normal tone	Normal	Normal	Clear, no ptosis
4	Lethargic response to name spoken in normal tone	Mild slowing or thickening	Mild relaxation	Glazed or mild ptosis
3	Responds only after name is spoken loudly and/or repeatedly	Slurring or prominent slowing	Marked relaxation (slack jaw)	Glazed and marked ptosis
2	Responds only after mild prodding or shaking	Few recognized words	Marked relaxation (slack jaw)	Glazed and marked ptosis
1	Does not respond to mild prodding or shaking	Few recognized words	Marked relaxation (slack jaw)	Glazed and marked ptosis

The final score is the sum of the responsiveness, speech, facial expression, and eyes component scores. Thus, a "wide awake" score = 5 and a "deeply sedated" score = 1.

2–2.5 min [11], we designed our sedation protocol to keep blinding of anesthesia care giver as follows:

A well trained anesthesia resident (un-blinded) was the one who prepared the drugs as boluses and infusions and he did not participate in either administration of drugs or collecting patients' data. For each group, the bolus and infusion doses were calculated according to patient weight. Dex bolus dose was 1 µg/kg diluted in Normal Saline Solution (NSS) and the starting infusion dose was 0.4 µg/kg/h (range: 0.1–1 µg/kg/h). Midazolam bolus dose was 0.01–0.03 mg/kg diluted in NSS, and the starting infusion dose was 0.04 mg/kg/h (range: 0.01–0.1 mg/kg/h).

The bolus dose was given by two successive fully filled 5 mL syringes labeled B1 and B2, B1 was injected slowly over 2.5 min while B2 was injected over the next 7.5 min. In group D: B1 contained 1/4 of the bolus dose and B2 contained the other 3/4. In group M: B1 contained the whole bolus dose, while B2 contained only NSS. Fifty mL syringes were used to prepare the infusion drug; in group D: Dex (Precedex, Hospira, USA) 200 µg was diluted in NSS to the concentration of 4 µg/mL, while in group M: midazolam (Dormicum, La Roche, Switzerland) 20 mg was diluted in NSS to the concentration of 0.4 mg/mL. So according to the used concentration and dose range of either drug, a starting infusion rate of 0.1 mL/h will be a correct dose for both groups.

By using syringe pump (AJ-5803; Shanghai Angel Electronic Equipment, China), modification of the infusion rate in a step of 25–50% faster or slower than the initial rate (and according to the dose range mentioned above) was titrated by the anesthesia care giver to maintain a BIS score between 70 and 80 throughout the whole surgery.

After sterilization and draping of the patient, oxygen was allowed to flow under the drapes. Drapes were put over a low set screen bar opposite to the site of surgeon to improve patient comfort and allow anesthetist to observe patient's face. When a BIS reading of 70–80 was reached (Adequate sedation), the surgeon was allowed to inject local anesthesia using 10–15 ml of lidocaine 2% with adrenaline 1/200,000 to block auricular and auriculotemporal nerves. The time from start of bolus drug injection till patient achieve adequate sedation was recorded. Patients were asked to rate the VRS (Verbal Rating Scale; 0 = no pain, 10 = maximal pain) for pain on local anesthesia injections. Duration of operation was calculated from the start of local anesthesia injection till skin closure. The

same surgeon performed all operations. Intraoperatively Mean Arterial Pressure (MAP) and Heart Rate (HR) were continuously monitored throughout surgery and recorded every 5 min, any episodes of lost CO₂ curve (apnea >15 s or obstruction), or oxygen desaturation (SpO₂ < 90%) were recorded.

Rescue fentanyl bolus 0.5 µg/kg was given if patient was still complaining of pain or discomfort during operation in spite of maintained desired BIS reading, and was allowed to be repeated once only. Fentanyl boluses were recorded. If MAP decreased < 60 mmHg and HR < 50 beats/min, these were considered as unwanted hypotension or bradycardia for which infusion rate was reduced to half of the previous rate with a fluid bolus of 250 ml given as intravenous push. If unwanted hypotension or bradycardia did not respond to previous conservative management, ephedrine 5 mg or atropine 0.5 mg intravenous bolus was used as appropriate. If apnea or desaturation occurred patient was encouraged to breath, and the rate of infusion was decreased as before. Any patient who received ephedrine or atropine, or needed advanced airway management for correction of desaturation was excluded from the study. When the surgeon started to close the skin we started to assess patient sedation score using Observer's Assessment of Alertness and sedation scale (OAA/S) [12] every 5 min and continued in the recovery room (Table 1). Infusion stopped when surgery was finished.

After the end of surgery, the surgeon was asked to rate the bleeding in the surgical field according to the 3-grades score used by Nasreen et al. by the end of operation (Grade I: Bloodless field not hampering surgery, Grade II: mild bleeding requiring occasional suctioning, and Grade III: excessive bleeding hampering surgery despite suctioning) [13].

In the postanesthesia care unit (PACU), the time from stoppage of infusion till the patient reaches OAA/S score of 5 was recorded as sedation recovery time. MAP and HR were recorded every 5 min. Patients were discharged to the ward according to the modified Aldrete score of ≥9 [14]. Postoperative nausea and vomiting were recorded and treated with metoclopramide 10 mg if any.

Just before leaving the PACU, Patients were given a paper form to rate their satisfaction with the sedation method (as excellent, good, fair, or poor), and also to rate their intraoperative pain scores by using VAS (Visual Analog Scale; 0 = no pain, 10 = maximal pain).

2.2. Statistical analysis

Medcalc version 12.0.3 was used for calculation of the sample size guided by: α error = 5% (confidence level = 95%), β error = 5% (power of the test = 95%), and a clinically significant difference from 80% to 40% surgical field bleeding score of Grade I. A total sample size of 54 divided into two equal groups was found to be sufficient to conduct the study. SPSS (statistical program for social science version 12) was used for statistical analysis. Quantitative variables were described as mean and SD while qualitative variables as number and percentage. Quantitative data were analyzed with unpaired student *t*-test, while qualitative data with Chi square or Fisher's exact tests as appropriate. $P < 0.05$ was considered significant, and < 0.01 was considered highly significant.

3. Results

The two groups were similar regarding data of patients' characteristics and types of surgery, while duration of surgery was found to be longer in the M group ($p < 0.001$) (Table 2).

The surgical field bleeding score was superior in group D compared to group M ($p < 0.001$). The surgeon observed Grade I surgical field in 18 patients of group D vs only in four cases in group M. Grade II was observed in nine patients in group D vs 19 patients in group M. While Grade III was not observed in any patient in group D, it was observed in four patients in group M (Table 3).

Patient satisfaction was better in group D (Table 3). The method of sedation was described as excellent in most of patients in group D (77.7%) vs 7.4% of patients in group M ($p < 0.001$). Poor satisfaction was not reported in group D, while reported in 25.9% of patients in group M.

Patients in group M felt more pain on local anesthesia injection than those in group D (VRS: 3.6 ± 0.9 vs 1.5 ± 0.25 , respectively). Also, intraoperative pain was more

in group M compared to group D (VAS: 2.9 ± 0.3 vs 1 ± 0.21 , respectively) $p < 0.001$ (Table 3).

Ten patients in group M required the injection of a single fentanyl bolus and 7 of them required the injection of the second bolus (Table 3), while no patient in group D required the administration of fentanyl.

In group D the HR values started to be lower from the baseline at 10 min, while MAP started to be lower from the baseline at 15 min from the start of sedation. This significant reduction in hemodynamics continued till the end of surgery and showed significant difference from those values recorded in group M that showed more stable hemodynamics with no change from the baseline (Fig. 1).

No intraoperative or postoperative adverse effects were reported in group D. In contrast, few patients in group M had oxygen desaturation, lost capnography wave form, nausea, and vomiting, while no cases of hypotension or bradycardia was reported (Table 4). Those patients who had desaturation or lost capnography, all had responded well to breath encouraging and reduction of infusion rate.

Patients in group M achieved adequate sedation level earlier than those in group D (6.7 ± 2.64 vs 17.1 ± 4.54 , respectively), ($p < 0.001$). After that, BIS values at the corresponding time points were similar in both groups till the end of operation (Table 2) (Fig. 2). Furthermore, the times taken for recovery from sedation and discharge from PACU were equal in both groups (Table 2).

4. Discussion

Our results demonstrate that Dex sedation for SMES was associated with significantly better surgical field bleeding score, lower HR and MAP values when compared to midazolam sedation. While midazolam group was earlier to achieve adequate sedation, Dex group was associated with less operation time, higher patient satisfaction, and lower pain scores. Both

Table 2 Patients' characteristics, and measured particular times.

	D ($n = 27$)	M ($n = 27$)	Test value	P-value
Age (years)	31.6 ± 10.8	33.26 ± 11.1	$t = 0.557$	0.579
Weight (kg)	78.5 ± 9	80 ± 7.5	$t = 0.665$	0.508
Height (cm)	171.4 ± 9.2	168.7 ± 10.8	$t = 0.989$	0.327
Sex				
Male: (n)	18 (66.7%)	16 (59.3%)	$\chi^2 = 0.079$	0.778
Female: (n)	9 (33.3%)	11 (40.7%)		
Types of surgery (n)				
Tympanoplasty	16 (59.3%)	18 (66.7%)	$\chi^2 = 0.953$	0.621
Mastoidectomy	8 (29.6%)	5 (18.5%)		
Stapedectomy	3 (11.1%)	4 (14.8%)		
ASA				
(I) (n)	15 (55.6%)	17(63%)	$\chi^2 = 0.077$	0.781
(II) (n)	12 (44.4%)	10(37%)		
Time for adequate sedation (min)	17.1 ± 4.54	$6.7 \pm 2.64^{**}$	$t = 10.290$	< 0.001
Duration of surgery (min)	69.2 ± 15.75	$88.5 \pm 19.40^{**}$	$t = 4.013$	< 0.001
Time of sedation recovery (min)	15.4 ± 4.88	16.8 ± 3.08	$t = 1.261$	0.213
Time for PACU discharge (min)	35.1 ± 12.5	32.6 ± 11.85	$t = 0.754$	0.454

Data were expressed as mean \pm SD, or numbers (%).

t: Student *t*-test, χ^2 : Chi square test, ASA: American Society of Anesthesiologist.

* $P < 0.05$; statistically significant.

** $P < 0.01$; statistically highly significant.

Table 3 Surgical bleeding score, patient satisfaction score, pain scores and rescue fentanyl boluses.

	D (n = 27)	M (n = 27)	Test value	P-value
Surgical field bleeding score		**	$\chi^2 = 16.481$	< 0.001
Grade I	18 (66.7%)	4 (14.8%)		
Grade II	9 (33.3%)	19 (70.4%)		
Grade III	0 (0%)	4 (14.8%)		
Patient satisfaction score		**	$\chi^2 = 32.094$	< 0.001
Excellent	21 (77.8%)	2 (7.4%)		
Good	5 (18.5%)	6 (22.2%)		
Fair	1 (3.7%)	12 (44.4%)		
Poor	0 (0%)	7 (25.9%)		
VRS on LA injection	1.5 ± 0.25	3.6 ± 0.90**	t = 11.682	< 0.001
VAS intraoperative	1 ± 0.21	2.9 ± 0.30**	t = 26.960	< 0.001
Rescue fentanyl				
Single bolus	0 (0%)	10 (37%)**	$\chi^2 = 9.941$	0.001
Two boluses	0 (0%)	7 (25.9%)**	$\chi^2 = 5.909$	0.015

Data are expressed as mean ± SD, or numbers (%).

t: Student t-test, χ^2 : Chi square test, VRS: Verbal Rating Scale, VAS: Visual Analog Scale.

* P < 0.05; statistically significant.

** P < 0.01; statistically highly significant.

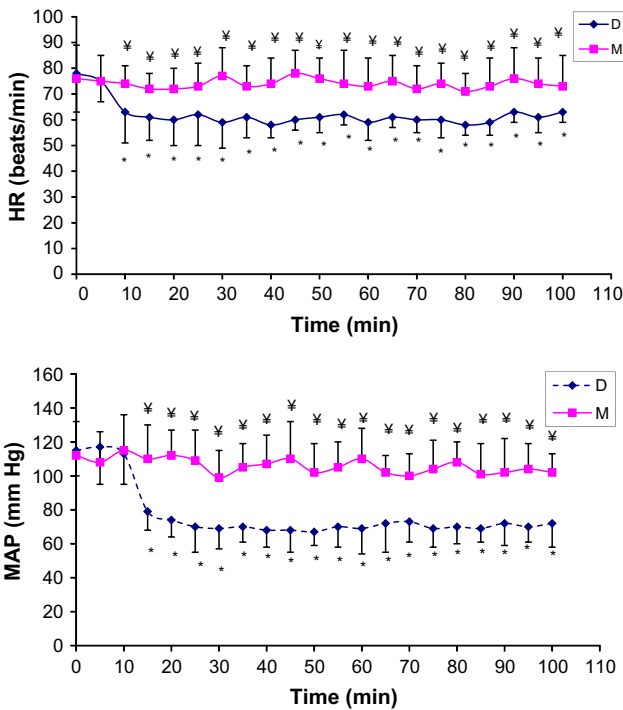


Figure 1 Intraoperative mean arterial blood pressure and heart rate values. D: Dexmedetomidine, M: Midazolam, HR: heart rate, MAP: Mean Arterial Pressure, * statistical difference from the baseline, and † statistical difference from the other group.

methods of sedation were equal in the incidence of adverse effects, time for sedation recovery and PACU discharge.

SMES like any other microscopic surgery needs special anesthetic techniques to provide controlled hypotensive anesthesia for better surgical field exposure. Many techniques are being implemented; using volatile anesthetics, beta blockers, vasodilators, opioids, magnesium and $\alpha 2$ agonists. However, controlled hypotension is not free of risk; it can lead to tissue

Table 4 Intraoperative and postoperative adverse effects.

	D (n = 27)	M (n = 27)	P
Desaturation SpO ₂ < 90%	0 (0%)	4 (14.8%)	0.110
Lost capnography	0 (0%)	2 (7.4%)	0.490
Hypotension	0 (0%)	0 (0%)	–
Bradycardia	0 (0%)	0 (0%)	–
Nausea	0(0%)	4 (14.8%)	0.110
Vomiting	0(0%)	1 (3.7%)	0.490

Data are expressed as numbers (%), Fisher’s exact test was used.

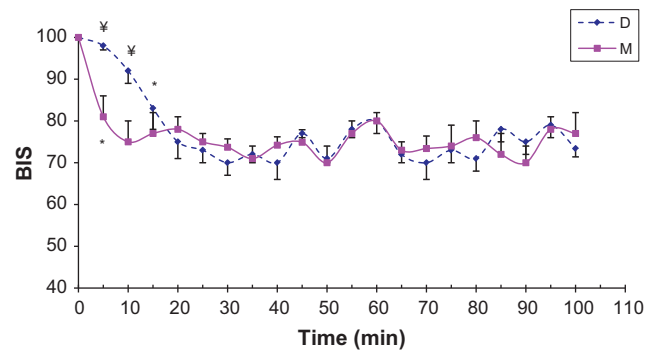


Figure 2 Intraoperative Bispectral Index values. D: Dexmedetomidine, M: Midazolam, BIS: Bispectral index, * statistical difference from the baseline, and † statistical difference from the other group.

hypoxia by lowering autoregulation of vital organ microcirculation. Also it may need the use of invasive blood pressure monitors, in addition to the adverse effects of specific drugs used [1]. $\alpha 2$ agonists were used before as an adjunct to general anesthesia to provide hypotensive anesthesia; Marchal et al. premedicated patients with clonidine and reported a significantly reduced bleeding, and decreased urapidil requirements for controlled hypotension [15]. Durmus et al. reported that Dex was associated with less bleeding, lower anesthetic

requirements, and more hemodynamic stability in response to anesthesia and surgery in patients undergoing septorhinoplasty and tympanoplasty under general anesthesia [16].

Dex was used in many settings to provide sedation for operations performed under local anesthesia. For aesthetic facial surgery under local anesthesia, Taghinia et al. compared the addition of Dex infusion to the usual sedative protocol (propofol, midazolam, fentanyl, and ketamine), they reported lower blood pressure values, but they did not comment on surgical field bleeding. They found that Dex improved the sedation safety as evidenced by the reported fewer incidences of oxygen desaturation, and the reduced need for the use of narcotics, and antiemetics [17]. Their results are consistent with the results of our study.

On the other hand, Dogan et al. evaluated the surgical bleeding in septoplasty operations, and found that those performed under local anesthesia with Dex sedation were associated with significantly less bleeding when compared to those performed under general anesthesia [9].

Dex when compared to midazolam to provide monitored anesthesia care for cataract surgery, Alhashemi found significantly better patient satisfaction scores in Dex group. Although he reported lower HR and MAP values in Dex group, he did not find any difference in the incidence of hypotension, bradycardia or desaturation between both groups [4]. His previous results match well with the results of our study. But in contrast to our results, he reported earlier recovery and discharge times for midazolam group. This difference in results may be attributed to two factors; firstly, he used midazolam as a repeat bolus technique while Dex as a continuous infusion. After an initial bolus of 20 µg/kg of midazolam, he used repeat boluses of 0.5 mg. According to his reports of mean total midazolam dose (1.5 mg) and mean body weight (70.6 kg), we can conclude that many of his patients might not have needed any repeat bolus. This could have allowed time for midazolam effect to fade while Dex was continuously infused in the other group. Secondly, he used Aldrete score of full 10 points to discharge patients from PACU which; in case of Dex, might have delayed discharge due to the expected lower HR or blood pressure values.

When compared to propofol in vitreoretinal surgery under sub-Tenon's block, Dex was associated with higher SpO₂ values, better patient satisfaction, lower VAS scores for pain, while similar surgeon satisfaction, discharge time and equivalent reduction in hemodynamics [18].

In our study, the shorter procedure time found in group D compared to group M could be explained by the better surgical bleeding score that might facilitate surgical dissection. Also some interruption of surgeon work could have happened more with group M patients either due to pain-related patient movements, or to allow time for rescue fentanyl to alleviate that pain.

Midazolam sedation in our study was associated with lower patient satisfaction, higher pain scores and more use of rescue analgesic. Benedik and Manohin reported similar results when they compared midazolam during sedation in SMES to propofol, the later provided significantly better patient and surgeon satisfaction scores, earlier recovery times [19]. In another study by Lee and Lee, the addition of remifentanyl to midazolam was associated with less intraoperative anxiety and greater patient satisfaction than midazolam alone [20].

4.1. Study limitations

One limitation of our study is using BIS for assessment of the level of sedation. It should be noted that BIS readings depend on the specific sedative used. While ketamine paradoxically increases BIS inspite of deep levels of sedation [21], α-2 agonists decrease it. A study by Kasuya et al. studied the correlation between BIS and OAA/S during Dex vs propofol sedation [22]. They found that BIS values were lower by 16 points in case of Dex (62 vs 78) at OAA/S score of 4. To the best of our knowledge, we could not find in the literature that benzodiazepines was comparable to propofol or showed the same difference from Dex.

Other clinical assessment scores like OAA/S and Ramsay score are well established widely used scores in clinical practice. However, they need clinician – patient interaction and this may lead to awakening of the patients or interrupting the state of sedation they achieved [22,23], especially when doing assessment every 5 min like in our study. This frequent communication with the patient may interfere with the surgeon work especially in microscopic surgeries. Also discrete observations may fail to detect changes that occur in the sedation level on every 5 min assessment. The results of our study showed better patient satisfaction when Dex was used for sedation, if we assume that BIS values were falsely low with Dex, this means it provided a lighter level of sedation compared to midazolam and inspite that it leads to better patient satisfaction.

Another limitation is the subjective assessment of the bleeding in the surgical field; we used a score used by Nasreen et al. [13]. Another similar subjective score was used by Turan et al. [7]. A more objective Doppler flowmetry for the measurement of middle ear blood flow could have improved the accuracy of our results, but we did not have the facility to implement it in our study. We tried to limit the bias of this subjective score by choosing a single surgeon to perform all the operations.

In conclusion: Dex sedation for SMES appears to be superior to midazolam in providing less surgical field bleeding that might facilitate surgical exposure and led to shorter operation time. In addition, it lowered pain scores and improved patient satisfaction. Although Dex moderately lowered MAP and HR, no cases of hypotension or bradycardia were reported in our study.

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