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ORIGINAL ARTICLE

Staggering Sugammadex for Reduction of Postoperative Complications: A Randomized Controlled Trial.

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ABSTRACT

Background: We investigated if staggering sugammadex would reduce postoperative complications (with special regards to cough), compared to single dose of sugammadex or standard neostigmine in patients undergoing thyroidectomy surgery.

Methods: A 36 adult patients aged 21-60 years old, ASA I and II undergoing thyroidectomy surgery, were randomized into 3 groups; (S group) that received 2 mg/kg sugammadex as single bolus, (SS group) that received sugammadex 2 mg/kg in a staggered dose of 1 mg/kg prior to extubation and another 1 mg/kg immediately after extubation and (N group) that received 0.05 mg/kg neostigmine combined with 0.02 mg/kg atropine.

Results: Cough was absent in (SS) group. The percent of cough was 33% in S group and about 67 % in N group. Patients of (SS) and (S) groups had significant shorter recovery time and extubation time. Patients of (N) group showed significant increase in HR and SBP at 5 min after reversal compared to both (SS) and (S) groups, but no significant difference in DBP between all groups. There was no significant difference between all groups regarding postoperative complications other than cough.

Conclusions: Staggered sugammadex reduces significantly risks for cough on emergence when compared to 2mg single bolus sugammadex. In addition, staggered sugammadex-as well as bolus sugammadex-has better recovery and more stable hemodynamics when compared to neostigmine.

Keywords: Sugammadex, Staggered, Reversal, Cough, Postoperative.

INTRODUCTION

Complete and rapid reversal of the effects of neuromuscular blocking agents is a cornerstone of safety in anesthesia [(1)]. Neostigmine, which is a cholinesterase inhibitor, is a standard drug for the reversal of the effect of non-depolarizing neuromuscular blockers, but it has some side effects, as bradycardia, increased secretion and bronchospasm[(1)].Meanwhile, antimuscarinic drugs used to antagonize these effects, also have unfavourable side effects such as dry mouth, tachycardia, and blurred vision. Moreover, traditional anticholinesterases are not able of reversing deep levels of neuromuscular blockade (NMB)[(2)].Their indirect mechanism of action means that, the reversal can be limited and unpredictable, resulting in potential risk of post-operative residual curarisation (PORC) [(3)].

Sugammadex is a new alternative to the cholinesterase inhibitors which received approval for clinical use from the United States of Food and Drug Administration (FDA) in December 2015.It has the ability to reverse NMB efficiently regardless its depth [(4)].Sugammadex has been considered to be selective for rocuronium and vecuronium [(2)].It is a modified gammacyclodextrin used as a reversal agent for steroidal neuromuscular blocking drugs. It forms a tight one-to-one complex with rocuronium or vecuronium, encapsulating them in plasma and thereby reducing its concentration at the neuromuscular junction resulting in rapid reversal of the NMB [(2)]. Although sugammadex has a fairly safe clinical profile, one of the most commonly reported adverse reactions with sugammadex reversal was cough [(5)]. In anesthesia, sudden cough on emergence should be avoided because it can be accompanied by severe laryngospasm or cardiovascular disturbances resulting in post-operative hemorrhage, raised intracranial, intraocular and intra-abdominal pressures. These can lead to detrimental outcomes in a large number of procedures in neurosurgery, thyroidectomy, nasal, eye and spinal surgeries [(6)].

We aimed at evaluation if staggering or single dose of sugammadex, compared to standard neostigmine is more effective for reduction of postoperative complications in patients undergoing thyroidectomy surgery. We hypothesized that staggering dose of sugammadex is more effective for reduction of postoperative complications (especially cough) than standard neostigmine in patients undergoing thyroidectomy surgery. Moreover, we also assessed outcomes including recovery time, extubation time hemodynamic changes after reversal and postoperative complications.

METHODS

This prospective double-blinded randomized study was approved by Institutional Review Board (IRB), carried out at Zagazig university hospitals on 36 patients.

Inclusion criteria included; aged from 21-60 years old, of both sexes, body mass index (BMI) <35 kg/m^2, ASA I and II, undergoing thyroidectomy surgery requiring general anesthesia with endotracheal intubation.

Exclusion criteria included; refusal of the patient, patients with history of allergy to drugs used, history of neuromuscular disease or malignant hyperthermia, patients with renal or hepatic impairment, patients with hemodynamic instability, patients known or expected to have difficult intubation and patients who were planned to remain intubated postoperatively for ventilation or needed reintubation after initial extubation.

Randomization was applied by computer generated randomization tables. Patients were randomly allocated into 3 equal groups, each of 12 Patients: *Group S* (received bolus dose sugammadex 2 mg/kg), *Group SS* (*received* staggered dose sugammadex 1 + 1 mg/kg), *Group N* (received 0.05 mg/kg neostigmine + 0.02 mg/kg atropine). The assignment belonged to each generated number was sealed in an opaque envelope to be handed to the attending anesthetist who administered the studied drugs and recorded the data. The studied reversal drugs were prepared in covered syringes by a nurse who was not involved in subsequent data handling.

Written informed consent was obtained from all participants. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

All patients were subjected to preoperative history taking, examination and investigation appropriately. At operating room, monitors were attached including: ECG, pulse oximetry, non-invasive blood pressure, capnograph and nerve stimulator, TOF-Watch®SX, an acceleromyography device, (Organon, Irelanad), of which its electrodes were placed over the ulnar nerve on the cleaned volar side of the forearm (near the wrist) to trigger stimulation of the adductor pollicis muscle. The transducer of the TOF-Watch-SX was placed on the thumb of the hand of the same side .The TOF-Watch is an instrument for monitoring the neuromuscular transmission during surgery or in the intensive care unit by means of acceleromyography[7]. Large bore IV cannula was inserted. Baseline HR, BP, SPO2 and $EtCO_2$ were recorded.

General anesthesia was induced, after proper pre-oxygenation, with administration fentanyl 1µg/kg IV, then propofol 2-3 mg/kg IV.Calibration and stabilization of neuromuscular monitoring were performed (a single TOF stimulation was provided(50 mA),then calibration of the TOF-Watch SX was performed after 1 min of TOF stimulation using the CAL2 mode of the device to determine supramaximal stimulation intensity).This is followed by administration of rocuronium 0.6 mg/kg to facilitate endotracheal intubation after TOF reached 0-1.Intubation was performed using tracheal tubes measuring 7.0 mm internal diameter for women and 8.0 mm for men with considering personal variations. Maintenance of anesthesia was achieved with minimum alveolar concentration (MAC) of 1.2–2% isoflurane in air/oxygen mixture (50% oxygen). Mechanical ventilation was performed to achieve a tidal volume of 7 ml/kg aiming for a target of $EtCO_2$ 35 - 45 mmHg. The TOF was assessed every10min. Rocuronium (0.1 mg/kg) was administered after TOF count becomes ≥ 1. The maintenance fluid was lactated ringer. Room temperature was adjusted throughout the surgery at 20-24°C to keep core temperature >35.5 C.

At the end of the surgery,*diclofenac sodium* 75mg diluted with 0.9% saline was given to patients as IV infusion over 30 min. Isoflurane administration was switched off .Then the patients were allocated into 3 equal groups , each of 12 Patients :

Group S patients were given single bolus dose of sugammadex 2 mg/kg, only when T2 reappeared on TOF.Additional dose of sugammadex (2 mg/kg) would be administered if TOF ratio did not reach 0.9 within 10 min.

Group SS: patients were given sugammadex 2 mg/kg, only when T2 reappeared on TOF, in a staggered dose of 1 mg/kg prior to extubation and another 1 mg/kg immediately after extubation. Additional dose of sugammadex (2 mg/kg) would be administered if TOF ratio did not reach 0.9 within 10 min.

***Group N*:** patients were given 0.05 mg/kg neostigmine + 0.02 mg/kg atropine only when T2

reappeared on TOF. Additional dose of 0.025 mg/kg neostigmine+ 0.01 mg/kg atropine would be administered if TOF ratio did not reach 0.9 within 10 min.

If respiration was adequate, hemodynamics were stable and upper airway reflexes were fully recovered, the patient would be extubated and sedation levels at 5 min postextubation was graded with Ramsay Sedation Scale (RSS) [8] (Table 1).

Study outcome measures:

Primary outcome measures: detect immediate post-operative adverse events (PONV, sore throat, agitation, tachycardia, bradycardia, hypertension, and hypotension) and respiratory events (cough, bronchospasm, respiratory depression and oxygen desaturation) during emergence and up to 60 min after extubation in staggered sugammadex group compared to both single dose sugammadex and neostigmine groups.

Secondary outcome measures: detect recovery time (time from administration of NMB reversal agent till reaching TOF ratio≥ 0.9), extubation time (time from NMB reversal to extubation), hemodynamics (HR, SBP and DBP were recorded before, after 1,5min of NMB reversal) and sedation levels graded with RSS.

Sample size:

By assuming that the expected frequency of severe cough is 70% in the group given single bolus of sugammadex and 19 % in the group given neostigmine [6], so the sample size is 36 (12 in each group) using E. P. I info 6 at power 80% & alpha error 5%.

Statistical analysis

Data analysis was performed using the software SPSS (Statistical Package for the Social Sciences) version 20. Quantitative variables were described using their means and standard deviations. Categorical variables were described using their absolute frequencies and to compare the proportion of categorical data, chi square test was used when appropriate. Kolmogorov-Smirnov (distribution-type) and Levene (homogeneity of variances) tests were used to verify assumptions for use in parametric tests.

RESULTS

There is no statistically significant difference between the studied groups regarding age, ASA or gender. Larger percentages within each group were males and ASA I (Table3).

There is statistically significant difference between the studied groups regarding presence and grade of cough (p=0.039) (Table 4). None of the patients of staggered sugammadex group experienced cough, while the percent of cough was about 33% in sugammadex group and about 67 % in neostigmine group. Those patients of sugammadex and neostigmine group had mostly grade 3 cough (Figure 1).

All studied groups showed no significant differences in both respiratory complications, other than cough, (bronchospasm, respiratory depression and oxygen desaturation) (Table 4) and postoperative complications (PONV, sore throat, agitation, tachycardia, bradycardia, hypertension, and hypotension).

There is statistically significant difference regarding recovery time which is longer in neostigmine group (6.83 ± 3.433 minutes) compared to each other group (2.92 ± 0.996 minutes in sugammadex group& 3.42 ± 2.193 minutes in staggered sugammadex group) (Figure 2). There is also statistically significant difference between neostigmine group and sugammadex group regarding extubation time which is,also,longer in neostigmine group(7.58 ± 3.988 minutes) versus sugammadex group (3.67 ±1.875 minutes)(Figure 2). However, there is no statistically significant difference between the studied groups regarding percent change in heart rate after 1 minute, but the change in heart rate is significant after 5minutes (p=0.046) as it increased in neostigmine group (18.71%) compared to both sugammadex groups (6.527% in sugammadex group& 3.09% in staggered sugammadex group) (Table 5). There is statistically significant difference between the studied groups regarding percent change in systolic blood pressure (SBP) after 1 minute which increased in neostigmine group compared to staggered sugammadex group (Figure 3).Also, SBP incrased significantly after 5 minutes in neostigmine group compared to each other group.(Figure 3).As regards diastolic blood pressure (DBP), there is statistically non-significant difference between the studied groups before reversal, after 1 and 5 minutes (Figure 4). Within staggered sugammadex group itself, the change is non-significant regarding heart rate, SBP or DBP.

As regards RSS,there is statistically non-significant difference between the studied groups.

Table(1): Ramsay Sedation Scale (RSS) [8].

Score	Level of Sedation
1	Patient is anxious and agitated or restless, or both
2	Patient is co-operative, oriented, and tranquil
3	Patient responds to commands only
4	Patient exhibits brisk response to light tactile stimuli or loud auditory stimulus
5	Patient exhibits sluggish response to light tactile stimuli or loud auditory stimulus
6	Patient exhibits no response

Once stable, the patient was transferred to post-anesthesia care unit (PACU) where post-operative adverse events were documented for 60 min postextubation. The number and severity of emergence cough will be graded as following: 0 - no cough,1 - Mild, single cough, 2 - Moderate, more than 1 lasting for < 5 s., 3 - Severe, sustained cough for >5 s or bucking with cough (a sudden contraction of the abdomen) [6] .Patients will be discharged from PACU once they fulfilled local discharge criteria, according to modified Aldrete scoring system**(**Table 2). A minimal score of 12 (with no score < 1 in any individual category) would be required for patients to be discharged[9].

Table (2): Modified Aldrete scoring system [9]

Discharge criteria	Score
Level of consciousness Awake and oriented	2
Arousable with minimal stimulation	1
Responsive only to tactile stimulation	0
Physical activity Able to move all extremities on command	2
Some weakness in movement of extremities	1
Unable to voluntarily move extremities	0
Hemodynamic stability Blood pressure is < 15% of baseline MAP value	2
Blood pressure is 15–30% of baseline MAP value	1
B1ood pressure is > 30% below baseline MAP value	0
Respiratory stability Able to breathe deeply	2
Tachypnea with good cough	1
Dyspneic with weak cough	0
Oxygen saturation status Maintains value > 90% on room air	2
Requires supplemental oxygen (nasal prongs)	1
Saturation < 90% with supplemental oxygen	0
Postoperative pain assessment None, or mild discomfort	2
Moderate to severe pain controlled with IV analgesics	1
Persistent severe pain	0
Postoperative emetic symptoms No, or mild nausea with no active vomiting	2
Transient vomiting or retching	1
Persistent moderate to severe nausea and vomiting	0
Total possible score	14

Table (3): Comparison between the studied groups regarding demographic characteristics.

	Study groups			Test	
	Sugammadex group (S)	**Staggered sugammadex group (SS)**	**Neostigmine group (N)**	**χ^2/F**	**p**
	N=12 (%)	N=12 (%)	N=12(%)		
Gender: Male Female	10 (83.3) 2 (16.7)	11 (91.7) 1 (8.3)	10 (83.3) 2 (16.7)	0.465	>0.999
Age (years): Mean ± SD Range	42.5 ± 7.91 30– 52	45.17 ± 10.23 22 – 57	40.42 ± 11.72 22 – 56	0.67	0.519
ASA: I II	9 (75) 3 (25)	9 (75) 3 (25)	7 (58.3) 5 (41.7)	1.047	0.731

N=number,F= One way ANOVA test , $\chi^{2=}$ Chi square test,

Table (4): Comparison between the studied groups regarding occurrence of respiratory complications.

Respiratory complications	Study groups			Test	
	Sugammadex group (S)	**Staggered sugammadex group (SS)**	**Neostigmine group (N)**	**χ^2**	**p**
	N=12 (%)	N=12 (%)	N=12(%)		
Respiratory depression: No Yes	12 (100) 0 (0)	12 (100) 0 (0)	11 (91.7) 1 (8.3)	2.057	>0.999
Desaturation: No Yes	11 (91.7) 1 (8.3)	11 (91.7) 1 (8.3)	8 (66.7) 4 (33.3)	3.6	0.316
bronchospasm: absent	12 (100)	12 (100)	12 (100)	0	>0.999
Cough: 0 1 2 3	8 (66.7) 1 (8.3) 0 (0) 3 (25)	12 (100) 0 (0) 0 (0) 0 (0)	4 (33.3) 3 (25) 1 (8.3) 4 (33.3)	13.214	0.039*

N= number , F= One way ANOVA test , $\chi^{2=}$ Chi square test, p< 0.05 is statistically significant

Table (5): Comparison between the studied groups regarding percent change in heart rate readings over time.

% change in heart rate	Study groups			Test	
	Sugammadex group (S)	**Staggered sugammadex group (SS)**	**Neostigmine group (N)**	**KW**	**p**
	Median (range)	**Median (range)**	**Median (range)**		
1 minute after reversal	4.066 (-15.79 – 17.46)	3.92 (-5.26 – 40.26)	15.76(0–57.41)	5.545	0.063
5minutes after reversal	6.527 (-17.895 – 18.75)	3.09 (-14.29 – 42.86)	18.71(-5.31–43.94)	6.167	0.046*

N= number , F= One way ANOVA test , $\chi^{2=}$ Chi square test, p< 0.05 is statistically significant

Figure (1): Combined bar chart showing comparison between the studied groups regarding degree of cough.

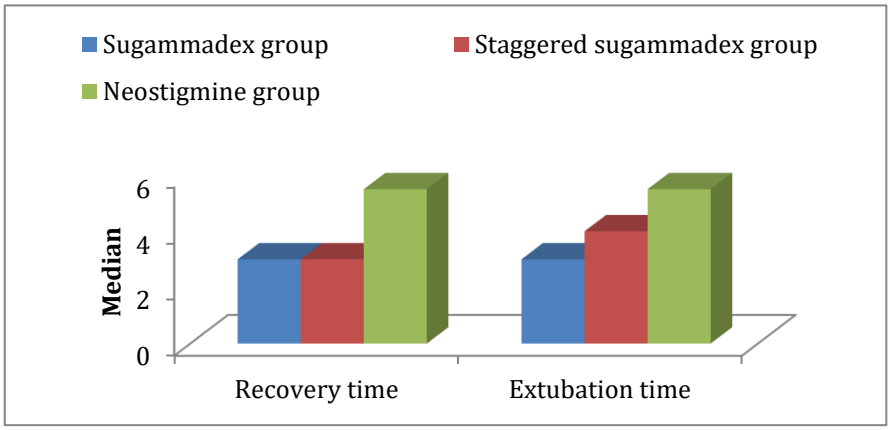

Figure (2): Combined bar chart showing comparison between the studied groups regarding recovery and extubation time.

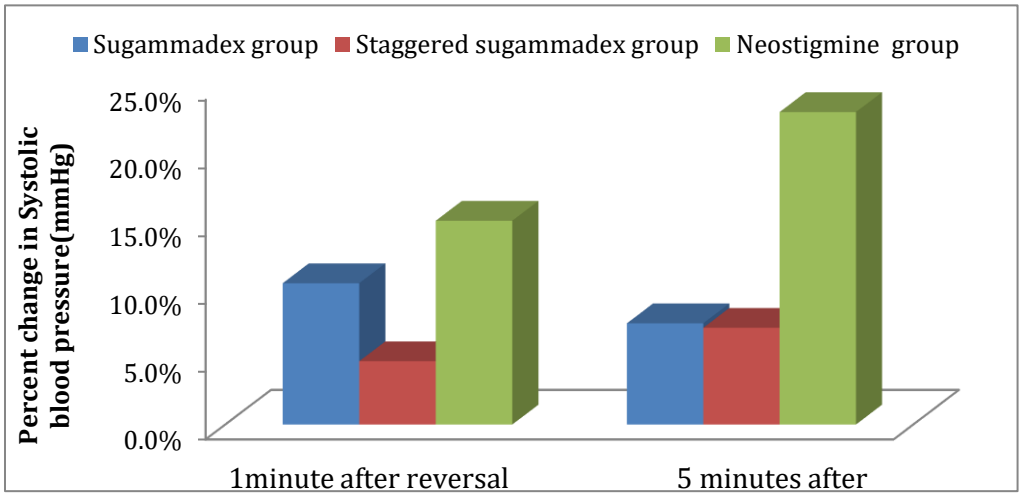

Figure (3): Combined bar chart showing comparison between the studied groups regarding percent change in systolic blood pressure over time.

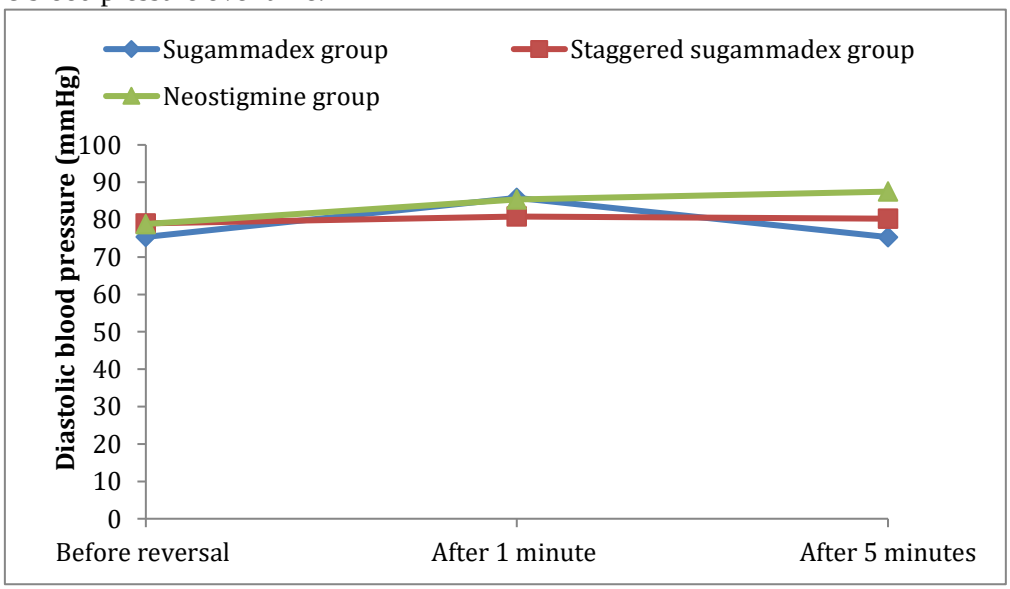

Figure (4): Multiple line graph showing comparison between the studied groups regarding diastolic blood pressure values over time

DISCUSSION

Considering the preoperative symptoms among the studied group, nasal obstruction was the commonest complain being present in 10 patients (83.3%) of the studied group followed by nasal discharge in nine patients (75.0%) and the least symptoms were facial pain & headache which was present in six patients (50.0%) of the studied group**.** These data were in agreement with that of **Comoglu et al.** [5] who found that the most common symptoms were nasal obstruction (12/12) (100.0%), snoring (9/12) (75.0%), rhinorrhea (7/12) (58.3%), and hyposmia (6/12) (50.0%) among their studied patients.

Similarily, **Ismaeil & Abdelazim** [6] whose study included 32 patients with antrochoanal polyp, divided into two equal groups the 1st group underwent endoscopic middle meatal antrostomy (EMMA), and the 2nd group underwent a combined surgical technique using EMMA together with endoscopic transnasal prelacrimal recess approach aiming to assess the effectiveness of ETPRA approach in preventing the recurrence of antrochoanal polyps. They found that the most common symptoms were unilateral nasal obstruction in 32/32 (100%), snoring 24/32 (75%), rhinorrhea 19/32 (59.38%), headache 31/32 (96.88%), and hyposmia 17/32 (53.13%). Nasal polyp protrusion into the MS was found in 27 (84.38%) patients.

Regarding the pathological lesion, the commonest pathological lesion in the present study was antrochoanal polyp (ACP) which was present in six patients (50.0%) of the studied group followed by Inverted papillomas (IP) in three patients (25.0%) and dental cyst which was present among two patients (16.7%) and the least one was maxillary retention cyst present on one patient (8.3%).

In this study, an important step in planning surgery is the study of the depth of the prelacrimal recess which will orient the surgeon to the amount of bone to be removed. The distance between the pyriform aperture and the superior most part of the NLD ranged from (3.2 to 6.2mm) with a mean of (4.8±0.91), between PA and the middle part of the NLD ranged from (6.1 to 9.3 mm) with a mean of (7.6±0.93) and from PA to the inferior most part of the NLD ranged from (6.9 to10.2 mm) with a mean of (8.6±0.98).

That was consistent with **Kashlan and Craig** [7] who found that the distance between the PA and the superior part of NLD ranged from 0-11.9 mm with a mean of 5.5 mm, between the PA and middle part of NLD ranged from 0-13.6 mm with a mean of 7.6 mm, between PA and inferior part of NLD ranged from 1.9 – 14.2 with a mean of 8.4 mm.

These observations directed us that the safest entery to the maxillary sinus along the prelacrimal approach would be in the inferior part of the maxillary sinus because it has the maximum depth away from the nasolacrimal duct.

Lin et al. [8] performed middle meatal antrostomy before the prelacrimal recess approach technique because middle meatal antrostomy provides a better drainage route for the MS and wider access to the MS for postoperative treatment.

In the same manner we performed wide MMA in all cases as we tried first to remove the lesions through the widened ostium and only the prelacrimal approach was performed if there is doubt about the completeness of removal.

The operation time was more when prelacrimal recess approach was done after doing MMA Mean increase about 33 minutes.

Near results were reported by **Al Ayadi, et al.** [9] where the operation time was prolonged by a mean of 30 min, which may be due to lack of experience and practice with the new approach and also in agreement with **Ismaeil & Abdelazim** [6] who reported that the operative time was longer when ETPRA was used. However, with this increase in time, there is the ability of complete removal of the polyp with no recurrence rate, which makes prolonged time a great benefit and is not to be considered a disadvantage. On the other hand, **Lee, et al. [10]** found that the prelacrimal recess approach had less operation time (P=0.825), more bleeding amount (P=0.999) and the same hospital stay (P=0.397) than other approaches.

Of the twelve patients operated by PLRA in our study, the approach was of benefit to eleven of them as residual pathology that, could not be removed through the wide MMA, was found and removed. However, in one patient with antrochoanal polyp no residual lesion was found and only thickened mucosa was removed from the anteromedial wall of the maxillary sinus through the approach.

Suzuki et al. [11] & Al Ayadi, et al. [9] described the approach the modified transnasal endoscopic medial maxillectomy'' and stated that it had the following advantages: (a) preservation of the IT, NLD and lateral nasal mucosa; (b) wide access to the MS by shifting the IT, NLD and lateral nasal mucosa in the medial direction; and (c) direct access to the MS, resulting in an easier operation with a straight endoscope and instruments. These advantages were encountered and are in agreement with our assessment of the PLRA. However, our work differs from their work in that we were able to remove the lesions without medial displacement of the nasolacrimal duct in eight cases and we only displaced it medially in four cases.

Regarding the lesion's attachment site, our study demonstrated that the commonest maxillary sinus lesions origin was the antero-inferior wall (41.7%) of the studied group followed by the lateral wall in four patients (33.3%) of the studied group and the least origin was postero-medial wall which was found on three patients (25.0%).

This is in agreement with **Lee, et al. [10]** study where the attachments in 10 cases of benign maxillary sinus tumor were found at the anterior wall (30.0%), lateral wall (10.0%), medial wall (20.0%), inferior wall (10.0%), and diffuse attachment (30.0%).

Regarding postoperative complications, our present study showed five cases had minimal facial pain at the side of which Prelacrimal recess approach was done which completely improved after two weeks and two cases had epiphora which persisted on only one patient after six months**.** This patient had an inverted pappiloma that necessitated sacrifice of his NLD.

Concerning post-operative endoscopic evaluation, the present study showed that eleven cases (91.7%) of the studied group had the flap in place and only one patient (8.3%) had a small perforation of the inferior meatal flap that spontaneously healed in two weeks. Nine cases (75.0%) of the studied group didn't show any crustation or granulation tissue in place of prelacrimal recess incision while three patients (25.0%) had a mimimal granulations and crustation for only four weeks. Eleven cases (91.7%) of the studied group didn't have synechia and only one patient (8.3%) had an adhesion between middle turbinate and the lateral nasal wall. No cases showed any bleeding or blood clots.

In **Al Ayadi, et al. [9]**, study the inferior turbinate stability was compromised in (15%) of patients; facial pain was present in (10%) of patients after a 3-month follow-up period; persistent epiphora was present in (5%) of patient 3 months after the operation; and inferior meatus adhesions were found in two (10%) patients.

Similarly, **Comoglu et al.** [5] nearly found the same results. NLD injury occurred in two patients during operation but neither had epiphora postoperatively. Three (3/12; 25%) patients had synechia formation between the lateral nasal wall (particularly on the inferior edge of the mucosal flap) and septum just superior to the inferior turbinate. One of the three (1/12; 8.3%) patients with synechia was symptomatic and required surgical treatment under local anesthesia. No patients developed recurrence during follow-up.

In the present study, there was no recurrence of the lesions during the follow up period. These findings are in similarity with the results of **Chaiyasate et al. [12]** who suggested that patients should be followed up for at least 2 years postoperatively to detect recurrence. In their study, no recurrence was seen, and no postoperative delayed complications were detected during the follow-up period (range: 24–36 months).

In **Yu, et al. [13]** study Postoperative follow-up period was 3–10 years, with an average of 5.5 years. Of the 71 patients, 6 (8.5%) had postoperative recurrence. Among the 20 patients with PLRA, 1 had recurrence, in which the lesion was located on the anterior-medial wall of maxillary sinus cavity and recurred 8 months after surgery. After surgery by PLRA, there was no vision disorder, diplopia or epiphora; no facial numbness, pain or swelling; and no nasal complications such as dry nose.

At re-examination at 3 months after surgery, the operated cavity was completely epithelialized and no tumor recurred. In 4 cases, cystic vesicles or granuloma hyperplasia occurred in the operated cavity, which were removed by nasal endoscopy, and disappeared 2–4 weeks after flushing the nasal cavity, and no recurrence was found. Stenosis of the middle meatal antrostomy and scarification were observed in 2 cases.

The low recurrence rate in our study is due to the fact that we only had 3 IP patients while Yu, et al. study was mostly on patients with IP.

Also, a study conducted by **Lee, et al. [10]** in comparison of surgical outcomes according to surgical approach. There were no cases of failure of gross total removal during surgery, and no recurrences were observed during the follow-up period for either group.

Additionally**, Ismaeil & Abdelazim [6]** Recurrence rate of antrochoanal polyp has been reduced with the usage of ETPRA in comparison with EMMA alone. And their results reported bleeding was found in only one (6.25%) patient in ETPRA group, and it was moderate bleeding and managed by anterior nasal pack in the outpatient clinic. However, one patient in the EMMA group had synechia formation between the middle meatus and the septum, whereas three patients in ETPRA group had synechia formation between the lateral nasal wall and the septum just superior to the inferior turbinate; the four patients in both groups were not complaining and needed no surgical interference. Recurrence was found in three (18.75%) patients in EMMA group, and there was no recurrence in the ETPRA group. They showed a statistically highly significant value ($P<0.001$). However, NLD injury was found in two patients in ETPRA group, and postoperative lacrimation presented in only one (6.25%) patient of the same group; they were statistically insignificant ($P>0.05$).

CONCLUSIONS

Transnasal endoscopic PLRA is a minimally invasive, safe and effective method for removal of benign maxillary sinus lesions that canot be adequately removed through a wiedened MMA.

The PLRA achieves the exposure range of medial maxillectomy and the Caldwell-Luc surgery, and retains the integrity of the IT and lacrimal duct system. While fully exposing the lesions for complete removal, the nasal function is well preserved.

In most cases, the PLRA can replace the Caldwell-Luc surgery and is an ideal surgical method in treating maxillary sinus IP under endoscopy. The approach has no major intraoperative or postoperative complications.

Endoscopic Transnasal Prelacrimal Recess Approach (ETPRA) is a novel, reliable, and useful method for the treatment of primary or recurrent MS lesions. It ensures good exploration of the maxillary antrum and easy access to the origin on the maxillary wall without the need of additional approaches.

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