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Randomized Comparison of Monitored Anesthesia Care and General Anesthesia Techniques in Patients Undergoing Sialendoscopies

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Abstract

Background and aim: The choice of anesthetic technique for sialendoscopy is not clear due to lack of enough evidence. The present study aimed at comparing general anesthesia (GA) and monitored anesthesia care (MAC) for adult patients undergoing sialendoscopies.

Methods: This was a randomized, open-label, single center study. Sixty ASA I/II adult patients undergoing sialendoscopy received either GA with endotracheal intubation and oropharyngeal packing or MAC with midazolam, fentanyl and lignocaine infiltration of mucosa surrounding the papilla. The primary outcome was time to discharge readiness from recovery room; whereas secondary outcomes included hemodynamic changes, operating room (OR) times, perioperative complications, patient satisfaction and surgical difficulty scores. Statistical analysis was performed using Student 't' test, Mann-Whitney U test, Chi-square test and Linear Mixed Model. P<0.05 was considered significant.

Results: The median (IQR[range]) time to discharge readiness was significantly shorter following MAC {0(0[0-30]) mins} as compared to GA {30(30[0-75]) min}; (p=0.000). The mean anesthesia, surgery and OR durations were also shorter under MAC. The patient satisfaction score appeared to be better with GA but this difference was statistically insignificant (p=0.052). The surgical difficulty level was significantly higher in group MAC (p=0.024). MAC resulted in more stable intraoperative hemodynamic parameters, lower postoperative pain scores and avoidance of complications associated with GA.

Conclusion: Selection of MAC for sialendoscopy hastens postoperative recovery, reduces perioperative complications and saves operating room time without significant difference in patient satisfaction.

Keywords: Sialendoscopy; Sialolithiasis; Anesthetic technique; Monitored anesthesia care; General anesthesia; Post anesthesia care unit; Time to discharge readiness

Introduction

Sialendoscopy is a relatively new procedure that allows endoscopic transluminal visualization of major salivary glands for diagnosis and treatment of both inflammatory and obstructive pathology related to ductal system [1]. Its indications include sialolithiasis, ductal stenosis, intraductal masses etc. [2].

Sialendoscopy can be performed under general anesthesia (GA), local anesthesia (LA) or monitored anesthesia care (MAC) [3], with GA being the most commonly used technique in our hospital. The choice of mode of anesthesia varies from hospital to hospital with no clear evidence available for the most suitable anesthetic technique for this procedure. Every technique has its own advantages and disadvantages. Some retrospective studies have assessed the feasibility of LA [3] or MAC [4] for sialendoscopy; However, there is no study available in literature that has prospectively compared MAC with GA. Therefore, the present study was conducted to compare GA and MAC as anesthetic techniques for adult patients undergoing sialendoscopies. The primary objective was to study the time to discharge readiness from recovery room; whereas secondary objectives included operating room (OR) times; hemodynamic changes; complications; level of patient satisfaction and surgical difficulty.

Methods

This randomized, open-label, single center study was conducted using a parallel design with 1:1 allocation ratio. Approval from the Institutional Ethics Committee for Human Research was taken and the clinical trial was prospectively registered at http://ctri.nic.in. The patients were recruited from February 2014 to March 2015. Written informed consent was taken from the patients prior to inclusion in the study. The manuscript follows the CONSORT statement. The study included 60 ASA I/II adult patients undergoing diagnostic or interventional sialendoscopy in a tertiary care teaching hospital. Uncooperative patients who refused to undergo surgery under either MAC or GA were excluded. The patients were randomly divided, using computer generated random number table, into two groups of 30 patients each, to receive either MAC or GA as anesthetic technique. Sequentially numbered sealed opaque envelopes were prepared by the

statistician for allocation concealment. These envelopes were opened immediately after shifting the patient to OR.

In the preoperative room, the patients were explained about pain assessment using Numerical Rating Scale (NRS) (0-10; 0-no pain; 10-worst imaginable pain). In OR, standard monitoring in the form of ECG, heart rate (HR), noninvasive blood pressure and pulse oximetry were instituted. An 18-gauge IV cannula was inserted and Ringer Lactate infusion started. No anti-sialogogue was used.

The patients in group GA were administered fentanyl 1 μg/kg and ondansetron 4 mg intravenously. Anesthesia was induced with propofol 2-2.5 mg/kg depending on loss of response to verbal commands. Orotracheal or nasotracheal intubation, depending on surgeon's requirements, was facilitated with vecuronium 0.1 mg/kg. Oropharyngeal pack was inserted in all the cases. Anesthesia was maintained with oxygen, nitrous oxide, isoflurane 1-2% to achieve 1 minimum alveolar concentration and top-up doses of vecuronium. Mucosa around papilla was not infiltrated with lignocaine in this group. Fentanyl 0.5 μg/kg was repeated if HR or systolic blood pressure (SBP) increased more than 20% above baseline despite adequate depth of anesthesia.

Neuromuscular blockade was reversed using neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg at the end of surgery. Extubation of trachea and shifting of patients to post anesthesia care unit (PACU) was done upon return of consciousness and adequate reversal of neuromuscular blockade, defined as response to verbal commands in the form of eye opening, tongue protrusion and sustained head-lift for a minimum of 5 sec. The patients in group MAC received IV midazolam 0.03-0.05 mg/kg, fentanyl 1μg/kg and ondansetron 4 mg. Fentanyl 0.5 μg/kg was repeated, as required. Oxygen was administered by nasal cannula. Surgeons infiltrated mucosa surrounding the papilla with 2% lignocaine. Rinsing solution of endoscope consisted of 5 ml 2% lignocaine and normal saline. More lignocaine was added to the rinsing solution, if required. The patients were shifted to PACU as soon as surgery was over and monitoring devices were removed.

Hemodynamic parameters and oxygenation were monitored throughout the surgery. Any complications or difficulties encountered were recorded and managed. Surgical time (from handing over the patient to the surgeons until end of surgery), anesthesia time (from beginning of intravenous drug administration to adequate recovery from anesthesia in group GA and removal of nasal cannula in group MAC) and the OR time (from wheeling in to wheeling out of the patient from OR) were recorded. In PACU, HR, SBP and oxygen saturation were recorded at the time of arrival to PACU (0 min) and then every 15 min till discharge readiness from PACU or at least 90 min, whichever was later. Pain scores were noted every 30 min.

Episodes of nausea, vomiting or any other complications were recorded and appropriately managed. NRS pain score>3 was treated with tramadol 1 mg/kg IV. Time to discharge readiness from PACU was recorded when the patients fulfilled the Fast-Track Score by Song et al. [5]. The patients scoring a minimum of 12 out of 14 were considered fit for discharge. The patients' satisfaction with anesthesia experience was assessed in the ward after discharge from PACU and graded as 'Good', 'Average' or 'Poor'. Their willingness to receive similar anesthesia for this procedure in future was also asked. The surgeons graded level of difficulty faced during the procedures 'No difficulty', 'Slight difficulty' and 'Great difficulty/impossible to proceed'.

The primary outcome was time to discharge readiness from PACU. The secondary outcomes included hemodynamic changes, OR time, intra-operative and post-operative complications, patient satisfaction score and surgical difficulty score. We could not find any study mentioning length of PACU stay following sialendoscopy. According to a previous study conducted in all patients undergoing GA, the mean length of PACU stay of adult patients was calculated as 101.7+53.7 min, when a predetermined discharge criterion was used [6]. A 50% reduction in PACU stay was considered clinically significant. Thus, sample size required at 5% level of significance and 90% power was 27 patients per group. Therefore, 30 patients were included in each group. Statistical analysis of recorded parameters was performed using SPSS version 20 (Armonk, NY: IBM Corp.). Student's 't' test was applied to compare quantitative demographic profile, intraoperative duration and intraoperative fentanyl requirements. Mann-Whitney U test was used to compare time to discharge readiness.

Chi-square test was used for analyzing patient's gender, satisfaction score, surgical difficulty score and complications. Since the surgery was completed at different time intervals, Linear Mixed Model with Best Covariance Structure selected using minimum AIC (Akaike Information Criterion), was used for intergroup comparisons of intra operative hemodynamic parameters. Two Factors Repeated Measures ANOVA was used to compare post-operative parameters, Fast-track scores and pain scores. $P<0.05$ was considered statistically significant.

Results

CONSORT flow diagram for the study is shown in Figure 1. Both groups were comparable with respect to demographic profile, types of cases, baseline HR and SBP (Table 1).

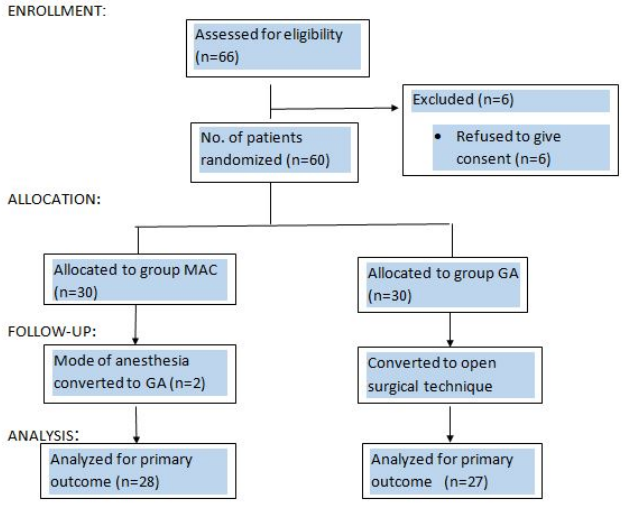

Figure 1: CONSORT flow diagram.

	Group MAC (n=30)	Group GA (n=30)	p value
Age (years)	33.7 ± 10.3	29.0 ± 9.9	0.075
Weight (kg)	61.7 ± 13.9	60.2 ± 8.7	0.603
Female:Male	12:18	14:16	0.602

ASA I/II	27:03	28:02	1.00
Parotid:Submandibular	08:22	13:17	0.176
Diagnostic:Therapeutic	17:13	15:15	0.605
Baseline Heart Rate (beats/min)	80.6 ± 14.4	80.7 ± 16.1	0.966
Baseline Systolic Blood Pressure(mmHg)	124.2 ± 15.4	119.6 10.7	0.185
Values are mean ± SD or number (proportion)			

Table 1: Demographic profile and other patient characteristics.

In group GA, 12 underwent nasotracheal intubation and the rest 18 had orotracheal intubation. In two cases in group MAC, anesthetic technique had to be converted to GA. Three cases in group GA turned out to be very difficult and surgical technique was converted to open surgery. This difficulty was not attributed to the anesthetic technique by the surgeons. Therefore, intraoperative durations, Fast-track scores, time to discharge readiness, intraoperative fentanyl requirement and post-operative pain scores were analyzed for 28 patients in group MAC and 27 in group GA. The mean durations of anesthesia, surgery and total OR time were significantly shorter in group MAC as compared to GA (Table 2).

	Group MAC (n=28)	**Group GA (n=27)**	**p value**
Operating room duration (min)	57.3 ± 23.1	98.9 ± 27.1	<0.001
Anesthesia duration (min)	42.5 ± 20.8	80.0 ± 25.8	<0.001
Surgery duration (min)	35.5 ± 20.7	56.7 ± 27.5	0.002
Values are mean ± SD			

Table 2: Intraoperative time durations.

The mean Fast-Track scores to assess discharge readiness from PACU for both groups are shown in Figure 2. The interaction between time and group was significant. Thus, to compare the groups at different time intervals, p-values were adjusted as per Bonferroni correction. The scores were greater in group MAC as compared to group GA and significant at each time interval (p values varying from 0.000 to 0.007). The median (IQR[range]) time to discharge readiness was significantly shorter in patients undergoing MAC,0 (0[0-30]) min; as compared to those receiving GA, 30 (30[0-75]) min; (p<0.001).

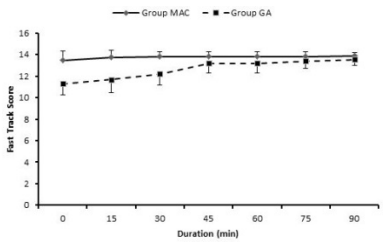

Figure 2: Fast Track scores for readiness to discharge. Values are mean ± SD. P value at 0 min, 15 min and 30 min=0.000.

Group MAC patients required significantly more fentanyl intraoperative, with nine patients requiring additional boluses in contrast to none in group GA (p=0.002). The mean total requirement in group MAC was 72.4 ± 22.1 μg compared to 61.3 ± 10.8 μg in group GA (p=0.023). On the other hand, in PACU, four patients in group GA required rescue analgesia as compared to only one in group MAC (p=0.112). Post-operative pain scores in both groups at varying time points are shown in Figure 3. The interaction between time and group was insignificant (P=0.474). At every corresponding time interval from 0 to 90th min, pain scores in group GA were significantly higher than that in group MAC (p=0.001) Figure 3.

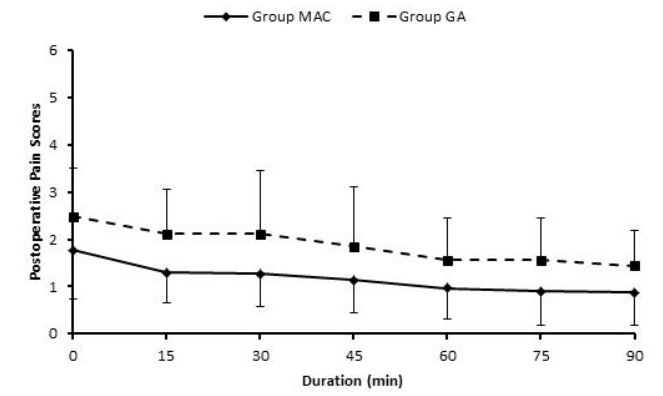

Figure 3: Postoperative pain scores.

Results of linear mixed model showed a significant interaction between group and intraoperative time with respect to HR and SBP. The pattern of HR and SBP was different between the two groups. In group GA, HR started declining 15 min onwards post-induction period, compared to the baseline value (p<0.01). No such decline was observed in group MAC. On inter-group comparison, there was a significant difference between the two groups, with HR values being significantly lower in group GA than in MAC from 15th to 75th min (p<0.001 to 0.023). Similarly, SBP was significantly lower in group GA than in group MAC from 5th to 75th min. (p<0.001 to 0.014). However, no patient in either group had SBP<90 mmHg. Best covariance structure was found autoregressive of first degree. When applying the same tests in 28 patients in group MAC and 27 patients in group GA, similar pattern of results was seen. During postoperative period, two factor repeated measures ANOVA showed no statistically significant difference in HR (p=0.833) and SBP (p=0.748) between the groups at different time intervals.

The patient satisfaction score appeared to be better with GA but this difference could not achieve statistical significance (p=0.052). In Group MAC, 23 (76.7%) patients had good experience with anesthetic technique, 6 (20%) had average and 1 (3.3%) had poor experience. On the other hand, in Group GA, 29 (96.7%) patients had good experience, 1 (3.3%) had average and none had poor experience. Twenty-six patients in group MAC and all 30 in group GA agreed for similar anesthetic technique in future (p=0.056). The surgical difficulty level was higher in group MAC (p=0.024). There was no difficulty in 24 cases, slight difficulty in four and great difficulty in two cases. Great difficulty was due to continuous severe pain in one patient and persistent nausea in another. This necessitated conversion of anesthetic technique to GA. In group GA, surgeons did not experience any difficulty due to anesthetic technique in any patient.

In group GA, three patients suffered trauma leading to nasal bleeding during nasal intubation, two developed laryngospasm at the time of extubation and one patient had intraoperative bradycardia requiring atropine administration. These complications were not present in group MAC. During postoperative period, one patient in group GA vomited and another developed shivering. Vomiting was managed by dexamethasone and shivering was treated with tramadol. No such complications were seen in group MAC. This difference in the incidence of complications between the two groups was statistically not significant (p=1.00).

For further analysis of primary outcome, i.e., time to discharge readiness from PACU, intention to treat analysis was applied substituting the median values. There was no change in results when compared to the analysis performed in 28 and 27 patients in groups MAC and GA respectively.

Discussion

The results of this study demonstrated that the time to discharge readiness from PACU and the total time spent by the patient in OR were shorter after MAC than after GA. MAC resulted in more stable intra operative hemodynamic parameters, lower postoperative pain scores and avoidance of complications associated with GA. Patient satisfaction after both techniques was statistically comparable. However, level of surgical difficulty was higher with MAC. GA provides better patient comfort. The surgeons also find it easier to perform procedures, even those with longer duration. However, GA may be associated with various complications like post-operative nausea and vomiting; cardiopulmonary disturbance; and complications associated with laryngoscopy and intubation e.g., dental injury, sore throat, bleeding from nose in case of nasal intubation, tachycardia and hypertension etc. [7]. In MAC the amount of drugs administered can be tailored to requirements of the patient and it is more economical as compared to GA [8, 9]. Moreover, by avoiding GA and thus its associated complications, the outcome may be improved and operating room as well as post-anesthesia recovery time may be reduced. As sialendoscopy is often done as a day care procedure, the possibility of bypassing PACU could be a great advantage. For the same reason, the Fast-Track Score by Song et al. was used to compare discharge readiness in the two groups.

Even after thorough search of literature, no prospective, randomized study could be found comparing different anesthetic techniques in patients undergoing sialendoscopies. There is a retrospective case series in which tolerability of sialendoscopy under LA has been assessed [3]. All the patients receiving GA were excluded from this study. A similar retrospective study was conducted in pediatric population [10]. Recently, another group of workers studied operative and anesthetic times for sialendoscopy under MAC and GA [4]. However, this was also a retrospective review.

In the present study, durations of anesthesia, surgery and OR time were significantly shorter in MAC than under GA. As the patients were randomized, it was by chance that the surgical procedures under GA were longer than those under MAC. This factor could have influenced the mean duration of anesthesia and OR time. Therefore, duration of surgery for each patient was subtracted from the respective OR duration. Means of this time duration for both groups were calculated and compared. These were 22.5 (8.9) min for group MAC and 44.4 (14.3) min for group GA. This difference was statistically significant (p=0.000). Thus, despite negating the effect of surgical duration, OR time was shorter in group MAC. This was because in MAC, minimal time was required to provide sedation and analgesia; whereas, considerable time was spent for induction and reversal of neuromuscular blockade in GA. MAC also significantly reduced the time spent in PACU, often almost bypassing it as in most cases, the patients fulfilled the criteria for discharge readiness almost immediately after being shifted out of OR. The reduction in time to discharge from PACU is advantageous as sialendoscopy is usually done as a day care procedure where early recovery from anesthesia is desirable.

Trujillo et al. conducted a retrospective review of patients undergoing sialendoscopies with MAC or GA with endotracheal intubation (GETA) [4]. Median OR and anesthesia times, postoperative nausea and pain were significantly less in group MAC compared to group GETA [4]. In the present study, 23 patients (76.7%) described their experience under MAC as good and only one patient had poor experience. Twenty-six (86.7%) patients in this group agreed for similar anesthesia in future. Our results are supported by the retrospective analysis by Luers et al. who studied 84 adult patients undergoing sialendoscopies under MAC [3]. The majority (80%) tolerated the surgery well under MAC, whereas 91% patients agreed to receive similar anesthesia in future. However, it was a retrospective case series in which only patients having undergone sialendoscopy under MAC were included and those receiving GA were excluded. Level of surgical difficulty was also not recorded.

In the present study, fentanyl was repeated during intraoperative period if HR or SBP increased more than 20% above baseline values. The lower intraoperative fentanyl requirement under GA may be explained by the use of balanced anesthetic technique using different agents including inhalational anesthetics and muscle relaxants to maintain adequate depth of anesthesia. However, in postoperative period, pain scores were lower in patients receiving MAC than GA. The residual effect of local anesthetic infiltration during MAC could have contributed to this. GA may be associated with various intraoperative and postoperative complications e.g. trauma during intubation, airway complications, hemodynamic instability, post-operative nausea and vomiting, shivering etc. Many sialendoscopies require nasal intubation as this does not interfere with the surgical field. In the present study, use of MAC reduced the incidence of complications commonly associated with GA and tracheal intubation. However, the difference was not statistically significant as our study was not adequately powered to detect this difference.

Use of anticholinergics was avoided as these drugs reduce salivary gland secretions and thus make localization of salivary duct's opening difficult. The hemodynamic stability was well maintained in group MAC. However, one patient in group GA required atropine to treat bradycardia. In our study only three cases (5%) were converted from sialendoscopy to open surgery. All of them had received GA. In these cases, the stones were deeply impacted in secondary branches of salivary duct. Thus, the success rate was 95%. Stones up to size of 7 mm were successfully extracted by sialendoscopy in both groups.

In both cases in group MAC requiring conversion to GA, indication of sialendoscopy was sialolithiasis and the stones were small (2.6 mm and 4 mm). Thus, nature of surgery was not difficult and conversion to GA was needed due to lack of cooperation from the patients. Surgeries of durations as long as 85 min could be successfully completed under MAC. This study has certain limitations. First, blinding was not possible due to nature of the study as the anesthetic techniques were entirely different. For the same reason, the grading of surgical difficulty

by the surgeons also could have been biased. Second, the lower intraoperative fentanyl requirement due to use of balanced anesthetic technique in group GA could have contributed to the higher postoperative pain scores in this group. Lastly, although the patients were divided randomly into two groups, the mean duration of surgery in group GA was longer and three cases in this group were converted to open gland excision. Thus, it appears that by chance, some more difficult cases were randomized to GA group. Hence the results of this study need to be interpreted with caution.

Conclusion

Sialendoscopy performed under MAC significantly hastens postoperative recovery. Additionally, it reduces perioperative complications, and saves OR time without significant difference in patient satisfaction as compared to GA. Thus, MAC can be a good and safer option in selected patients.

References

1. Marchal F, Dulguerov P (2003) Sialolithiasis management: The state of the art. Arch Otolaryngol Head Neck Surg 129: 951-956.
2. Nahlieli O, Nakar LH, Nazarian Y, Turner MD (2006) Sialendoscopy: A new approach to salivary gland obstructive pathology. J Am Dent Assoc 137: 1394-1400.
3. Luers JC, Stenner M, Schinke M, Helmstaedter V, Beutner D (2012) Tolerability of sialendoscopy under local anaesthesia. Ann Otol Rhinol Laryngol 121: 269-274.
4. Trujillo O, Drusin MA, Pagano PP, Askin G, Rahmati R (2017) Evaluation of monitored anesthesia care in sialendoscopy. JAMA Otolaryngol Head Neck Surg 143: 769-774.
5. White PF, Song D (1999) New criteria for fast tracking after outpatient anesthesia : A comparison with the modified Aldrete's scoring system. Anesth Analg 88: 1069-1072.
6. Brown I, Jellish WS, Kleinman B, Fluder E, Sawicki K, et al. (2008) Use of post anesthesia discharge criteria to reduce discharge delays for inpatients in the post anesthesia care unit. J Clin Anesth 20: 175-179.
7. Hagberg C, Georgi R, Krier C (2005) Complications of managing the airway. Best Pract Res Clin Anaesthesiol 19: 641-659.
8. Asahq.org. American Society of Anesthesiologists. Position on monitored anesthesia care. [Updated October 17 2018; Cited 2018 November 11]. Available from: https://www.asahq.org/standards-and-guidelines/position-on-monitored-anesthesia-care.
9. Ghisi D, Fanelli A, Tosi M, Nuzzi M, Fanelli G (2005) Monitored anesthesia care. Minerva Anestesiol 71: 533-538.
10. Konstantinidis I, Chatziavramidis A, Tsakiropoulou E, Malliari H, Constantinidis J (2011) Pediatric sialendoscopy under local anaesthesia: Limitations and potentials. Int J Pediatr Otorhinolaryngol 75: 245-249.