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Comparative analysis of labetalol and remifentanil for inducing hypotension in oncological patients undergoing functional endoscopic sinus surgery

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ABSTRACT

Background: Surgical procedures involve head and neck had propensity to bleed because rich blood supply. Aim of study was to compare using labetalol and remifentanil to create controlled hypotension during Functional Endoscopic Sinus Surgery (FESS) among Iraq patients. Methods: In this prospective randomized clinical trial 40 patients underwent FESS under general anesthesia at Ghazi Al Harerri hospital, Baghdad Iraq. Patients were divided into two groups; the Labetalol Group (LG) received 20 mg bolus dose during 2 min followed by 0.5 mg/min-2 mg/min by infusion pump, and the Remifentanil Group (RG) received 0.5 mcg/kg/min -1 mcg/kg/min during 30 sec. Then infusion was given at rate of 0.25 mcg/kg/min-0.5 mcg/kg/min. Hemodynamic parameters during anesthesia were measured, complication and surgeon satisfaction rate was recorded. Results: hemodynamic parameters are compared in both groups at different time of study [55 min duration of surgery]. The mean of systolic blood pressure are significant at min 55 when P value [0.002] and the mean of diastolic blood pressure are significant at min 10,15,55 when P value[0.03, 0.05,0.02] respectively while the mean of pulse rate was significant at min 45 when P value[0.05], the mean differences in mean arterial blood pressure was significant at min 55 when P value (0.001), but mean of $ETCO_2$ and SPO_2 are insignificant between groups. Surgeon satisfaction score is better in remifentanil group when P value [0.006] with less complication in the same group Conclusion: With infusion of labetalol and remifentanil, we can induce effective controlled hypotension with both drugs, but remifentanil as sole agent is better with short action and rapid recovery time and less complication with better surgeon satisfaction score over labetalol but economically labetalol is better.

Keywords: hypotensive technique, syringe pump, remifentanil, labetalol, functional endoscopic sinus surgery, oncological Patients

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INTRODUCTION

One of the most serious brain conditions Head and neck surgeries can be associated with significant blood loss due to the rich blood supply in the region. Reduction in the surgeon's visibility, extended surgical times, lowering the quality of the surgery, and increasing the risk of complications are the common consequences. Therefore, to minimize these risks, several measures are usually taken, such as hypotensive anesthesia, and other blood-saving techniques to decrease the blood loss during surgery [1]. Endoscopic Sinus Surgery (ESS) is a minimally invasive surgical procedure that uses an endoscope to visualize and remove blockages in the sinus cavities. The procedure is typically performed to alleviate symptoms associated with chronic sinusitis, such as nasal congestion, facial pain, and difficulty breathing. ESS can also be used to treat other conditions such as nasal polyps, tumors, and certain types of headaches. It is done under general anesthesia and the patient will have a faster recovery than traditional sinus surgery [2]. Endoscopic Sinus Surgery (ESS) is an elective surgery that is commonly performed. However, it can carry some risks, one of which is bleeding. During the surgery, the surgeon will remove blockages in the sinus cavities which can cause minor bleeding. In some cases, this bleeding can be significant enough to require additional treatment or intervention. However, the bleeding is generally well-controlled during the procedure and most patients have minimal blood loss. The bleeding can also occur after the procedure and it could be treated by packing the nose, but this is not common [3]. Hypotensive anesthesia, which is a technique used to lower blood pressure during surgery, has been shown in clinical trials to be associated with less intraoperative blood loss compared to normotensive anesthesia in maxillofacial operations. However, hypotensive anesthesia can have the potential risk of decreased blood flow to vital organs such as the brain, heart, and kidneys [4]. Therefore, it is important for physicians (anesthesiologists) to carefully monitor the patient's blood pressure and make adjustments as

necessary to minimize these risks. A close collaboration between the surgeon and the anesthesia team is needed. Tang et al. found that there is a significantly increased risk of postoperative Acute Kidney Injury (AKI) when the intraoperative Mean Arterial Pressure (MAP) is under 55 mm Hg for more than twenty minutes [5]. In normotensive anesthesia, the technique is to keep the patient's blood pressure within normal levels during surgery. In other word, is to maintain the blood pressure within the range that was measured before the operation. In contrast, hypotensive anesthesia is to deliberately lowering the patient's blood pressure by thirty percent below the baseline level. The goal is to reduce the patient's Mean Arterial Pressure (MAP) to 50 mm-65 mm Hg and the systolic blood pressure to 80 mm-90 mm during the surgery. Praveen et al [6]. conducted a clinical trial which found that patients who underwent orthognathic surgery under hypotensive anesthesia had substantially less intraoperative blood loss compared to those who underwent the same surgery under normotensive anesthesia. Prasant et al [7]. Found that using hypotensive anesthesia during maxillofacial surgical procedures resulted in a significant reduction in blood loss ($P<0.05$), and an improvement in the quality of the surgical field. However, there was no significant difference in the duration of the procedures with and without induced hypotension. There are several hypotensive drugs (e.g Sodium nitroprusside, Nitroglycerin, Esmolol, Labetalol, Nicardipine, Fenoldopam, Remifentanil, Dexmedetomidine, Clonidine, Phentolamine) that can be used alone or in combination. However, simultaneous use of hypotensive anesthesia drugs can increase the risk of certain cardiac arrhythmias, such as ventricular fibrillation. These include: two studies, one by Sajedi et al, and another by Abdelraheem and Elkeblawy found that remifentanil was superior to labetalol in terms of surgical quality, patient and surgeon satisfaction, and significant intraoperative lowering of blood pressure [8, 9]. Zayed et al. concluded that compared to labetalol, Nitroglycerin-induced deliberate hypotension was associated with higher Peripheral Perfusion Index (PPI) and lower serum lactate levels during sinus endoscopic surgery. Lee et al. found that the recovery was faster in patients receiving remifentanil compared to those receiving dexmedetomidine in the immediate postoperative period after endoscopic sinus surgery [10, 11]. This study aims to compare the use of labetalol and remifentanil as hypotensive anesthesia drugs during elective endoscopic sinus surgery, and evaluate the incidence of adverse effects such as ventricular fibrillation. The goal is likely to find the most effective and safe combination of drugs for this specific surgical procedure.

MATERIALS AND METHODS

Study design and setting

A prospective randomized comparative clinical trial was conducted from 1st January to 1st September 2021 at the department of otorhinolaryngology, Ghazi Al-Hariri Hospital for surgical specialties in Baghdad Medical City, Iraq.

Randomization and patient selection

According to including and excluding criteria forty (40) patients were scheduled for Endoscopic Sinus Surgery (ESS) under general anesthesia. The surgical staff including the anesthesiologists and the hypotensive induced anesthesia drugs were blinded. The computer technique was recruited to generate randomization numbers and to allocate the eligible patients into two different groups (each consisted of twenty patients). The first group coded (RG) received bolus dose of remifentanil (0.5 mcg\kg-1 mcg\kg) over 30 sec., then a syringe pump infusion at rate of 0.25 mcg/kg/min-0.5 mcg/kg/min. The second group coded (LG) received bolus dose of labetalol [20mg within 2 min.], then infusion at rate of 0.5 mg/min-2 mg/min until reaching the suitable response (maximum dose of 300mg should not be exceeded).

Inclusion and exclusion criteria

All patients scheduled for elective Endoscopic Sinus Surgery (ESS), both genders, aged 18-65 years, scored (I-II) according to the American Society of Anesthesiologists (ASA) Physical Status Classification System have no history of allergy to drug, or bleeding tendency, willing to participate were included in the study [12]. We excluded patients with preoperative systolic blood pressure less than 90 mmHg, pre-operative arrhythmia, asthma, previous surgery of the nose, pregnant, and those not willing to participate.

Sample size

The estimated sample size of 36 patients was calculated using a formula to compare two means. The calculation considered a confidence level of 95% ($Z_{1-\alpha/2}$ =1.96), a test power of 80% ($Z_{1-\beta}$ =0.87), a standard deviation of the Mean Arterial Pressure (MAP) of 1.43, and a least significant difference between the two groups of 0.82. The sample size was increased to 40 patients (20 patients per group) to account for possible dropouts.

Anesthesia protocol

In the pre-operative stage, an informed consent form and a detailed medical history was registered to ensure the patient's fitness to study. Full physical examination was performed including weight and height measurements, with a list of the important laboratory tests such as Complete Blood Count (CBC), Prothrombin Time (PT) and renal and liver function tests.

During the intraoperative stage, patients in the two groups (RG, LG) underwent to standard measures to monitor various vital signs such as body temperature, plus rate, "the non-invasive blood pressure, electrocardiographic and capnography". After induction of GA, close monitoring also performed to control the "invasive blood pressure and saturation of arterial oxygenation". Before induction of GA, intravenous premedication midazolam at a dose

of 0.05 mg/kg, fentanyl at a dose of 50 mcg, and dexamethasone at a dose of 4mg were administered. While patient is lying in supine position, two IV. cannulas (20G) were inserted. Preoxygenation is secured for 3 minutes. General anesthesia was induced using Propofol at a dose of 1-2 mg/kg, and atracurium at a dose of 0.5 mg/kg, and paracetamol at a dose of 0.5-1 g as analgesia. The GA was maintained by isoflurane 1.5%, and at a dose of 0.01 mg/kg every twenty minutes. Intubation done and throat pack was inserted and patient positioned with slightly head up and mount catheter inserted to the circuit to be away from surgical field. Randomly assigned LG patients received labetalol bolus dose (20 mg over 2 min) and IV infusion using syringe pump at rate (0.5 mg/kg -2 mg/kg) slowly until desired response reached. The RG patients received remifentanil bolus dose (0.5-1)mcg/kg and then IV infusion using syringe pump at rate (0.25-0.5)mcg/kg/min. Additional dose using nitroglycerine at (50-100) mcg in case of lack of providing controlled hypotension. In RG, LG groups, the rate of Intra-Venous Infusion (IVI) was adjusted to make Mean Arterial Blood Pressure (MABP) twenty percent lower than the baseline of the patients. In both groups, systolic, diastolic, MAP, HR, SPO_2 and $ETCO_2$ were measured at baseline minute which is before induction of anesthesia. The monitor was set to measure blood pressure every 2.5 minutes. Readings of 5 minutes intervals were recorded for statistical analysis during first 25minutes. Then, the readings at 10 minutes interval after stabilization of blood pressure were recorded. Infusion of Ringer lactate was given at rate of 5 mL/kg. End-tidal carbon dioxide CO_2 at a rate of 30 mmHg – 35 mmHg was adjusted with mechanical ventilation. Hypotension was significant when the MABP decreased by thirty percent or more under the values of baseline. IV ephedrine (0.2 mg/kg) used to control the hypotension. Bradycardia considered Significant when the HR come down below 60 beats/min. IV atropine (0.01 mg/kg) used to control bradycardia. Ten minutes before the end of surgery, the IVI of labetalol or remifentanil was stopped. Intravenous Neostigmine (0.05 mg/kg) and atropine (0.02 mg/kg) were to revers muscle relaxation. Patients prepared for the recovery position with spontaneous breathing after discontinuing of the inhalation anesthesia and removing the endotracheal tube. A six-point scale grading system for bleeding assessment during operation was recruited after the end of surgery [13, 14]. The grading system was explained to the surgeons to give their opinions about the surgical field and the results were recorded and compared between groups. The surgical operations have been done by more than one surgeon, therefore, the consistency to estimate the surgical field was not ensured.

Statistical analysis

Data was analyzed using SPSS version 16 (IBM©, Chicago, IL, USA). The mean and Standard Deviation (SD) was recruited to present the quantitative variables, while the frequency and percentage were used to present the qualitative variables. An independent sample t-test and Chi-square tests were used in bivariate analysis. The statistically significant was considered below 0.05.

RESULTS

Forty-three patients underwent screening for eligibility. Three patients were excluded due to inclusion criteria, and 40 patients were randomly and equally distributed to receive either remifentanil or labetalol for hypotension induction (Figure 1).

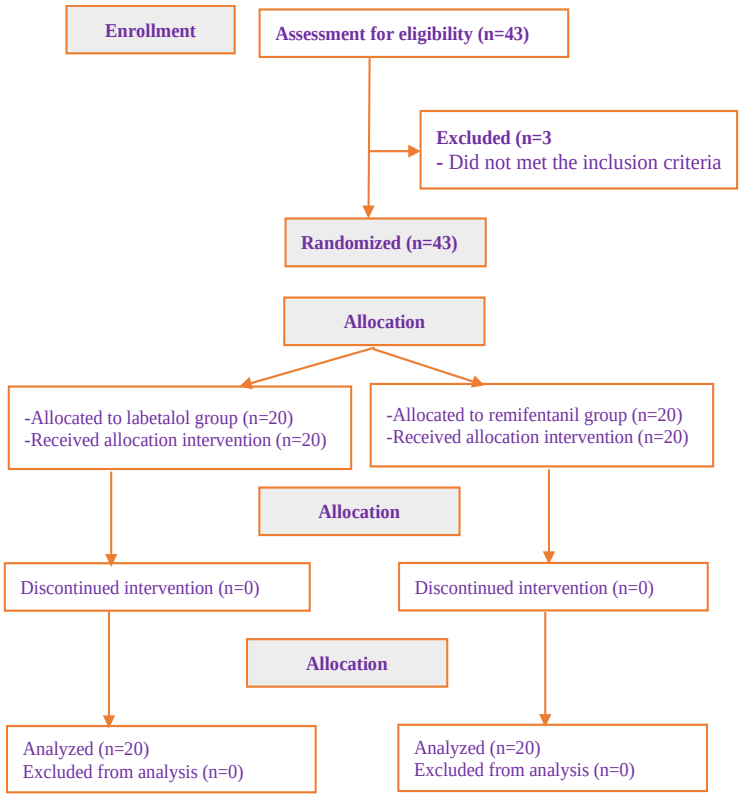

Fig. 1. Flow diagram showing patient's requirements

The patient's characteristics were presented in Table 1. The mean age of patients was 28.80+7.28 and 31.90+9.36 for LG and RG, respectively. The male to female ratio was 1:1. Based on findings of either "independent sample t-test or Chi-square test", there were no significant differences between LG and RG for "mean age, gender, weight, ASA status, and mean time to perform surgery" (P>0.05).

Tab 1. Patient's characteristics in two studied groups (n=40)

Patients' characteristics	LG (n-20)	RG (n=20)	*P*-value
Age (years)	28.80 ± 7.28	31.90 ± 9.36	0.25
Weight (kg)	76.45 ± 4.65	74.66 ± 5.09	0.135
Gender			
Female	7 (17.5)	11 (27.5)	0.342
Male	13 (32.5)	9 (22.5)	
ASA status			
I	19 (95.0)	18 (90.0)	0.076
II	1 (5.0)	2 (10.0)	
Duration of surgery (minutes)	117.2 ± 17.33	116.3 ± 13.56	0.312

The trend of readings of systolic blood pressure, diastolic blood pressure and MAP in both groups almost was similar with no significant differences at different points till the last measure in min 55. The systolic blood pressure, diastolic blood pressure, and MAP were statistically higher in RG than LG (P=0.002, P=0.021, P=0.001), respectively. Moreover, the trend of HR, ET-CO_2, and SPO_2 was similar in different time reading points, and there were no significant differences (Table 2).

Tab. 2. Comparison of different variables during ESS procedures at baseline and several time points between LG and RG (N=40

Variable	Drugs	Mean (± SD)	5 min	10 min	15 min	20 min	25 min	35 min	45 min	55 min
Systolic BP	LG	120.20 (10.34)	104.35 (7.54)	96.75 (4.45)	91.40 (2.96)	86.65 (2.47)	82.85 (2.81)	79.90 (3.32)	76.65 (5.2)	100.20 (7.67)
	RG	124.10 (15.29)	107.15 (6.46)	95.25 (5.60)	90.35 (4.97)	85.75 (2.98)	83.55 (3.10)	79.30 (4.48)	73.25 (7.10)	109.20 (9.55)
	P-value	0.35	0.217	0.357	0.436	0.312	0.462	0.601	0.091	0.002*
Diastolic BP	LG	71.65 (9.54)	64.00 (9.48)	53.90 (4.63)	49.95 (6.29)	47.15 (4.88)	43.40 (4.75)	39.90 (4.98)	36.90 (4.88)	56.75 (5.21)
	RG	77.68 (8.83)	63.70 (6.43)	57.45 (5.11)	53.30 (3.85)	48.65 (4.22)	43.80 (4.21)	40.45 (4.35)	37.65 (5.79)	62.60 (9.69)
	P-value	0.071	0.906	0.0311	0.05	0.385	0.874	0.702	0.745	0.021*
MAP	LG	86.85 (8.57)	76.00 (5.67)	67.95 (3.74)	63.55 (4.00)	60.55 (3.37)	56.65 (3.18)	53.10 (3.24)	50.00 (3.30)	70.95 (5.58)
	RG	92.35 (9.68)	77.95 (5.62)	69.95 (4.72)	65.20 (2.68)	60.65 (2.72)	56.75 (2.84)	53.05 (2.94)	49.55 (4.52)	78.45 (7.85)
	P-value	652	0.287	0.143	0.135	0.901	0.924	0.96	0.71	0.001*
PR	LG	89.65 (10.44)	78.25 (6.86)	69.70 (3.61)	65.40 (3.10)	62.60 (2.66)	59.85 (3.48)	57.20 (4.58)	55.90 (5.28)	80.00 (7.73)
	RG	88.35 (9.56)	78.35 (5.63)	69.15 (2.99)	65.60 (2.58)	60.30 (6.27)	58.30 (3.34)	56.65 (3.40)	52.95 (3.91)	81.80 (9.20)
	P-value	0.771	0.965	0.602	0.823	0.144	0.161	0.743	0.05	0.533
ET-CO_2	LG	37.55 (3.77)	35.40 (3.26)	33.50 (2.35)	32.30 (1.41)	31.80 (1.43)	31.85 (1.34)	30.75 (1.37)	30.50 (1.43)	32.50 (2.35)
	RG	38.90 (3.71)	35.90 (3.19)	33.20 (1.73)	32.35 (1.34)	31.10 (1.48)	31.10 (1.07)	31.10 (1.07)	30.70 (1.12)	32.20 (1.73)
	P-value	0.323	0.654	0.611	0.925	0.551	0.522	0.401	0.62	0.667
SPO_2	LG	99.00 (0.97)	98.95 (0.94)	98.90 (0.96)	98.85 (0.98)	98.81 (0.97)	98.87 (0.97)	98.90 (0.91)	98.85 (0.98)	98.90 (0.85)
	RG	99.20 (0.95)	98.60 (1.04)	98.65 (0.98)	98.65 (0.93)	98.63 (0.91)	98.64 (0.91)	98.65 (0.98)	98.65 (0.97)	98.75 (1.02)
	P-value	0.554	0.375	0.432	0.578	0.506	0.581	0.405	0.533	0.67

In Table 3, the finding showed that the level of surgeon's satisfaction was higher in RG than LG. In RG the visual field was good in about 90.0% compared to 75.0% in RG (P=0.035). Moreover, the surgeons scored better quality of surgical field in RG than LG (P=0.027).

Tab 3. Quality of surgical field and surgeon satisfaction about both techniques

Variable	Group L	Group R	P value
	N=20	N=20	
Quality of surgical field score	N (%)	N (%)	-
0	2(10.0)	1(5.0)	0.027*
1	3(15.0)	10(50.0)	
2	6(30.0)	4(20.0)	
3	4(20.0)	3(15.0)	
4	5(25.0)	2(10.0)	
5	0	0	
Good visual field (score≤3)	15(75.0)	18(90.0)	0.035*
Surgeon satisfaction score	N (%)	N (%)	-
5	6(30.0)	13(65.0)	0.008*
4	11(55.0)	6(30.0)	
3	3(15.0)	1(5.0)	
2	0	0	
1	0	0	

Data are presented as frequency (%); * Significant as P value <0.05; LG: Labetalol Group; RG: Remifentanil Group

Table 4 presents the percentage of possible complication. Two cases in LG and one case in RG had some complication, however, there were no significant differences between the two studied groups.

Tab 4. Percentage of complication between two LG and RG (n=40)

Variable	Category	LG	RG	P -value
		N (%)	N (%)	
Complications*	No	18 (90.0)	19(95.)	0.65
	Yes	2(10.0)	1(5.0)	-

*Complications: bradycardia, hypotension and bleeding; LG: Labetalol Group; RG: Remifentanil Group

Table 5 showed that 5 cases needed an additional medication during the surgery. Three cases in LG received 50 mcg for each. While in RG one case received Ephedrine 3 mg, and another case received Atropine 0.3 mg, respectively.

Tab 5. Additional drugs used in LG and RG (n=40)

Additional drugs	LG	RG
Nitroglycerine 50 mcg	3 cases	0 case
Ephedrine 3 mg	0	1 case
Atropine 0.3 mg	0	1 case

LG: Labetalol Group; RG: Remifentanil Group

DISCUSSION

In this study 40 patients were divided into two groups (L and R) to induce hypotension. Various variables were compared between these groups, such as gender distribution, age, weight, and ASA classification. The percentages of patients were slightly different between the L and R groups, however, finding of this study did not find any significant differences between the L and R groups in terms of gender distribution (P=0.342), mean age (P=0.250), weight (P=0.135), and ASA classification (0.076). The study's results are consistent with findings from other studies that have looked at similar variables from Iran Egypt Poland and republic of Korea [8, 10, 15, 16].

When comparing results of this study with the findings from another study by Sajedi et al. It seems that both studies found no significant differences in systolic blood pressure during the majority of the operation, but significant differences occurred after stopping drug infusion. Specifically, in this study, there were significant differences at min 55 after stopping drug infusion, while the other study found that significant differences occurred near recovery. Additionally, both studies found significant differences in diastolic blood pressure at various time points. This study found significant differences at min 10, min 15 from baseline, and near recovery at min 55, with lower diastolic blood pressure in the L group. The other study found significant differences at min 10 and min 15 from baseline. It is interesting to see that both studies found similar patterns of blood pressure changes between the two groups, suggesting that the two drugs had different effects on blood pressure. However, it is important to note that the two studies used same drugs (labetalol and remifentanil) and different dosages, which may have contributed to the differences in the timing and magnitude of the blood pressure changes observed. Indeed, the comparison with another study adds some further support to the findings of this study and suggests that there may be important differences in the effects of different drugs on blood pressure during ESS procedures [17].

Furthermore, it appears that the current study found no significant differences in Mean Arterial Pressure (MAP) during operation until minute 55 between the LG and RG. However, at minute 55, the MAP was significantly lower in the LG compared to the RG. The study also found a significant difference in mean pulse rate at minute 45, with the RG having a lower pulse rate than the LG. These findings are in agreement with the study by Sajedi et al. and Seikiewicz et al. which both found that remifentanil infusion led to the lowest pulse rate and optimal operative field [8, 15]. It is important to consider these results when selecting the appropriate anesthesia for surgical procedures, as the optimal operative field is crucial for a successful outcome. In both groups, there was a significant reduction in end-tidal CO_2 (ET-CO_2), but the p-value was not significant between the two groups (Table 2). There were no significant differences in arterial oxygen saturation between the two groups (Table 2). This finding is also consistent with the previous studies [8, 12].

According to the results presented in Table 3, the Boezzart and Van der Merwe grading system for surgeon satisfaction was used to compare the two groups, and the mean bleeding in the RG was lower than in the LG. This led to a better satisfaction score in the RG, which is consistent with the findings of the earlier studies [12,15]. Additionally, there were no significant differences in complications between the two groups (Table 4). These findings suggest that the use of remifentanil infusion may be effective in reducing bleeding and improving surgeon satisfaction during surgical procedures without significantly affecting ET-CO_2 or arterial oxygen saturation [18,19]. It is important to note that one case in the RG developed bradycardia near recovery, which was treated with atropine. Another case in the RG developed hypotension with bradycardia near recovery, which was treated with ephedrine and stopping the drug infusion.
These complications suggest that close monitoring of vital signs is necessary during and after the administration of remifentanil infusion [20].
One case in developed bleeding that necessitated blood transfusion, indicating the importance of carefully monitoring bleeding during surgical procedures [19]. Additionally, 3 cases in the LG required boluses of “glyceryl trinitrate” to achieve the desired level of hypotension, indicating that careful titration of medication is necessary to achieve the desired effect without causing adverse events. These findings highlight the importance of careful monitoring and titration of medication during surgical procedures to minimize the risk of complications and ensure optimal patient outcomes. Previous studies suggest that clonidine may be superior to remifentanil in achieving controlled hypotension and a less bloody surgical field [21, 22]. Nitroprusside and remifentanil both appear to be effective in achieving a good operative field in endoscopic sinus surgery, but remifentanil may be preferred due to its lower incidence of tachycardia [16]. Dexmedetomidine and remifentanil were found to provide safe anesthesia equally, but dexmedetomidine may have a longer recovery time. Labetalol was found to be a better hypotensive agent than glyceryl trinitrate with less tachycardia [11, 23].

Overall, these studies suggest that there are several different anesthetic drugs that may be effective in achieving controlled hypotension and a good operative field in endoscopic sinus surgery, and the choice of drug may depend on factors such as the patient's medical history, the specific surgical procedure being performed, and the preferences of the anesthesiologist and surgeon. This study complains of some limitation such as the study's sample size which was relatively small, with only 40 patients divided into two groups. This may limit the generalizability of findings to a larger population. Additionally, the variables compared in the study may not be the only relevant factors in study, and there may be other factors that could influence the results. Although, the study's results may provide some insight into the variables being examined, it may be necessary to conduct further research with larger sample sizes and more comprehensive analyses to fully understand the factors that contribute to differences or similarities between groups.

CONCLUSION

Based on our results, it appears that remifentanil may be a good choice for achieving hypotensive anesthesia in endoscopic sinus surgery due to its rapid recovery time and lower incidence of complications compared to labetalol. However, careful monitoring of vital signs is required with both drugs. While remifentanil was used as the sole agent in your study, it may be beneficial to use a combination of hypotensive agents, especially for labetalol, to achieve a better surgical field with fewer side effects and lower dose requirements. From an economic standpoint, labetalol may be a better option. The choice of hypotensive agent may depend on various factors such as the patient's medical history, the specific surgical procedure, and the preferences of the anesthesiologist and surgeon. Further studies may be needed to compare the efficacy and safety of different combinations of hypotensive agents in endoscopic sinus surgery.

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