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Study of dexmedetomidine and propofol for monitored anaesthesia care in patients undergoing cataract surgery

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ABSTRACT

Aim: This study is to evaluate the efficacy of dexmedetomidine and propofol as an appropriate sedative drug for monitored anaesthesia care in patients undergoing cataract surgery. **Materials and methods:** A total of 60 patients are being recruited into this study, Patients were randomized into 2 groups, as group D and group P to receive dexmedetomidine and propofol patients undergoing cataract surgery respectively. **Results:**. MAP, HR, RR, SPO2 were compared between the 2 groups, group P and D at various time points from T1-T9 were found not to be statistically significant as p>0.05. ISAS of group D is 53.50 ±2.193 and ISAS of group P is 43.10 ±2.090. The p value between the 2 study groups is 0.0001 which is highly statistically significant. Ramsay sedation scale of 3 was maintained throughout the operation in both the study groups. **Conclusion:** The study showed that dexmedetomidine seems to be an acceptable agent for MAC compared to propofol in patients undergoing cataract surgery. Satisfaction scores are also in favor of the patients treated with dexmedetomidine.

Keywords: Dexmedetomidine, Propofol, Cataract surgery.

Introduction

Cataract surgery can be safely performed under monitored anaesthesia care (MAC) with or without local anaesthesia [1]. Several drugs such as propofol, benzodiazepines and opioids have been used for MAC either alone or in combination [2]. Benzodiazepines may cause excessive sedation and confusion especially in elderly patients[3], and propofol can also result in disorientation and excessive sedation. Because these drugs have no analgesic component topical local anaesthestics were often used to prevent the unintentional reflex to painful stimuli. Considering that, most of the patients undergoing cataract surgery are elderly; the above mentioned aspects can be serious potential problems. Based on the analysis of the American Society of Anaesthesiologists Closed Claim database, over dosage of sedative leading to respiratory depression was the most common (24%) in MAC claims and 40% of these resulted in permanent brain damage or death [4]. Dexmedetomidine is a novel selective α2 receptor agonist that produces sedation and analgesia without causing respiratory depression [5]. It also allows patients to respond to the verbal commands during sedation. It has been used in various clinical fields such as sedation in ICU, awake intubation, shockwave lithotripsy, endoscopic examination [6] and as an adjuvant to anaesthetics. The present study is undertaken to perform a controlled comparison and evaluation of efficacy of dexmedetomidine and propofol as an appropriate sedative drug for MAC in outpatients undergoing cataract surgery, which included a survey of patient's satisfaction.

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Materials and methods

The study was approved by the Institutional Review Board and all the participants gave written informed consent for this study.

Inclusion criteria: 20 and 75 years. They were American Society of Anaesthesiologists (ASA) classification I, II or III and scheduled for cataract surgery under MAC.

Exclusion criteria: Pre-operative exclusion criteria were pregnancy, kidney or hepatic disease, chronic medication with analgesic or sedative drug, or history of alcohol or drug abuse. Patients were randomized to receive either dexmedetomidine (group D) or propofol (group P). Patients fasted at least 8 hours before the operation and did not receive any preoperative sedative drug. On arriving at the operating room, standard monitoring, including electrocardiography, non-invasive arterial blood pressure cuff, and peripheral pulse oximetry were applied. Oxygen was administered via nasal cannula at 5 L/min. Topical anaesthesia using sterile 0.5% proparacaine hydrochloride ophthalmic solution was applied to the eye of patients. Patients of group D received 0.6 mcg/kg/h of dexmedetomidine, and patients of group P were given 2 mg/kg/h of propofol infusion over a period of 15 minutes before surgery respectively. Dexmedetomidine was diluted in 2 mcg/ml in normal saline for group D, and 100 mg of propofol accounting to 10 ml volume for group P. Each drug was titrated every 5 min to Ramsay sedation scale 3 during the operation. Administration of dexmedetomidine was adjusted by 0.1mcg/kg/h, and propofol was adjusted by 0.3 mg/kg/h respectively. Injection Ephedrine 5 mg was kept ready to be administered in case systolic blood pressure decreased below 90 mmHg or 70% of the preoperative value. Injection Atropine 0.5 mg was kept ready to be administered in case heart rate (HR) decreased below 40 beats/ min. The infusion was stopped at the end of the surgery in both groups. In the recovery center for outpatients, patients were asked to answer the 11 questions of Iowa satisfaction with anaesthesia scale (ISAS) using a 6 point rating scale at least 1 hour after the operation. It was performed by one anaesthesiologist who was blinded to the group assignment. MAP, HR, RR, and peripheral oxygen saturation (SpO2) were recorded at each time point as follows; T1 = preoperative baseline, T2 = anaesthesia start, T3 and T4 = 5 and 10 min after anaesthesia, T5 = operation start, T6, T7, and T8 = 5, 10, and 15 min after operation, T9=postoperative value. Moreover, the incidence of adverse events including hypertension, hypotension, bradycardia (HR< 50 beats/min), respiratory depression (RR<10 breaths/min), and oxygen desaturation (SpO2<93%) were evaluated.

Results

A total of 60 patients were recruited in this study. After initiation of the study, 30 patients were assigned to group D and the other 30 patients were assigned to group P. The characters of subdivided groups found no significant differences between the two groups. Total anaesthesia time was 36.0 ± 6.1 min in group D and 38.2 ± 7.3 min in group P, and operation time was 21.0 ± 5.6 min and 20.7 ± 5.1 min in group D and P, respectively.

Table 1: Demographic distribution in present study

Mean Age Distribution of study group					
Parameter	**Drug**	**N**	**Mean**	**Std Deviation**	**P value**
Age	**Dexmedetomidine**	30	56.70	5.503	0.924
	Propofol	30	56.57	5.224	
Mean weight distribution of study group					
Weight	**Dexmedetomidine**	30	63.63	8.479	0.689
	Propofol	30	64.63	10.669	
Mean ISAS Score distribution of study groups					
ISAS Score	**Dexmedetomidine**	30	53.50	2.193	0.001 *S
	Propofol	30	43.10	2.090	

It can be seen that the difference in mean age between the two study groups is not statistically significant. ($p > 0.05$) and it also shows the mean weight of both the study groups. It can be seen that the difference in the mean weight between the two groups is not statistically significant. ($p > 0.05$) and it also shows the ISAS SCORE of both the study groups. It can be seen that the difference in ISAS SCORE between the two study groups is statistically significant. ($p < 0.05$).

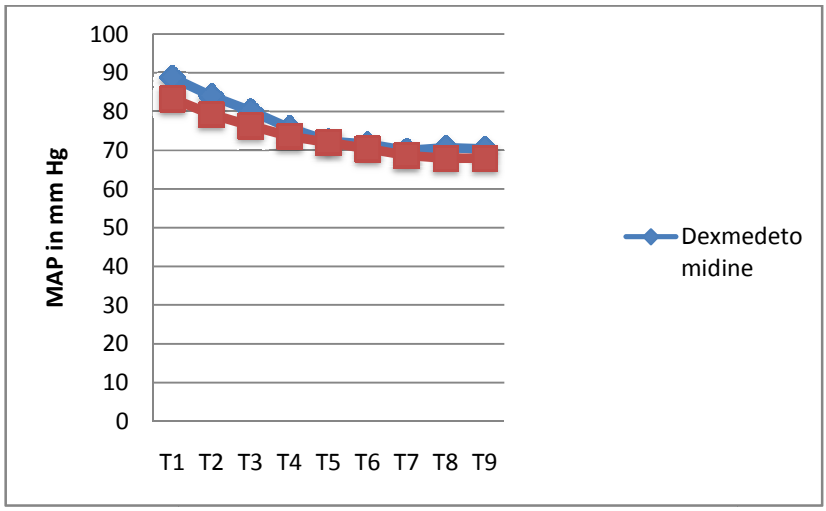


Figure 1: Shows the comparison of mean arterial pressure between both the groups

Mean Arterial Pressures of both the study groups at various time points from T1 to T9. It can be seen that the difference in MAP between two study groups is not statistically significant. ($p > 0.05$).

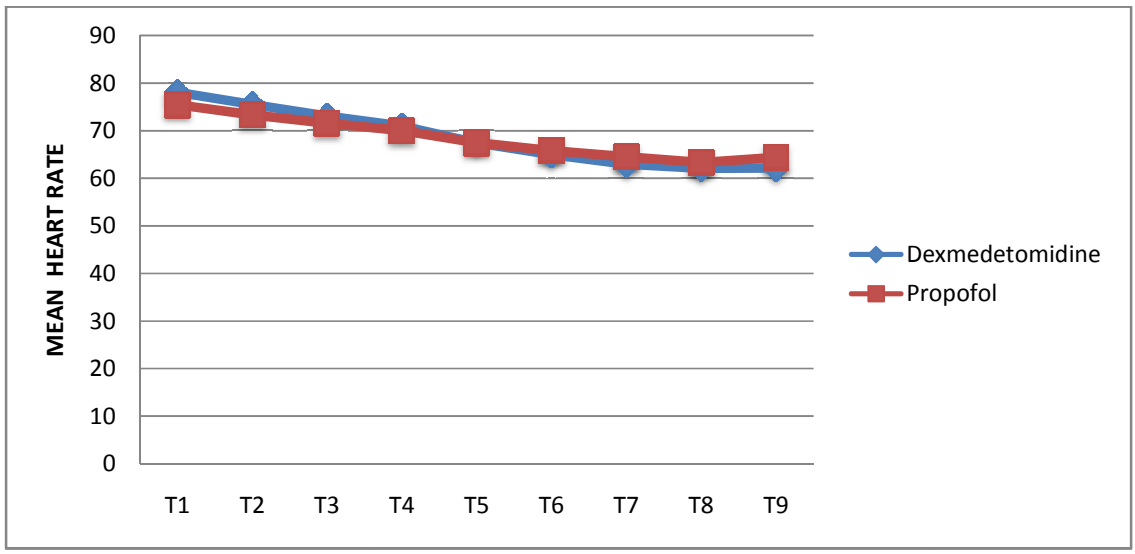
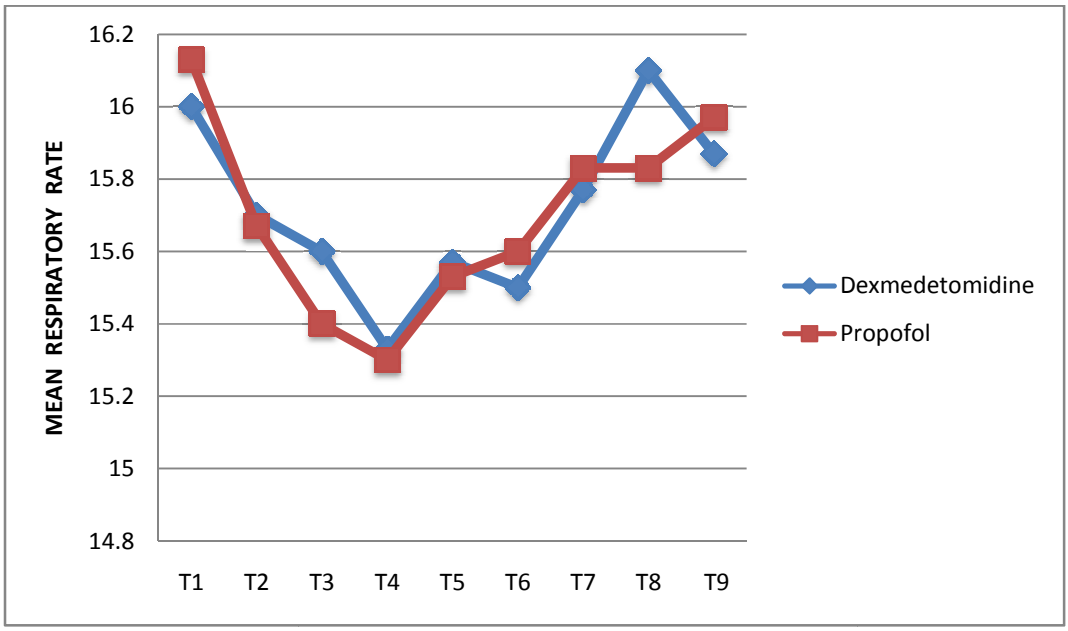


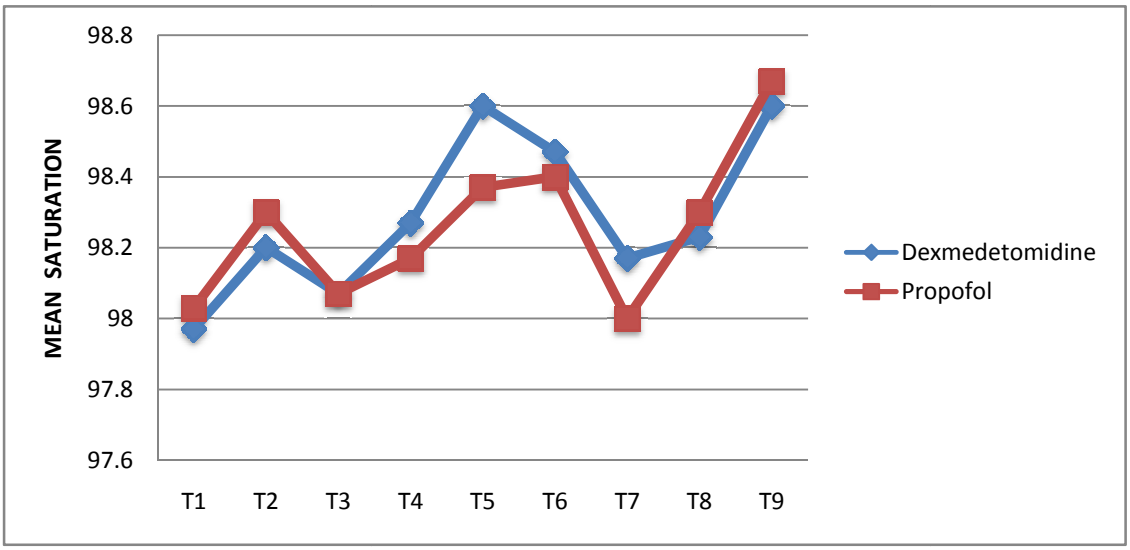
Figure 2: Comparison of mean heart rate between both the groups

It can be seen that the heart rate difference between two study groups is not statistically significant ($p>0.05$).



It can be seen that the RR difference between the two study groups is not statistically significant. (p >0.05).

Figure 3: Comparison of mean respiratory rate between both the groups



It can be seen that the saturation difference between the two study groups is not statistically significant. (p >0.05).

Figure 4 : Comparison of mean saturation between both the groups

Discussion

Results suggest that dexmedetomidine is an effective and safe drug for MAC in outpatients undergoing cataract surgery. Many studies were undertaken comparing dexmedetomidine with propofol for short surgical procedures, day care surgeries under MAC. Supporting the present study is a study conducted by **Nahs, Song IA *et al***[7] titled "Dexmedetomidine is effective for Monitored Anaesthesia care in outpatients undergoing cataract surgery". Postoperative ISAS was 50.3 (6.2) in group D and 42.7 (8.7) in group P, which was statistically significant (P < 0.001). SBP was significantly lower in group D compared with group P from the beginning of the operation. HR, RR, and SpO_2 were comparable between the two groups. There were 8 cases (25.8%) of hypertension in group P, and 1 case (3.2%) in group D (P < 0.05). In contrast, 1 case (3.2%) of hypotension and 1 case (3.2%) of bradycardia occurred in group D. This study concluded that, compared with combined use of propofol and alfentanil, dexmedetomidine could be used appropriately for monitored anaesthesia care in cataract surgeries with better satisfaction from patients and more stable cardiovascular state. Another study by **G.Harinath *et al***[8] was conducted for a period of 1 year on 60 patients with age groups 20-50 years both males and females, belonging to ASA I and II, undergoing short surgical procedures. Patients were divided into two groups. Group-1 received injection fentanyl and injection dexmedetomidine, group-2 received injection fentanyl and injection propofol. Comparing both the drugs for short surgical procedures, showed that onset of sedation time longer in D group (26.8Vs16.7 p<0.01) .However, there was no significant difference in the Ramsay sedation score levels throughout the sedation period in both groups. In the recovery room, it was found that the time to achieve an Aldrete score of 10 was similar in both groups. Therefore dexmedetomidine can be a useful adjuvant rather than the single sedative analgesic during short surgeries and can be an alternative to propofol for moderate sedation with haemodynamic stability and with minimal side effects. Previous studies have reported that dexmedetomidine can also be used effectively in cataract surgery. **Ayoglu *et al*** [9] demonstrated that intraocular pressure was decreased and satisfactory sedation and analgesia were achieved by a sole loading infusion of 1 mcg/kg dexmedetomidine for 10 min preoperatively.When additional sedation was needed, dexmedetomidine 2 mcg/ml for patient-controlled sedation (PCS) was prepared. The mean dexmedetomidine dose of the Group D was [66.4 (3.7)] mcg. In Group D, intra operative mean heart rate was found to be lower up to 50 min (P<0.05) and arterial pressure lower up to 30th min (P<0.05). NRS values during retrobulbar block were lower in Group D [1.9 (0.5)], compared with Group C [3.9 (0.6)] (P=0.016). After the dexmedetomidine loading dose, intraocular pressure (IOP) was significantly decreased [12.3 (1.0) mm Hg] compared with preoperative value [16.1 (0.8) mm Hg] (P<0.05). Intra operative RSS were higher in Group D after the loading dose of dexmedetomidine (P<0.05). Incidences of mouth dryness were higher in the Group D after surgery (P<0.05), but patient satisfaction was also higher (P=0.001). There were no differences in Aldrete Scores or surgeon satisfaction scores between the groups. This study demonstrates that sedation with dexmedetomidine decreases intraocular pressure, pain on injection and provides sedation effectively without causing respiratory depression. A single dose of dexmedetomidine appears to be enough. Dexmedetomidine sedation enables full cooperation and potentially better operating conditions without significant respiratory depression. **Apan *et al*[**10] also reported that dexmedetomidine made the intra operative HR more stable and postoperative pain less severe compared with midazolam, thus it was appropriate for sedation and analgesia during MAC in cataract surgery. This study evaluated the role of α_2 agonist infusion, with dexmedetomidine or midazolam, on haemodynamic and respiratory parameters while titrating the sedation level with the bispectral index (BIS) during cataract surgery. Results showed In Group D, heart rate decreased in the later periods of surgery (35-50 min) and in the early postoperative period (5 (th) and 15 (th) min). Dose adjustments were required in six and ten patients in Groups D and M, respectively. Pain scores were lower with dexmedetomidine infusion. The study concluded that dexmedetomidine infusion mildly decreased heart rate in the later periods of surgery with better pain scores in the postoperative period. Dexmedetomidine should be an alternative for intra operative sedation in outpatients undergoing cataract surgery. **Reetu , Verma *et al* [**11] showed that dexmedetomidine and propofol provides adequate sedation but the use of propofol is associated with more requirements of rescue analgesia and poor patient and surgeon satisfaction. **Ashraf S *et al*[1**2] compared both the drugs in paediatric patient during Gastrointestinal Endoscopy and concluded that dexmedetomidine sedation during Gastrointestinal endoscopy provides more safety and heart rate stability

presenting itself as a suitable alternative agent especially for the relatively longer procedures.

Studies were also done comparing dexmedetomidine in combination with different sedatives Vs various other combinations of sedatives. **Ashraf Darwish *et al*[**13] showed that both groups provided a similar significant reduction in heart rate and mean arterial pressure compared with baseline. The oxygen saturation values of Dexmedetomodine/Ketamine (DK) group were higher than those of Propofol/ Ketamine (PK) group. The respiratory rate values of the Dexmedetomidine/Ketamine (DK) group were higher than those in the Propofol/Ketamine (PK) group. The time required to achieve targeted levels of sedation was significantly longer in the Dexmedetomidine/ ketamine (DK) group. Postoperatively the time to achieve an Aldrete score of 10 was higher in Propofol/Ketamine (PK) group. Conclusion of study was that dexmedetomidine in combination with small dose of Ketamine is a valuable adjuvant for sedation in patients undergoing DCR surgery and valuable alternative to P/K combination. A study conducted by **Ozgur Yagan *et al*[**14] There was a statistically significant decrease in mean arterial pressures following drug administration compared to initial measurements in both groups. However, there was a statistically significant decrease in heart rate only in Group D. There was no significant difference between the two groups regarding respiratory rate and protection of spontaneous respiration. Although the time for Aldrete score to be 9 was 16.1 minutes for Group K, it was 24.9 minutes for Group D, and this difference was statistically significant ($p<0.01$). There was no significant difference between the two groups regarding adverse effects, pain scores and satisfaction levels of the patients and surgeon. The study concludes that, ketofol compared to dexmedetomidine, at similar sedation levels, is superior agent as it enables satisfactory analgesia and has more rapid onset of action and shorter recovery periods from anaesthesia without causing significant haemodynamic and respiratory adverse effects. Dexmedetomidine has been used in short or long term sedation in the intensive care unit, sedation for various procedures, or as a supplementary drug during general anaesthesia.

Tsai CJ *et al* [15]made a comparison of effectiveness of dexmedetomidine Vs propofol target controlled infusion for sedation during fibreoptic nasotracheal intubation in 40 anticipated difficult airways. Dexmedetomidine allows better tolerance, more stable haemodynamic states and preserves a patent airway. **Nitesh Goel *et al*** [16] Results had shown successful intubation in both cases but dexmedetomidine had a better outcome with respect to sympathetic response and patient tolerance. p value was significant for sedation score, pre and post bronchoscopic intubation sympathetic response. No episodes of airway obstruction and hypoxia were noted with dexmedetomidine as compared with propofol. Mean Ramsay sedation score was 3.77 as compared to 2.33 with propofol. The study concludes that dexmedetomidine had offered better patient tolerance with adequate sedation and preservation of airway as compared to propofol and a reduced haemodynamic response to intubation.

Ashraf Darwish *et al* [13] comparing dexmedetomidine/ketamine with propofol /ketamine combination for sedation in patients undergoing dacrocystorhinostomy surgery under local anaesthesia The conclusion of study was that the two groups gave comparable ($p>0.05$) data in reduction in heart rate, Mean arterial pressure with respect to baseline. Additionally, the subjective satisfaction score by ISAS in group D was higher than that of group P. Dexmedetomidine enables the patient to convert easily between sedative and cooperative state; therefore, cooperative sedation makes patients more comfortable during the cataract surgery. **Mahfouz A *et al*** [17] compared dexmedetomidine with propofol for sedation in patients undergoing vitreoretinal surgeries under subtenon anaesthesia. This study showed similar surgeon satisfaction and higher patient satisfaction supporting ISAS scores in the present study with significant p value. **Shen SL *et al*[**18] compared dexmedetomidine with propofol for conscious sedation in awake craniotomy .The conclusions of the study are arousal time shorter in group D than P ($p<0.001$), degree of satisfaction in surgeons higher in group D ($p<0.001$), degree of satisfaction in patients in 2 groups -no difference ($p=0.8$) which contrasts with the present study. **Reetu Varma *et al*[** 11] studied both the drugs for MAC in middle ear surgery , made similar conclusions supporting the present study, suggested that dexmedetomidine provides good surgeon and patient comfort for patients undergoing Tympanoplasty under local anaesthesia. When propofol was used, immediate interactions with the surgeon did not go smoothly due to the patient's sedated state; however inadequate sedation would lead to patient discomfort. In this study, we did not check the surgeon's satisfaction. However, dexmedetomidine property of cooperative sedation may enable the surgeon to perform surgery more efficiently. **Priyamvada Gupta *et al*[**19] studied the safety and efficacy of two different doses of dexmedetomidine for sedation and analgesia were evaluated. 90 patients were distributed

in three groups of 30 each: Dexmedetomidine 0.5 mcg/kg (DL), dexmedetomidine 1.0 mcg/kg (DH) and normal saline (C). Results in groups DL and DH fewer patients required supplemental midazolam, 56.7% (17/30) and 40% (12/30), compared with control, where 86.7% (26/30) needed midazolam supplements. P = 0.000. Both groups DL and DH required significantly less fentanyl (84.8 and 83.9 µg) versus control (144.2 mcg). There was significantly increased ease of achieving and maintaining targeted sedation and analgesia in both dexmedetomidine groups when compared with placebo (P = 0.001). Adverse events observed with dexmedetomidine were bradycardia and hypotension. They concluded that dexmedetomidine in the doses studied was considered safe and effective sedative and analgesic for patients undergoing procedures under MAC. In contrary to the present study results was a prospective single blind, randomized study by **Irwin Gratz *et al* [**20] found that baseline systolic arterial blood pressure and mean heart rate at the end of surgery to baseline in both groups showed statistically significant fall in dexmedetomidine group compared to the propofol group. The study concluded dexmedetomidine is a less suitable sedative compared with propofol for use in older patients undergoing cataract surgery due to decrease in haemodynamic parameters and noted increases in complication rates. The reason for these contrasting results between this study and the present study could be the following: The loading dosage of intravenous dexmedetomidine 1 mcg/kg over 10 min followed by maintenance intravenous infusion at 0.2 - 0.7mcg/kg/hr whereas in the present study a loading dose was not given , only 0.2 - 0.7mcg/kg/hr infusion and even this infusion was titrated to RSS of 3,

Joung, Kyoung-woon, Choi *et al*[21] in their study comparing effects of dexmedetomidine and propofol on Ultrasound guided Radiofrequency Ablation of Hepatic neoplasm under MAC. There were significant differences in opioid consumption (50.1±16.8ng/kg/min [group D] vs 71.2±18.7ng/kg/min [group P]; P=0.001) and delta PaCO2 (10.4±6.4mm Hg vs 17.2±9.2mm Hg, respectively; P=0.016). Moreover, respiratory rates were significantly different between groups during RFA (P<0.001). However, blood pressure and heart rate did not significantly change during Radiofrequency ablation. Neither patient nor interventional radiologist satisfaction was significantly different between groups. Dexmedetomidine provides better respiratory stability and reduces opioid consumption in comparison with propofol when administered under MAC when performing Radiofrequency ablation for hepatic neoplasm. In conclusion, the present study showed that dexmedetomidine seems to be an acceptable agent for MAC in outpatients undergoing cataract surgery. Compared with propofol, dexmedetomidine reduced arterial pressure during the period of operation. Satisfaction scores were also in favor of the patients treated with dexmedetomidine.

CONCLUSION

MAP, HR, RR, SPO2 were compared between the 2 groups, group P and D at various time points from T1-T9 were found not to be statistically significant as p>0.05. ISAS of group D is 53.50 ±2.193 and ISAS of group P is 43.10 ±2.090. The p value between the 2 study groups is 0.0001 which is highly statistically significant. Ramsay sedation scale of 3 was maintained throughout the operation in both the study groups. The study showed that dexmedetomidine seems to be an acceptable agent for MAC compared to propofol in patients undergoing cataract surgery. Satisfaction scores are also in favor of the patients treated with dexmedetomidine based on the p values.

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