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A Randomized Controlled Study on Effects of Dexmedetomidine, Magnesium Sulphate and Propofol in Middle Ear Surgeries

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ABSTRACT

BACKGROUND AND AIMS: Controlled hypotension in middle ear surgeries minimizes intraoperative blood loss. The primary objective of this study was to compare the intraoperative hemodynamic efficacy of Propofol, Dexmedetomidine and Magnesium Sulphate, and the secondary objective was to assess oligemic field during surgery, postoperative pain, nausea and vomiting.
METHODS: This prospective randomised controlled study (CTRI/2022/11/047639) included seventy-five ASA I & II patients aged 18-60 years who were randomized into three groups. Group P received Propofol IV bolus of 6mg/kg followed by infusion of 4mg/kg/hr, Group D received Dexmedetomidine IV bolus of 1 mcg/kg followed by infusion of 0.3mcg/kg/hr and Group M received Magnesium sulphate IV bolus of 30mg/kg followed by infusion of 10 mg/kg/hr. Hemodynamics and degree of oligemic field were monitored intraoperatively. Postoperatively, pain, nausea and vomiting were noted.
RESULTS: All three drugs affirmed utility for controlled hypotension. Group P provided the best surgical conditions, with only 8 % of patients experiencing slight bleeding, compared to 32 % in Group D and 63 % in Group M. Three patients in Group M had moderate PONV, and two patients in Group D had mild PONV. Group D showed significantly lower post-operative pain compared to Group M (P <0.001).
CONCLUSION: Propofol remains the gold standard for antiemetic protection and surgical clarity in middle ear surgeries, while dexmedetomidine provides superior postoperative analgesia and better PONV profile.

Keywords: *Propofol, Dexmedetomidine, Magnesium Sulphate, Middle ear surgery, Hypotensive Anaesthesia.*

INTRODUCTION

Hypotensive anaesthesia refers to controlled low mean arterial pressures of 60-70 mmHg during anesthesia that maintains perfusion pressure, keeps surgical field clear and helps minimize intraoperative blood loss. [1]. Various drugs are used to provide hypotensive anaesthesia such as opioids, propofol, nitroglycerin, magnesium sulphate and dexmedetomidine. There is paucity of literature to understand which drug is best suited in patients posted for middle ear surgeries. An ideal hypotensive agent should be simple to administer, have a quick onset, provide consistent results, be rapidly eliminated without producing toxic byproducts and cause minimal changes in blood flow to essential organs.[2]

Middle ear surgeries can be performed by various surgical approaches. Commonly practiced techniques include, (a) transcanal approach, involving direct entry into the ear canal, often using an endoscope, (b) endaural approach where an incision is made within the ear for better access to the epitympanum and (c) post aural approach involving an incision behind the ear for full access in extensive surgeries. Both surgical microscopes and newer high-definition endoscopes are

commonly used to visualize small structures in this confined space. Bleeding occurs predominantly from the microvasculature, so arterial pressure, small vessel tone, and venous pressure are all important factors that affect the degree of bleeding.[3]

The dense vascularity of the region, with increased risk for blood loss, combined with limited access to the operative field, associated with potential risk for recurrent infections leading to fibrosis, can pose significant challenges to both the surgeon and the anesthesiologist. The use of a magnifying microscope can worsen these issues, as even small amounts of blood may obscure the surgical field. [1] Hence, it is imperative that blood pressures are maintained. While multiple methods may be taken into account, such as, reduced IV fluid administration, a 10° reverse Trendelenburg position, positive pressure ventilation with normocapnia and the prevention of acidosis that may lead to vasodilation and further blood loss, the use of specific IV agents to cause deliberate, controlled hypotension has been proven to be the most beneficial.

Dexmedetomidine is a highly selective α2-adrenergic receptor agonist widely used as an adjuvant in anaesthesia for its sedative, analgesic, and sympatholytic properties. It produces controlled hypotension by reducing central sympathetic outflow. Magnesium sulphate has calcium channel blocking properties. It induces vasodilation and attenuates catecholamine release, thereby contributing to a reduction in blood pressure. Propofol is a commonly used intravenous anaesthetic agent known for its rapid onset and short duration of action. It produces hypotension primarily through systemic vasodilation.

Our primary objective was to compare the efficacy of Propofol, Dexmedetomidine, and Magnesium sulphate to produce controlled hypotension in middle ear surgeries and the secondary objectives were to assess the oligemic field intraoperatively and to compare the degree of postoperative pain (POP), postoperative nausea and vomiting (PONV) post-procedure.

MATERIALS AND METHODS

This prospective, parallel arm randomized control, triple-blinded study was conducted at a tertiary care hospital following ethical approval from the Institutional Ethical Committee (IEC/137/2022, dated 23rd July 2022). The trial was registered with the Clinical Trials Registry–India (CTRI/2022/11/047639; accessible at www.ctri.nic.in). Data collection spanned from January 2023 to December 2024.

A total of 75 patients were systematically enrolled. The inclusion criteria were patients aged between 18 and 59 years, of either gender, undergoing general anaesthesia with endotracheal intubation for elective middle ear surgeries, belonging to the ASA physical status I–II. Individuals who were on chronic analgesic medications, obese individuals with BMI> 30 kg/ m^2, pregnant individuals, and patients with motion sickness were excluded. The drug administration complied with the ethical standards of the responsible human experimentation committee and adhered to the principles of the Declaration of Helsinki (1975), as revised in 2013. Written informed consent was obtained from all participants after a detailed explanation of the study procedure and data use for research and educational purposes. Each patient underwent a thorough preoperative evaluation, including medical history, physical examination, and were explained in detail the need, objectives and methods of the study. They were randomly allocated into one of the three groups – propofol group (Group P), dexmedetomidine group (Group D) and magnesium sulphate group (Group M) using a computer-generated table. Allocation concealment was done using opaque sealed envelope method. (Fig 1: Consort diagram)

On the day of the surgery, the patient's NPO status and consent to participate were reconfirmed. Standard monitoring was implemented upon admission to the operating theatre, as recommended by ASA. This included continuous electrocardiography, non-invasive blood pressure monitoring, pulse oximetry (SpO2), capnography to monitor end-tidal carbon dioxide (EtCO2) levels, and temperature monitoring. Baseline hemodynamic parameters were comparable between the three groups. Preoxygenation with 100% oxygen was done until end tidal oxygen concentration was greater than 90%, followed by premedication comprising intravenous (IV) glycopyrrolate (0.01 mg/kg), IV midazolam (0.03 mg/kg), and IV ondansetron (0.15 mg/kg). Anaesthesia induction was achieved using IV fentanyl (2 µg/kg) and IV propofol (1-2 mg/kg), with neuromuscular blockade established via IV atracurium (0.5 mg/kg). At the end of 3 minutes, airway was secured with an appropriate size endotracheal tube (females 7.5mm and males 8.5mm). Confirmation of the tube in the trachea was done by checking bilateral equal air entry with auscultation and seeing traces of capnography. Anaesthesia was maintained with Oxygen, Air and Isoflurane, fresh gas flows of 1L/min with isoflurane to achieve a MAC of 0.8-1. As per instituition protocol a bolus of 10 mg Atracurium was given at 30 minutes intervals. Patients were ventilated with settings of 8mL/kg tidal volume, respiratory rate set to maintain $EtCO_2$ of 30-35, I:E ratio of 1:2, PEEP of 5 and FiO_2 of 0.5.

All study drugs were started after intubation; a bolus dose was given before incision followed by infusion throughout surgery. Group P (n = 25) received bolus of Propofol 6mg/kg over 15 min followed by maintenance of 4 mg/kg/hr. Group D (n = 25) received bolus dose of Dexmedetomidine 1mcg/kg in 100ml Normal Saline over 15 min followed by maintenance of 0.3mcg/kg/hr until end of surgery. Group M (n = 25) received bolus dose of Magnesium Sulphate

30mg/kg in 100ml Normal Saline over 15 min followed by maintenance of 10mg/kg/hr until end of surgery. The infusion of study drugs was stopped once graft was placed and closure of surgical site began.

During the surgical procedure, patient's vitals Heart Rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), SpO_2, $EtCO_2$, End-tidal concentration of anesthetic agent (EtAA) and Minimum alveolar concentration (MAC) were monitored every 5 minutes for first half an hour and then every 15 minutes thereafter until end of surgery. If the MAP was lower the 60mmHg, IV fluid bolus of 200 mL was given and if hypotension persisted, 6mg Mephenteramine was given to patients in all the three groups. Oligaemic field was assessed and scored using Boezaart's Grading Scale (Table 1). Following completion of surgery, patients were reversed with Neostigmine (0.05 mg/kg) and Glycopyrrolate (0.01 mg/kg). Patients were extubated once they met the extubation criteria. They were then shifted to the post-anaesthesia care unit. The patients were assessed for POP and PONV in early postoperative period 5 minutes and 30 minutes post-surgery. Patients were shifted to the ward once Modified Aldrete Score Criteria was met. Patients were assessed again for POP and PONV at 1 hour,2 hours and 8 hours (late postoperative period). Postoperatively, all patients received standardised analgesics: paracetamol 1 gm 8^{th} hourly orally. Rescue analgesia with Tramadol 1mg/kg was given if Numeric Rating Scale was more than four. Rescue antiemetic Metaclopromide 10 mg slow IV was given, if the IMPACT score was more than 2 (Table 1). Data were compiled in an Excel sheet, tabulated and statistically analyzed.

Sample size was calculated based on a pilot study we did. Accordingly, 15 patients per group were considered adequate to detect an intergroup difference of at least 20% in blood pressure and heart rate. To account for potential dropouts, 75 patients were enrolled and randomized into three groups (25 in each group): Group P (control group), was compared with Group D and Group M (intervention group) (Fig.1). All statistical analyses were performed using R, version 4.2.1 (R core team,2023, Vienna, Austria). All qualitative variables were summarized by frequency and percentage and quantitative variables were summarized by mean, median, standard deviation (SD) and interquartile range (IQR). The distributions of quantitative variables were compared between three dose groups by one way ANOVA with F-test if normally distributed, otherwise by Kruskal Wallis H test. The association of all qualitative variables with three levels of doses were measured by Chi-square test. Linear and generalized linear (Baseline-Logistics) mixed effect models were used to measure the overall association of the doses on HR, SBP, DBP, MAP, POP and PONV. P value <0.05 was considered statistically significant.

RESULTS

Demographics in all the three groups were comparable and were statistically insignificant. ($P < 0.05$). (Table 2)

Blood Pressure and Heart Rate:
Intergroup blood pressure comparisons revealed no statistically significant differences. Although a statistically significant difference in mean heart rate was observed between the 10- and 30-minute intervals ($P < 0.05$), this variation lacked clinical relevance. (Fig 2 & 3)

Surgical Field Assessment:
According to Boezaart's scoring system, Group P provided the highest quality surgical conditions, with only 8% of patients experiencing slight bleeding, compared to 32% in Group D and 63% in Group M. (Table 3)

Post Operative Complications:
Postoperative pain scores were lowest in Group D, followed by Group M, with both groups showing significantly less pain than Group P. Group D also demonstrated a significantly lower incidence of PONV compared to Group M (P 0.021). Emetic episodes were limited to mild cases in two Group D patients and moderate cases in three Group M patients. Group P reported zero PONV events; however, comparisons of Groups D and M against Group P did not reach statistical significance. (Table 4)

DISCUSSION

Our randomized controlled trial compared efficacy of dexmedetomidine, magnesium sulfate, and propofol as adjunctive agents in attenuating the hemodynamic disturbances and enhancing perioperative outcomes during middle ear surgeries under general anesthesia. The success of microsurgical procedures in the middle ear is dependent on the quality of the surgical field. Even minimal intraoperative bleeding within the highly vascular and confined anatomical space of the tympanic cavity can significantly obscure the microscopic field, leading to surgical errors and prolonged operative times [3]. Deliberate hypotension, targeting a mean arterial pressure (MAP) of 60–70 mmHg, remains a foundational tenet of anesthetic strategy in this domain. [1,6] Our findings highlight critical pharmacological differences that influence hemodynamic stability, operative conditions and postoperative recovery.

In our study, demographic characteristics were comparable across the three groups, ensuring that the results were attributable to the drugs administered rather than baseline patient variability. This methodological consistency mirrors high-

impact clinical trials where groups were matched for age, gender and weight as these significantly influence their pharmacokinetic distribution, clearance and help in isolating the specific effects of alpha-2 agonists and NMDA receptor antagonists. [1, 7, 8, 9]

All agents used affirmed their utility in controlled hypotension scenarios, with no significant differences in systolic, diastolic, or mean arterial pressures at any time interval. However, a statistically significant difference was observed in mean heart rate (HR) between 10 and 30 minutes, with Group D exhibiting the lowest heart rate compared to the other groups (at 30 minutes HR in group D was 77± 9/ min v/s group M (84 ± 8 / min) and group P (85 ± 9 / min), $P < 0.05$), which had no clinical impact. Bradycardia is a well-documented effect of dexmedetomidine, a highly selective α_2-adrenoceptor agonist that reduces central sympathetic outflow from the locus coeruleus, consistently resulting in a dose-dependent decrease in heart rate and MAP. [6,10] Our results mirror the findings of similar studies, where dexmedetomidine patients consistently displayed significantly lower heart rates than those in magnesium or propofol cohorts. [7-14] This is attributed to dexmedetomidine's sympatholytic effect compared to the more gradual vasodilatory onset of magnesium sulphate or the myocardial depression associated with propofol resulting in slow decline in HR with magnesium or propofol.

The ultimate clinical goal of inducing hypotension in middle ear surgery is the achievement of an oligemic surgical field. According to Boezaart's scoring system, our study revealed a remarkable result: Group P provided the highest quality surgical conditions, with only 8% of patients experiencing slight bleeding, compared to 32% in Group D and 63% in Group M. This finding presents a unique contrast to much of the established literature, which frequently cites dexmedetomidine as superior for blood loss reduction primarily due to its ability to induce peripheral vasoconstriction via postsynaptic α_2 receptors, thereby reducing oozing from the microvasculature. [3,12] Similarly, Modir et al. (2018) reported that dexmedetomidine provided the lowest bleeding scores when compared to magnesium or remifentanil. [2]

However, our result supporting propofol's efficacy finds validation in research advocating for Total Intravenous Anesthesia (TIVA). Studies emphasize that TIVA with propofol optimizes operative conditions through stable vasodilation and decreased myocardial contractility without the airway irritability or middle ear pressure changes associated with volatile agents [3,15]. The high incidence of bleeding in our magnesium group (63%) is also consistent with Modir et al., Bayoumy et al. and Chhabra et al. where magnesium was found to be an effective hypotensive but often resulted in higher bleeding scores than dexmedetomidine due to its potent vasodilatory action. [2, 9, 16]

Our study found that postoperative pain was significantly lower in Group D and Group M compared to Group P ($P < 0.001$), with Group D showing the most effective pain control. This finding is anticipated since propofol lacks intrinsic analgesic properties, whereas both dexmedetomidine and magnesium are recognized as effective anesthetic adjuvants for pain management. [3,7,17] Our results also showed superiority of dexmedetomidine over magnesium for analgesia ($P < 0.001$) which is supported by literature showing that dexmedetomidine acts on alpha 2 receptors in the spinal cord and locus coeruleus to significantly reduce the requirement for rescue opioids in the post-anesthesia care unit (PACU). [6,9,11,18] Srivastava et al. also concluded that the analgesic-sparing effect of dexmedetomidine was 20% greater than that of magnesium sulphate. [7] While magnesium sulphate provides effective analgesia via NMDA receptor antagonism—a mechanism validated in various surgical contexts—it is generally regarded as less potent than dexmedetomidine in the immediate postoperative phase, a trend confirmed by our results. [17, 19, 20]

Middle ear surgery is frequently associated with high rates of PONV, often reaching 80%, due to stimulation of the vestibular system during surgical manipulation. [3,17] In our study, PONV was significantly lower in Group D than in Group M ($P < 0.021$). However, the more striking clinical result was that none of the patients in Group P (Propofol) experienced PONV. This result is perfectly aligned with the established intrinsic antiemetic properties of propofol, which make it the drug of choice for managing high-risk patients in otologic surgery. [3, 15] The meta-analysis by Xu et al. confirms that dexmedetomidine is highly effective at reducing the occurrence of nausea and vomiting by reducing the total perioperative narcotic burden. [12] Conversely, magnesium sulphate has a more variable effect on PONV; while it may reduce emesis relative to standard narcotics, it does not provide absolute protection as in propofol-based anaesthesia. [17]

While our results highlight the analgesic and antiemetic benefits of these agents, it is critical to consider the recovery profile. Literature consistently notes that dexmedetomidine is associated with significantly longer recovery times and higher sedation scores compared to other agents. [1, 2,13] In our study, Group D had superior pain management with deeper level of postoperative sedation, as noted with higher Ramsay Sedation Scores, similar to other studies. [8,9] Magnesium sulphate, while offering earlier PACU discharge than dexmedetomidine, was associated with the highest rate of "slight bleeding" in our cohort, which may present a disadvantage for the surgeon.

Our results suggest that the choice of agent should be tailored to individual patient risks, with dexmedetomidine ideal for maximizing postoperative comfort and propofol-based TIVA remaining the standard for antiemetic protection and surgical

clarity in complex ear procedures. However, its limitations include restricted generalizability due to the single-center design, possible surgeon-related bias in intraoperative field scoring, and a short 24-hour follow-up.

CONCLUSION

Dexmedetomidine, Magnesium Sulphate, and Propofol are all safe and efficacious for inducing deliberate hypotension in middle ear surgeries. However, Dexmedetomidine provides superior postoperative analgesia and a better PONV profile compared to magnesium sulphate. Unique to our study is the finding that Propofol provided the highest quality surgical field visibility and a perfect record for PONV prevention. These results suggest that while dexmedetomidine is the ideal choice for enhancing holistic postoperative patient comfort through pain management, propofol remains the gold standard for antiemetic protection and surgical clarity in complex middle ear microsurgery.

FIGURE LEGENDS

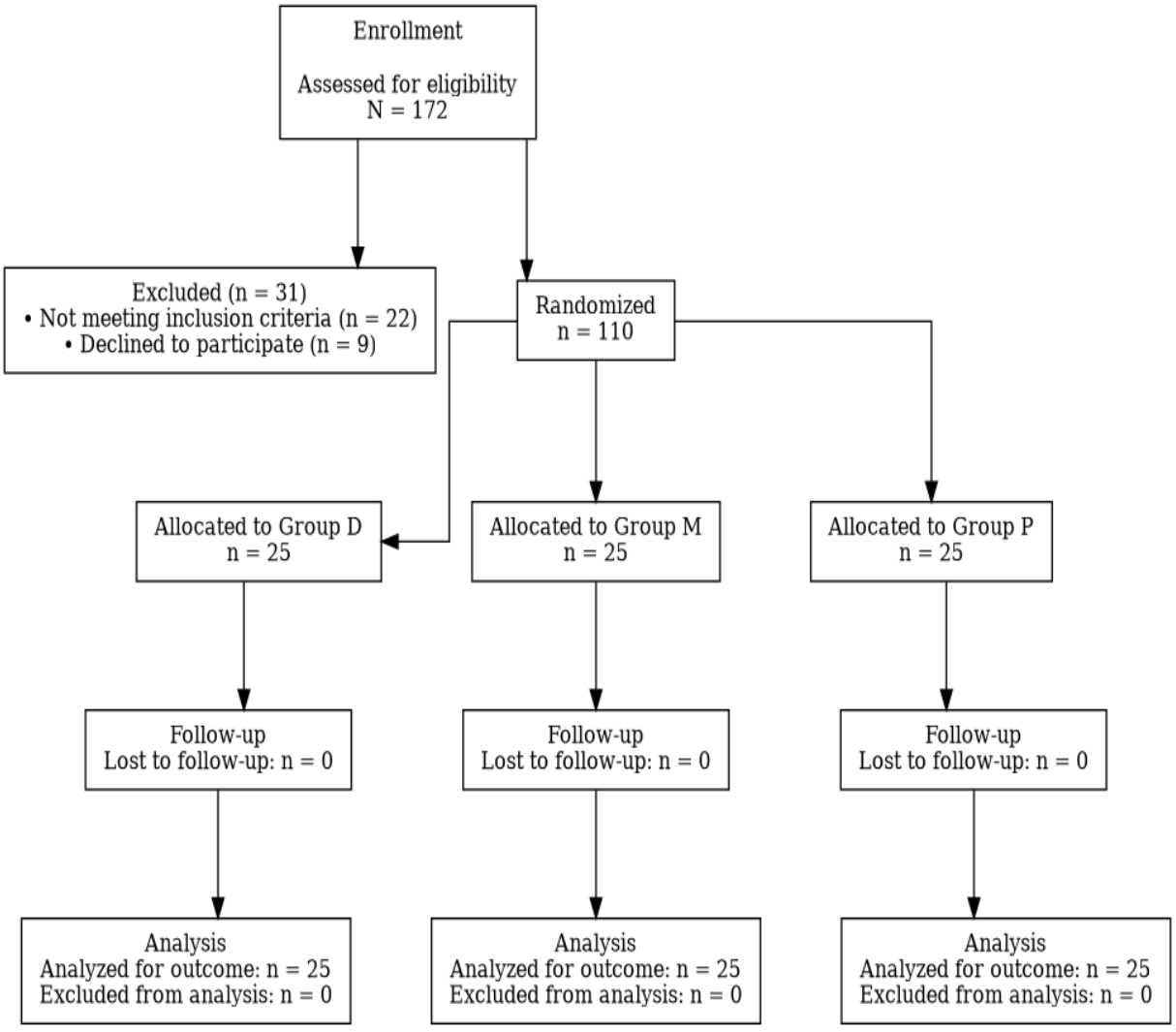

Figure 1: CONSORT diagram

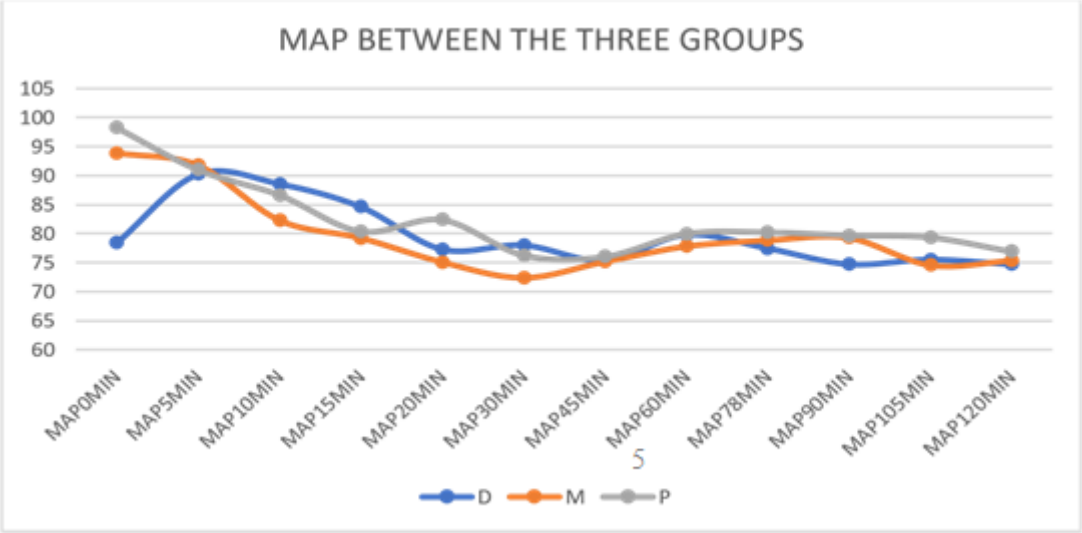

Figure 2: Mean Arterial Pressure Comparison

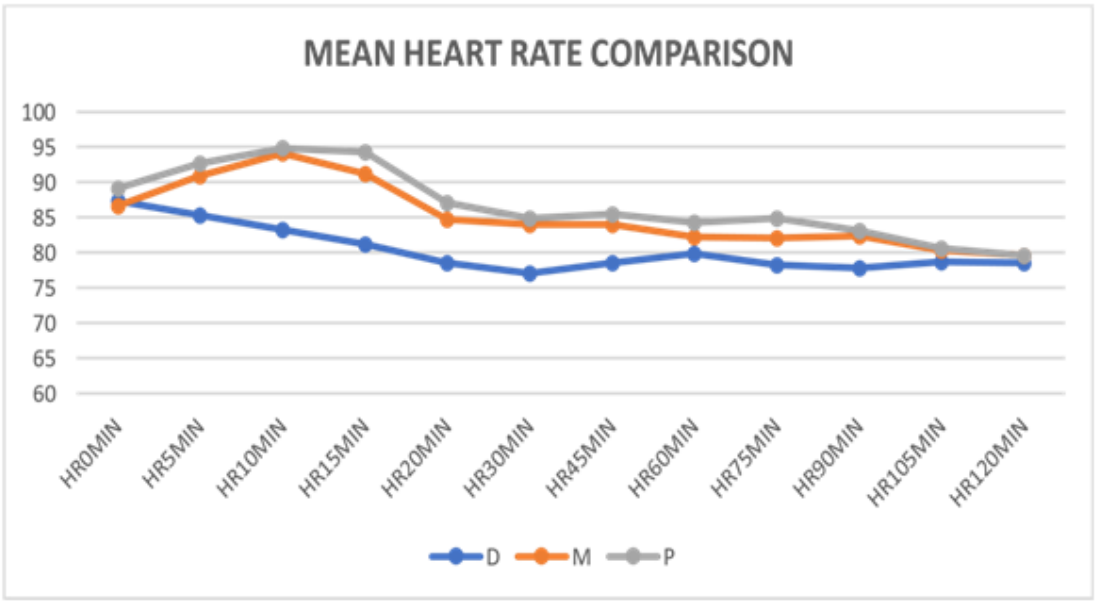

Figure 3: Heart Rate Comparison

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CONFLICTS OF INTEREST: There are no conflicts of interest.
DATA AVAILABILITY: The data that support the findings of this study are available from the corresponding author, [Dr. Anchu Abraham], upon reasonable request.

Dr. Anchu Abraham

TABLES:

Table 1: Surgical Field- Boezaart's Grading Scale and Severity of Postoperative Nausea and Vomiting- Impact Score. [4,5]

SURGICAL FIELD- BOEZAART'S GRADING SCALE	
AMOUNT OF BLEEDING	SCORE
No bleeding	0
Slight bleeding, no suctioning required	1
Bleeding, occasional suctioning required	2
Slight bleeding, frequent suctioning required, bleeding threatening the surgical field a few seconds after suctioning is removed	3
Moderate bleeding, frequent suctioning required, bleeding threatening the surgical field immediately after suctioning is removed	4
Severe bleeding, continuous suctioning, bleeding is faster than suctioning	5
SEVERITY OF POSTOPERATIVE NAUSEA AND VOMITING-IMPACT SCORE	
No nausea and vomiting	0
Mild nausea, not requiring treatment	1
Moderate nausea, mild vomiting and requiring treatment	2
Severe vomiting	3

Table 2: Demographics

DEMOGRAPHIC PARAMETER	MEAN VALUES			P-VALUE
	D	M	P	
AGE (years)	36.04	36.44	37.72	0.884
GENDER DISTRIBUTION				
MALE	8	12	12	0.418
FEMALE	17	13	13	
HEIGHT (cm)	162.22	159.79	162	0.408
WEIGHT (kg)	61	59.75	58.96	0.722

Table 3: Surgical Field Assessment

VARIABLE	LEVEL	GROUP D	GROUP M	GROUP P	P VALUE
SURGICAL FIELD	Bleeding	0(0%)	8(36.4%)	23(92%)	<0.001
	No bleeding	17(68%)	0(0%)	0(0%)	
	Slight bleeding	8(32%)	14(63.6%)	2(8%)	

Table 4: Comparison Of Postoperative Complication between the Group D, Group M to Control Group P

Variable	**Group**	**P Value**
POPAIN (Mild / None)	Group D / Group P	<0.001
	Group M / Group P	<0.001
	Group D/ Group M	<0.001
PONV (Yes /No)	Group D / Group P	0.996
	Group M / Group P	0.996
	Group D/Group M	0.021

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