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RESEARCH ARTICLE

Investigating the Influence of Melatonin on the Respiratory Rate, Heart Rate and Oxygen Saturation in Paediatric Surgical Care: A Randomized Double-Blinding Trial

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ABSTRACT

Melatonin, an endogenous hormone the pineal gland produces, is recognized for its sleep-inducing, anxiety-reducing, and pain-relieving characteristics. It has been used as a premedication in pediatric patients to reduce preoperative anxiety and enhance the quality of anesthesia induction. Nevertheless, the impact of melatonin on the respiratory rate (RR) and heart rate (HR) of children undergoing elective surgeries has not been well investigated. This study is a randomized, double-blind trial aiming to assess the influence of melatonin on oxygen saturation, respiratory, and heart rate in the pediatric age group undergoing elective surgeries. The objective is to investigate whether melatonin administration before surgery can benefit physiological parameters before the induction of anesthesia. This study was conducted at a specialized pediatric hospital using a randomized and double-blind trial. A sample of 126 children, ranging from 4 to 14 years, with ASA physical status I or II, who were scheduled for elective surgery under general anesthesia, were included in the study. They were randomly divided into M4 (n = 63) and M2(n=63). Children in the M4 and M2 groups were administered oral syrup melatonin at 0.4 and 0.2 mg/kg with a maximum dose of 10 mg. Administer the medication 60-90 minutes before induction of anesthesia; all patients recorded the SPO2, RR, and HR before premedication and before anesthesia induction. The two study groups were comparable in terms of mean age, weight, and sex; before induction anesthesia, the HR mean recorded 100.65 ± 14.66 BPM in the M 4 group, which was lower than the mean HR in the M 2 group (104.67 ± 18.39 BPM). The two groups had no statistically significant difference according to HR (p=0.178). The mean RR prior to induction of anesthesia recorded 25.71 ± 4.53 breaths per minute in the M 4 group, which was lower than the mean RR in the M 2 group (26.7 ± 4.71 BPM). The two groups had no statistically significant difference according to RR (p=0.234). Before induction of anesthesia, the mean SPO2 was recorded 99.13 ± 0.71 % in the melatonin 0.4 mg/kg group, which was higher than the mean SPO2 in the melatonin 0.2mg/kg group (98.97 ± 0.59 %). There was no statistically significant difference between the two groups according to SPO2 ($p=0.175$). The administration of melatonin at a dosage of 0.4 mg/kg was found to be more efficacious than M2 in reducing heart rate prior to the induction of anesthesia, with no statistical significance. Melatonin can be used safely as a premedication in children without inducing notable respiratory depression. No patient's SpO2 fell below 98 % prior to induction of anesthesia.

INTRODUCTION

Melatonin, a hormone synthesized in the pineal gland, is crucial in regulating sleep, the circadian clock, and oxidative stress. The impact of this substance on the respiratory and heart rate of children is not well understood. However, its overall effect on the autonomic nervous system indicates that it may have the potential to stabilize heart rate and respiratory function during times of stress (1). The central nervous system (CNS) is essential for the body's reaction to surgical stress. The growing brains of pediatric patients having major surgery are particularly vulnerable to the effects of anesthesia, pain, and physiological stress, which can have a considerable impact on the central nervous system(2). The administration of oral Melatonin in the preoperative area in children undergoing surgeries has become more popular in recent years**.** Anesthesia and surgery affect melatonin secretion and circadian rhythms. These events disrupt melatonin production, causing sleep disturbance, pain, and cognitive issues. Melatonin supplements prior to surgery can be beneficial for reducing anxiety, controlling pain, improving sleep, and reducing disorientation in post anesthesia care unit, in addition to supporting the immune system against surgical stress (3, 27).

In addition, melatonin has antioxidant characteristics, such as its ability to remove harmful free radicals and increase the activity of antioxidant enzymes, helping to decrease oxidative stress. This is important since oxidative stress can impact cardiovascular and respiratory health (4). Melatonin has been observed to enhance sleep quality among children suffering neuro disabilities, indirectly promoting cardiac wellness by guaranteeing enough recovery and rest (5). The sympathetic nervous system (SNS) tightly regulates heart rate, and an increased heart rate suggests that the sympathetic tone is superior to the parasympathetic nervous system. Melatonin displays sympatholytic properties by decreasing heart rate in both animals and humans. This indicates the possible preventive effects of melatonin not just in cardiovascular diseases but also in mood disorders associated with excessive sympathetic activation, such as anxiety (6, 26).

Moreover, the involvement of melatonin in diminishing inflammation and regulating immunological responses, as shown by its ability to protect against influenza-induced acute lung injury, suggests its potential to promote respiratory function during infections (7). Children have anatomical and physiological variations such as smaller airways and greater metabolic rates, which make them more likely to have higher baseline heart rate (HR) and respiratory rate (RR) compared to adults (8). Many children suffer preoperative stress surgery, which triggers a stress response in the body. Lead to the elevated secretion of hormone stress like adrenaline and cortisol, which can increase heart and respiratory rates (9, 28).

Melatonin influences heart rate by regulating the autonomic nerve system, which governs the heart's rate and contractility. (10) This will positively influence heart rate variability, indicating its potential to regulate cardiovascular balance during major operations (11). There were no studies that directly compared the efficacy of melatonin on vital signs during preoperative stress surgery, so we conducted a study to evaluate the efficacy of oral pre-medication with Melatonin by comparison of different doses (0.2 and 0.4 mg /kg maximum10 mg) in decreasing respiratory rate and heart rate in children undergoing major surgeries. The objective is to investigate if the administration of melatonin before surgery can benefit physiological parameters before the induction of anesthesia.

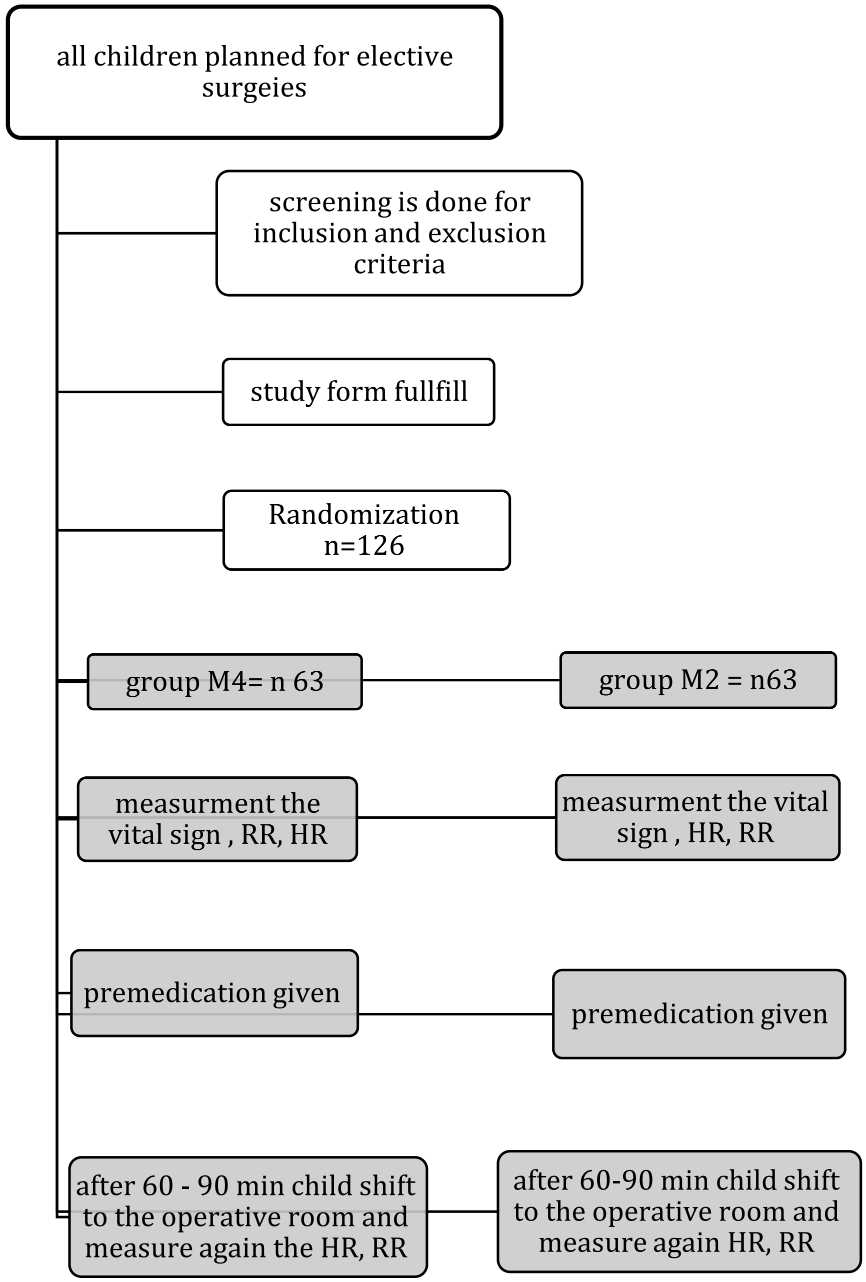

Figure 1: Flow chart of the study

Patients and methods:

This study was a prospective double-randomized comparative investigation conducted in the Department of Anesthesia and Intensive Care Unit at Babil Teaching Hospital for Maternity and

Children; the study population included children aged from 4 to 14 years, including male and female patients which informed ASA I or II prepared for elective surgery. Nevertheless, Criteria for exclusion included patients who refused to participate, had taken benzodiazepines, opioids, or other sedatives in the previous month, or were on emergency surgery. The study began from November 2021 to February 2023, after permission from the institution's ethical committee (Reference No. 59/10/2021) and parents by informed consent of participating individuals; the study sample size included 126 patients who were randomly divided into two groups using the closed envelope method: group M4 (n= 63)took melatonin 0.4 mg/kg and group M2 n=(63) took melatonin 0.2 mg/kg; the total maximum dose for both groups was 10 mg; both of them took oral syrup melatonin pre medications in the preoperative holding area in the morning day of operation 60-90 min before operation. The heart rate, respiration rate, and oxygen saturation are recorded throughout the premedication administration and again after 60 minutes before anesthesia induction. The Anesthesiologist investigator prepared the pre-medications and was given by another one. The investigator anesthesiologist was unaware of which drug was given to the patients and was not part of the research team.

PROCEDURE OF THE STUDY

Information extracted about the prior medical and surgical operation, drug allergies, respiratory and cardiac disease, and general investigation, e.g. (complete blood count, general urine examination. Chest X-ray) are assessed in a pre-anesthetic evaluation and recorded in the study form. The objective of this study was clarified to the parents of the child in their natural language.

-Both groups followed a fasting regimen where children were banned from taking any food orally for at least 6 hours for solids and 2 hours for clear fluids on the day of surgery. Before initiating the procedure,

- Participants in the trial were children aged 4 to 14 years who had been scheduled for elective surgical procedures.

Sample Size

The sample size was determined using SE changes, $\alpha = 0.5$, $\beta = 0.8$, and a 15% drop-out rate. The study requires 126 patients. Each group n = 63.

Statistical Analysis

The data was collected and entered into Excel 2007. The analysis was conducted using the Statistical Package for the Social Sciences program for Windows, specifically version 20.0, developed by IBM Corporation, headquartered in Armonk, NY, USA. The unpaired t-test was used to compare quantitative factors such as mean age, pulse rate, respiratory rate, and oxygen saturation between groups. The Chi-square or Fisher's exact test was used to compare qualitative variables, such as weight and gender. The significance level was established at a confidence level of 95% with a P-value less than 0.05.

RESULTS

The study included 126 children who underwent elective surgeries. Patients were randomly assigned to two groups: M4 (melatonin 0.4mg/kg) included 63 children, and M2 (melatonin 0.2 mg/kg) included 63 other patients. The mean age of M 4, M 2, and total patients was 8.59 ± 2.89, 7.78 ± 3.18, with no significant difference between the two groups (p=0.254). More than half of the patients were in groups M4 and M2. The mean weight of patients in M 4, M 2, and total were 28.24 ± 11.06 , 26.32 ± 11.96 with no statistically significant difference among groups (p=0.351) (Table 1).

Table 1: Demographic characteristics of the studied groups

Variable	**Parameter**	**M 4 (n=63)**	**M 2 (n=63)**	**Test**	**p-value**
Age	Mean ± SD	8.59 ± 2.89	7.78 ± 3.18	χ^2=2.74	0.254
	Range (Min-Max)	4-14	4-14		
	4 to 7 years	26 (41.3%)	33 (52.4%)		
	>7 to 10 years	16 (25.4%)	17 (27%)		
	>10 years	21 (33.3%)	13 (20.6%)		
Sex, n (%)	Male	44 (69.8%)	37 (58.7%)	χ^2=1.69	0.196
	Female	19 (30.2%)	26 (41.3%)		
Weight	Mean ± SD	28.24 ± 11.06	26.32 ± 11.96	0.876	0.351
	Range (Min-Max)	14-57	11-55		

P-value: the difference between M 4 and M 2. SD: standard deviation, Min: minimum, Max: maximum, χ^2:Chi–Square, t: Student t-test.

The majority of the surgeries conducted were related to hernias and appendectomy of subjects in group M4 and group M2 (Figure 2).

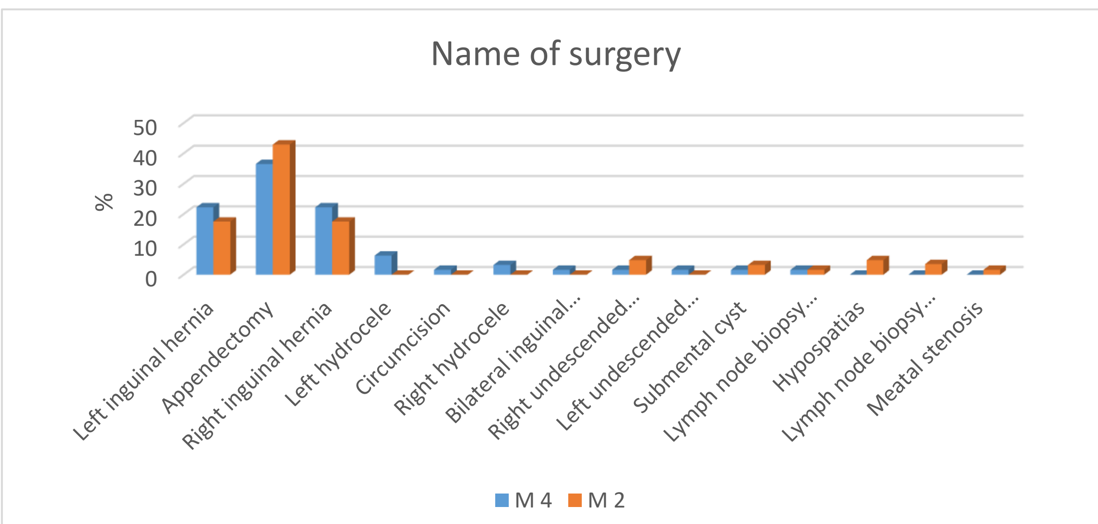

Figure 2: Surgeries performed among the studied groups

PREOPERATIVE AND PRIOR INDUCTION OF ANESTHESIA IN OR HEART RATE (HR)

Pre-operatively, the HR mean was recorded at 99.86 ± 14.1 BPM in the melatonin M 4 group, and the HR mean was recorded in the M2 group (102.08 ± 15.627 BPM). The two groups had no statistically significant difference according to HR preoperative (p=0.4). Before induction anesthesia, the HR mean recorded 100.65 ± 14.66 BPM in the M 4 group, which was lower than the mean HR in the M 2 group (104.67 ± 18.39 BPM). The two groups had no statistically significant difference according to HR (p=0.178) (Table 2 and Figure 3).

Table 2: Mean HR pre-operatively and prior induction of anesthesia in OR among the studied groups

Variable	Parameter	M 4 (Melatoni 0.4mg/kg) (n=63)	M 2 (n=63)	Total (n=126)	Test	P-value
HR pre	Mean ± SD	99.86 ± 14.1	102.08 ± 15.627	100.97 ± 14.87	t=0.7	0.4
	Range (Min-Max)	76 – 142	78 – 150	76 – 150		
HR post in OR	Mean ± SD	100.65 ± 14.66	104.67 ± 18.39	102.66 ± 16.68	t=1.837	0.178
	Range (Min-Max)	67-142	73-155	67-155		

P-value: the difference between M 4 and M 2, p non-significant if >0.05, *P significant if <0.05, ** p highly significant if <0.001. %: percentage, χ^2: Chi–Square.

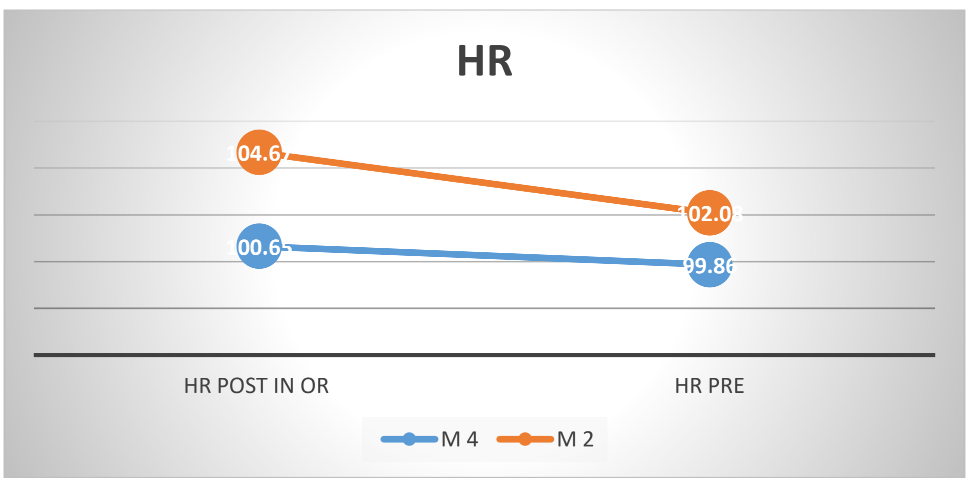

Figure 3: HR distribution pre and post-medication among the studied groups.

PREOPERATIVE AND PRIOR INDUCTION OF ANESTHESIA IN OR RESPIRATORY RATE (RR)

Pre-operatively, the mean RR recorded 25.3 ± 4.04 breaths per minute in the M 4 group, and the mean RR recorded in the M2 group (24.57 ± 4.13 BPM). The two groups had no statistically significant difference according to RR (p=0.318). Post medication, the mean RR recorded 25.71 ± 4.53 breaths per minute in the M 4 group, which was lower than the mean RR in the M 2 group (26.7 ± 4.71 BPM).

The two groups had no statistically significant difference according to RR (p=0.234) (Table 3 and Figure 4).

Table 3: Comparison between M4 and M2 regarding RR pre and post-medication

		Mean	SD	Std. Error	95% Confidence Interval for Mean: Lower Bound	95% Confidence Interval for Mean: Upper Bound	Min	Max	Test	p-value
RR pre	M 4	25.30	4.035	.508	24.29	26.32	18	38	t=1.007	0.318
	M 2	24.57	4.134	.521	23.53	25.61	18	38		
	Total	24.94	4.085	.364	24.22	25.66	18	38		
RR post prior induction	M 4	25.71	4.527	.570	24.57	26.85	18	38	t=1.429	0.234
	M 2	26.70	4.713	.594	25.51	27.89	18	36		
	Total	26.21	4.629	.412	25.39	27.02	18	38		

P-value: the difference between M 4 and M 2 pre-and post-operatively, p non-significant if >0.05, *P significant if <0.05, ** p highly significant if <0.001. SD: standard deviation, Min: minimum, Max: maximum.

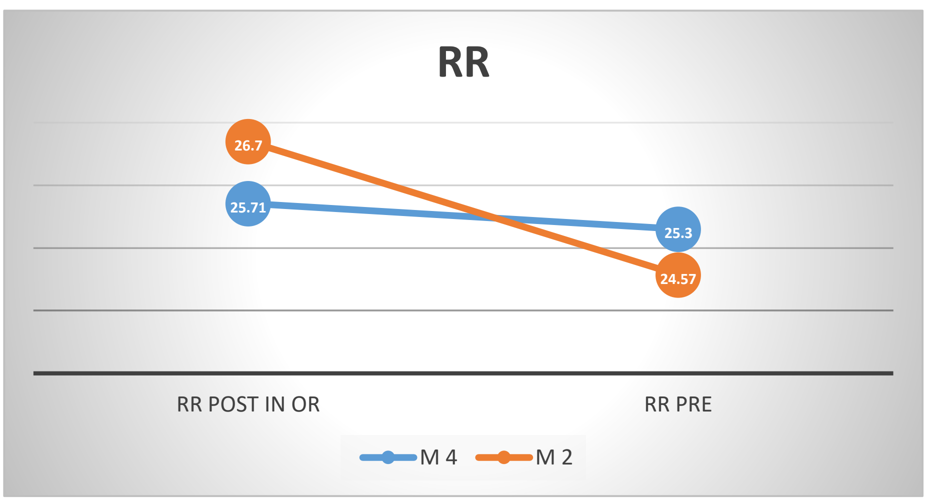

Figure 4: RR distribution pre and post-operatively among the studied groups

PREOPERATIVE AND PRIOR INDUCTION OF ANESTHESIA IN OR RESPIRATORY RATE (RR)

Pre-operatively, the mean SPO2 recorded 97.65 ± 11.38 % in the M 4 group, which was lower than the mean SPO2 in the M 2 group (98.62 ± 0.851 %). There was no statistically significant difference between the two groups according to SPO2 (p=0.5)

Before induction of anesthesia, the mean SPO2 was recorded 99.13 ± 0.71 % in the melatonin 0.4 mg/kg group, which was higher than the mean SPO2 in the melatonin 0.2mg/kg group (98.97 ± 0.59 %). There was no statistically significant difference between the two groups according to SPO2 (p=0.175)

Table 4: Mean SPO2 pre-operatively and prior induction of anesthesia in OR among the studied groups

					95% Confidence Interval for Mean				Test	p-value
		Mean	**SD**	**Std. Error**	**Lower Bound**	**Upper Bound**	**Min**	**Max**		
SPO2 PRE	M 4	97.65	11.379	1.434	94.78	100.52	97	100	t=0.454	0.5
	M 2	98.62	.851	.107	98.40	98.83	96	100		
	Total	98.13	8.051	.717	96.72	99.55	96	100		
SPO2 post in OR	M 4	99.13	.707	.089	98.95	99.31	97	100	t=1.86	0.175
	M 2	98.97	.595	.075	98.82	99.12	98	100		
	Total	99.05	.656	.058	98.93	99.16	97	100		

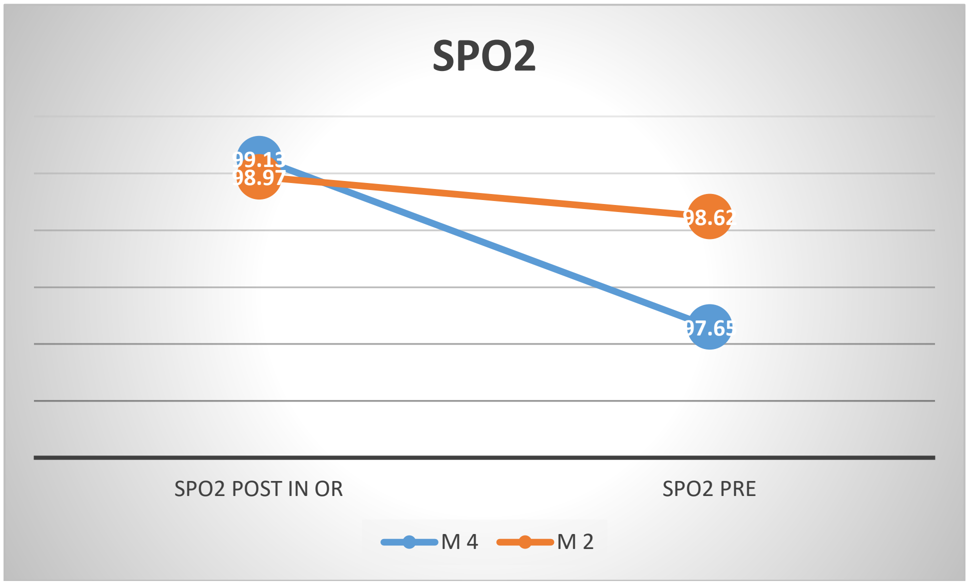

Figure 5: SPO2 distribution among the studied groups

DISCUSSION

Melatonin, a hormone produced by the pineal gland, is known for regulating sleep by activating MT1 and MT2 receptors. Extensive research has been carried out on its use in the perioperative setting because of its anxiolytic, soothing, and analgesic properties (12, 13). Melatonin has been suggested for its pre-medication properties in pediatric patients who need sedation or general anesthesia in operating or non-operating rooms for diagnostic or therapeutic procedures, leading to positive outcomes (14-18). Previously, Patel and Kurdi found that the peak effect of exogenous Melatonin as an oral pre-medication ranges from 60 to 150 minutes in pediatric patients (12). Therefore, we administered the pre-medication in both groups within 60- 90 minutes before the induction of anesthesia. We recruited participants between the ages of 4 and 14 to ensure their comprehension and completion of the required assessments. In a correlated investigation, Melatonin was orally administered at dosages of 0.2 or 0.4 mg/kg up to a maximum of 10 mg; previous research has indicated the safety and advantageous sedative properties associated with these specific doses (19). Our study's primary aim was to assess oral melatonin's efficacy at the two doses (0.2 and 0.4 mg/kg) in reducing surgical stress by observing oxygen saturation, heart rate, and respiratory rhythm before induction of anesthesia. Our study shows that 0.4 mg /kg of oral melatonin caused a better heart rate decrease before anesthesia induction. In the current investigation, both groups were comparable regarding HR, SPO2, and RR before and after medication. In another study (20) comparing the effect of oral midazolam and oral melatonin on anxiety score and HR post-medication at 15,30,45,60 min, the mean HR was 122.42 ± 15.08, 117.72 ± 14.08, 115.42 ± 13.85 and 111.69 ± 13.66 after pre-medication in M group. In the MT group, the mean HR was 129.33 ± 12.50, 127.25 ± 11.57, 126.42 ±11.01, and 124.61 ± 10.95 after pre-medication. Thus, the HR scores decreased with time in both groups, which is highly statistically significant (P<0.001), contrasting our result. Another study (21) showed that the melatonin group had a greater mean heart rate than the dexmedetomidine and midazolam groups. However, the differences were not statistically significant. Another study (22) showed no differences between the groups in HR, SAP, DAP, or SpO2 (P= >0.05). In a different study (23), researchers found no clinical significance regarding SpO2, and no patient's SpO2 fell below 95% during the observation period following premedication. At baseline, 15, 30, and 45 minutes, there were no differences in the mean HRs, SpO2, and RR between the two groups (p>0.05). This was in line with our results, explain the insignificant difference in respiratory rate between the two groups indicates that there is no significant influence on the function of the respiratory system in children pre-operatively. This observation is significant because it suggests that melatonin can be used safely as a premedication in children without inducing notable respiratory depression. In contrast, to review study (24) mentioned that melatonin caused respiratory depression. Another study (25) showed that children prescribed melatonin for inducing adequate sedation in EEG have minimal to NO effect on heart rate.

LIMITATION

In this study, several limitations must be acknowledged before conclusions are drawn. As the drugs were available in syrup form, we encountered difficulty in accurately measuring and administering the drug based on body weight. Restricted to children aged 4-14 for elective surgeries and Lack of control: The absence of appropriate control groups may affect the investigation's ability to get accurate outcomes.

CONCLUSION

The administration of melatonin at a dosage of 0.4 mg/kg was more effective than M2 in reducing heart rate before the induction of anesthesia, with no statistical significance. Melatonin can be used safely as a premedication in children without inducing notable respiratory depression. No patient's SpO2 fell below 98 % before induction of anesthesia.

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