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A Study of Ondansetron and Dexmedetomidine to Prevent Post-op Nausea and Vomiting in Patients Undergoing Laparoscopic Cholecystectomy Under General Anaesthesia

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Abstract

Introduction

Post-operative nausea and vomiting is one of the most distressing problems faced by the anaesthesiologists worldwide which causes unpleasant side effects, delayed discharge and delayed wound healing.

Aim

To compare the efficacy of ondansetron with dexmedetomidine to prevent post operative nausea and vomiting.

Materials and Method

This randomised clinical trial study was performed on patients who were candidates for laparoscopic cholecystectomy referring to St. Stephens hospital in New Delhi. In this study, 60 patients with laparoscopic cholecystectomy were randomly assigned to two groups (ondansetron and dexmedetomidine).

Results

We found that total incidence of PONV in 24 hours was 46.7% in Dexmedetomidine group and 30% in Ondansetron group. No significant side effects were noted by the use of the two drugs.

Conclusion

We concluded that the use of both Ondansetron and Dexmedetomidine is recommended for ameliorating PONV. In terms of efficacy, both the drugs are equally effective in reducing the incidence of PONV.

Keywords

Post-op nausea and vomiting, i/v Dexmedetomidine, i/v Ondansetron, Laparoscopic Cholecystectomy

Introduction

Post-operative nausea and vomiting (PONV) is defined as any nausea, retching or vomiting occurring during the first 24hours after surgery.[1]

The medical complications of PONV can be dehydration, risk of aspiration of vomitus, possible wound disruption and esophageal tear.

Various methods to reduce PONV include acupuncture, acupressure and drugs like metoclopramide, prochlorperazine, droperidol, atropine etc[2]

Ondansetron is a 5-HT3 antagonist, it's the gold standard anti emetic due to its safety and effectiveness[3]. A dose of 4mg iv just before extubation helps to reduce PONV.

Dexmedetomidine is a selective α2 adrenoceptor agonist. It has various properties like sedative, amnestic, analgesic and sympatholytic[4]. A dose of 1mcg/kg in 100 ml NS over 10 minutes given just before extubation prevents PONV.

Aims and Objectives

1. To compare the efficacy of ondansetron with dexmedetomidine to prevent post operative nausea and vomiting.
2. To compare the haemodynamic changes in the patients after administration of the study drugs.

3. To compare the time required for rescue anti-emetic drug after administering the study drugs.
4. Evaluate the influence of such variants as age, sex of the patient and duration of the surgery.
5. To compare which drug causes lesser side effects to the patient.

Material and Methods

This prospective, randomised, single blind comparative study was conducted in the Department of Anaestehsia, St. Stephens Hospital, New Delhi during the period 2020-2022 after getting ethical clearance from the institutional ethical committee. 60 cases posted for elective Laparoscopic cholecystectomy were included in the study after taking informed consent to study the effect of iv ondansetron and iv dexmedetomidine on PONV. Subjects were randomly allocated in two groups by using simple randomization method. Each group included 30 subjects. Group 1 subjects received iv Dexmedetomidine 1 mcg/kg in 100ml NS over 10 mins before extubation.and Group 2 subjects received intravenous Ondansetron 4mg iv just before extubation and

INCLUSION CRITERIA:

- Patients belonging to ASA Grade I and II.
- Patients aged 18-60 years of age.
- Patients who were scheduled to undergo elective laparoscopic cholecystectomy under general anaesthesia.
- Availability of informed consent.

EXCLUSION CRITERIA:

- Patients with ASA physical status III or more.
- Patients below 18 years and above 60 years of age.
- Patients posted for emergency procedures.
- Patients with major neurological, cardiac, respiratory, metabolic, renal, hepatic disease or with coagulation abnormalities.
- Patients with history of motion sickness or previous PONV.
- Patient who had taken antiemetic drugs within 24 hours before surgery.
- Patients with known allergies to the study drugs.
- Pregnant patients

Methodology

- Detailed preoperative history was taken and physical examination was done on the previous day of surgery.
- The procedure was explained to the patient and written informed consent was taken.
- Induction- In the operation theatre, standard monitors were attached to the patients like pulse-oximetry, non-invasive arterial blood pressure and electrocardiogram. An IV line was established. General anaesthesia was given using Inj Fentanyl (2 mcg/kg IV), Inj Propofol (2 mg/kg, IV) and Inj Vecuronium (0.1 mg/kg IV) and endotracheal intubation was done in all patients.
- Maintenance-. Anaesthesia was maintained with Isoflurane, Air and oxygen. At the end of surgery, patients allocated to Group 1 were given Inj Dexmedetomidine 1mcg/kg IV in 100 ml NS over 10 minutes and patients allocated to group 2 were given Inj Ondansetron 4mg IV.
- Emergence-Neuromuscular blockade was reversed with intravenous Neostigmine and Glycopyrrolate. Patient was extubated and shifted to post- anaesthesia care unit.
- During the surgery, monitoring was done and vitals were noted as follows:
    - o Continuous pulse rate monitoring
    - o Continuous blood pressure monitoring (S.B.P, D.B.P,)
    - o Oxygen Saturation
    - o etCO_2 o RR

Patients were also monitored for any changes in the vitals suggestive of side effects of the study drugs.

Post- operatively, vitals including pulse rate, non invasive blood pressure, pulse oximetery using a portable pulse oximeter were monitored again and any signs and symptoms of nausea and vomiting were noted using the PONV score at 2 hours, 4 hours, 6 hours, 12 hours, 18 hours and 24 hours interval.

T0–Immediately post operatively T2–2 hours post-operatively

T4- 4 hours post-operatively

T6-6 hours post-operatively T12-12 hours post-operatively

T18-18 hours post-operatively T 24–24 hours post-

- SCORE TABLE TO ASSESS POST-OPERATIVE NAUSEA AMD VOMITING IS AS FOLLOWS:

  0. 1. 2. 3

  |_____|_____|_____| SCORE TABLE:

- 0- NO SYMPTOM
- 1- MILD NAUSEA
- 2- SEVERE NAUSEA BUT NO VOMITING
- 3- VOMITING

Results

1. PONV (in 24 hours)
   Table 1, compares if the patient had PONV in 24 hours after surgery. In Group 1, 46.7 % patients had PONV and in group 2, 30% patients had PONV. Statistically, there is no significant difference between the two groups (P value= 0.18)

Table 1: Statistical Analysis of PONV in 24 hours

			PONV		Total
			no	yes	
Groups	Group 1	N	16	14	30
		%	53.3%	46.7%	100.0%
	Group 2	N	21	9	30
		%	70.0%	30.0%	100.0%
Total		N	37	23	60
		%	61.7%	38.3%	100.0%

Chi-square test, P value=0.18

2. Observations at 0 hrs

Table 2 shows the statistical analysis of vitals at 0 hours for both groups. In Group 1, the mean heart rate (HR) was 70.23 beats per min and in Group 2, it was 89.60 beats per min. Statistically, there is significant difference between the two groups (P value= 0.001). However, there was no significant variation between the two groupson other parameters such as SBP, DBP and SPO2 as the P value

Table 2: Statistical analysis of vitals at 0 hours

		N	Mean	Std. Deviation	P value
HR	Group 1	30	70.23	20.969	0.001 (S)
	Group 2	30	89.60	11.527	
SBP	Group 1	30	124.90	15.890	0.12
	Group 2	30	131.43	16.311	
DBP	Group 1	30	79.23	11.640	0.08
	Group 2	30	84.27	10.336	
SPO2	Group 1	30	98.50	1.196	0.72
	Group 2	30	98.60	1.003	

3. PONV score at 0 hours

Table 3 shows the statistical analysis of PONV score at 0 hours for both groups. Statistically, there is no significant difference between the two groups (P value= 0.47).

Table 3: PONV score at 0 hours

			PONV score				Total
			0	1	2	3	
Groups	Group 1	N	21	5	2	2	30
		%	70.0%	16.7%	6.7%	6.7%	100.0%
	Group 2	N	26	2	1	1	30
		%	86.7%	6.7%	3.3%	3.3%	100.0%
Total		N	47	7	3	3	60
		%	78.3%	11.7%	5.0%	5.0%	100.0%

Chi-square test, P value=0.47

4. PONV score at 2 hours

Table 4 shows the statistical analysis of PONV score at 2 hours for both groups. Statistically, there is significant difference between the two groups (P value= 0.04).

Table 4: PONV score at 2 hours

			PONV score				Total
			0	1	2	3	
Groups	Group 1	N	20	1	5	4	30
		%	66.7%	3.3%	16.7%	13.3%	100.0%
	Group 2	N	22	5	0	3	30
		%	73.3%	16.7%	0.0%	10.0%	100.0%
Total		N	42	6	5	7	60
		%	70.0%	10.0%	8.3%	11.7%	100.0%

Chi-square test, P value=0.04 (S)

5. PONV score at 4 hours

Table 5 shows the statistical analysis of PONV score at 4 hours for both groups. Statistically, there is no significant difference between the two groups (P value= 0.74).

Table 5: PONV score at 4 hours

			PONV score				Total
			0	1	2	3	
Groups	Group 1	N	22	1	2	5	30
		%	73.3%	3.3%	6.7%	16.7%	100.0%
	Group 2	N	24	2	1	3	30
		%	80.0%	6.7%	3.3%	10.0%	100.0%
Total		N	46	3	3	8	60
		%	76.7%	5.0%	5.0%	13.3%	100.0%

Chi-square test, P value=0.74

6. PONV score at 6 hours

Table 6 shows the statistical analysis of PONV score at 6 hours for both groups. Statistically, there is no significant difference between the two groups (P value= 0.51).

Table 6: PONV score at 6 hours

			PONV score				Total
			0	1	2	3	
Groups	Group 1	N	24	3	0	3	30
		%	80.0%	10.0%	0.0%	10.0%	100.0%
	Group 2	N	26	1	1	2	30
		%	86.7%	3.3%	3.3%	6.7%	100.0%
Total		N	50	4	1	5	60
		%	83.3%	6.7%	1.7%	8.3%	100.0%

Chi-square test, P value=0.51

7. PONV score at 12 hours

Table 7 shows the statistical analysis of PONV score at 12 hours for both groups. Statistically, there is no significant difference between the two groups (P value= 0.35).

Table 7: PONV score at 12 hours

			PONV score				Total
			0	1	2	3	
Groups	Group 1	N	28	1	0	1	30
		%	93.3%	3.3%	0	3.3%	100.0%
	Group 2	N	30	0	0	0	30
		%	100.0%	0.0%	0	0.0%	100.0%
Total		N	58	1	0	1	60
		%	96.7%	1.7%	0	1.7%	100.0%

Chi-square test, P value=0.35

8. Need for rescue antiememtic

Table 8 shows the statistical analysis og the need for rescue anti emetic during 12 hrs. There is no significance difference between the two groups in terms of the requirement of rescue anti emetic.

Table 8: need for rescue antiemetic

	Group 1	Group 2
0 H r	6.7%	3.3%
2 Hr	13.3 %	10.0 %
4 Hr	16.7 %	13.3%
6 Hr	10.0%	6.7%
12 Hr	3.3%	1.7%

Discussion

The present study was undertaken to assess the extent of PONV after laparoscopic cholecystectomy and to compare the relative efficacy of iv Ondansetron and iv Dexmedetomidine. Sixty ASA I and II in the age group of 18-60 years scheduled to undergo elective laparoscopic cholecystectomy under general anaesthesia were chosen.

The choice of 4mg Ondansetron was based on pooled data from studies that suggested this was the optimal dose for the prophylaxis of PONV.

Dexmedetomidine was also given at the end of surgery just before extubation. It was given in a dose of 1mcg/kg given in 100 ml NS over 10 minutes. The antiemetic effect of Dexmedetomidine is best appreciated when it is given at the time of extubation [5].

After the administration of the study drugs,

patients were observed for any possible side effects. Significant drug related side effects attributed to Ondansetron include headache, light headedness, warm sensation in the epigastrium[6] but no such side effects were observed in our study during 10 minutes of observation after drug administration or in the recovery room.

Adverse effects of Dexmedetomidine are hypotension, bradycardia, pulmonary edema, dry mouth and atelectasis. In our study, some patients had bradycardia which resolved spontaneously within 2 hours of administering the drug. Although it is difficult to assess the preoperative anxiety levels of the patient, most of them appeared calm. Factors like periods of CO2 insufflation, duration of the surgery and duration of anaesthesia were comparable among the groups. After random allocation of patients using computer generated data into different study groups, sex and age in different groups were found to be comparable.

We found that total incidence of PONV in 24 hours was 46.7% in Dexmedetomidine group and 30% in Ondansetron group. Our results were consistent with the studies conducted by Kamali et al[5]

Metoclopramide 10 mg intravenous was used as the rescue antiemetic if the patients vomited more than once or when the patient demanded. The need for rescue antiemetic in 24 hours post surgery in both the groups was comparable. The difference in metoclopramide requirement was not statistically significant between Dexmedetomidine group and Ondansetron group.

The total episode of PONV was lesser in the Ondansetron group than Dexmedetomidine group. But the efficacy of both the drugs was comparable in view of the incidence of PONV. Possible explanations for the success of dexmedetomidine in PONV prevention include multiple mechanisms. The dexmedetomidine-induced opioid-sparing and inhaled anesthetics- sparing effect may contribute to the reduction in PONV. Also, dexmedetomidine decreases noradrenergic activity through reducing sympathetic outflow or inhibiting α2 presynaptic in the locus coeruleus which may relate to PONV [7].

Dexmedetomidine and Ondansetron significantly reduced the consumption of rescue antiemetic during 24 hour postoperative period.

Conclusion

In conclusion, the results of the present study indicate that :

1. Prophylactic Ondansetron in a dose of 4mg iv given near the end of surgery is highly effective in reducing the incidence of PONV. It significantly reduces the consumption of rescue antiemetic during 24 hour postoperative period.
2. Prophylactic Dexmedetomidine in a dose of 1mcg/kg iv in 100 ml NS over 10 minutes given at the end of the surgery is highly effective in reducing the incidence of PONV. It also reduces the consumption of rescue antiemetic during 24 hour postoperative period.
3. No undesirable side effects were observed after using the study drugs during 24 hour postoperative period.
4. Both the drugs significantly reduced the requirement of rescue antiemetic during 24 hours postoperative period.
5. It was found in my study that there was no significant difference in PONV due to the sex of the patients. The age limit of the patients under study was within 18-60 years and we did not find any association between ages of the patient with the increased incidence of PONV in any study group.

Hereby it is concluded that the use of both Ondansetron 4mg iv at the end of the surgery and Dexmedetomidine 1mcg/kg iv in 100ml NS over 10 minutes at the end of the surgery is recommended for ameliorating PONV. In terms of efficacy, both the drugs are equally effective in reducing the incidence of PONV.

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