EFFICACY OF HYOSCINE BUTYL BROMIDE SUPPOSITORY FOR POSTOPERATIVE PAIN RELIEF

Soniya C. Alphonse[1], Acka Priya Varghese[2]

[1]Assistant Professor, Department of Obstetrics and Gynaecology, Government Medical College, Kottayam.
[2]Associate Professor, Department of Obstetrics and Gynaecology, Government Medical College, Kottayam.

ABSTRACT

BACKGROUND

Caesarean Section is on the rise all over the world. Women undergoing Caesarean section often wish to be awake post operatively and to avoid excessive medications affecting interactions with the new born infant. Multimodal pain therapy has been advocated for postoperative pain management after caesarean section.

MATERIALS AND METHODS

The study is a prospective randomized controlled study conducted at a tertiary care hospital to study the effect of Hyoscine Butyl Bromide Suppositories for postoperative analgesia following elective repeat caesarean section. The study included sixty patients divided into two groups- Group1 (study group) were given Hyoscine Butyl Bromide Suppository (10 mg) along with Injection. Tramadol 50 mg IM and Group II (control group) were given Injection Tramadol IM only at the end of surgery. Pain score of the patient assessed at 1 hr, 2 hrs, 6hrs and 24 hrs post operatively. The total no of doses of injection tramadol needed in 24 hrs and the interval between 1st and 2nd dose of tramadol was also noted. The adverse effects of the drug and additional advantages of the drug if any were also assessed.

RESULTS

There was no statistically significant difference in pain score during the assessment intervals between the two groups. There was no difference in the number of doses of tramadol needed in the first 24 hrs. The mean interval between the 1st and 2nd dose of tramadol was found to be 7.6538 hours for group 1 patients and 6.9130 for group patients which was found to be statistically significant. There was no statistically significant side effects/ additional advantages for the drugs.

CONCLUSION

Concurrent administration of Hyoscine Butyl Bromide Suppository (10 mg) and injection Tramadol 50 mg IM offers a longer postoperative analgesia without any increased adverse effects.

KEYWORDS

Postoperative Pain Relief – Hyoscine Butyl Bromide Suppository – Injection Tramadol.

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BACKGROUND

Pain relief is a basic human right and failure to relieve pain is morally and ethically unacceptable. Despite the advances in the knowledge of pathophysiology and pharmacology of analgesics and development of more effective techniques for postoperative pain control many patients continue to experience discomfort.[1]

Postoperative pain is unique by its transitory nature which makes it more amenable to therapy. Inadequate knowledge regarding the necessity and adequacy of pain relief combined with difficulty in assessment of severity of pain has resulted in under treatment of pain.[2] The risks associated with postoperative use of opioids as respiratory depression and addiction also contribute.[3] Inadequate postoperative analgesia has an adverse physiological impact leading to increased postoperative morbidity.

Balanced analgesia means combining the various analgesic regimen to achieve adequate analgesia with concomitant reduction of adverse effects which can be achieved with a combination of pain relieving modalities that act at different levels along the pain pathway.[4] Drugs with different mechanism of action can be used to achieve optimal analgesia through additive or synergistic effects. Tramadol is a weak opioid agonist which acts on opioid receptors in CNS, has NSAID like properties and also a Serotonin uptake inhibitor without causing respiratory depression. Postoperative pain is both somatic due to released mediators of inflammation as well as visceral pain arising from intestinal and genitourinary smooth muscles. Hyoscine Butyl Bromide Suppository exerts spasmolytic action on these smooth muscles.[5] Administration of the

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Corresponding Author:
Dr. Acka Priya Varghese,
Associate Professor,
Department of Obstetrics and Gynaecology,
Government Medical College, Kottayam-686008.
E-mail: drsoniyaalphonse@gmail.com
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drug as suppository is useful as the patient is not able to make use of the oral route immediately after surgery.[6]

Good quality analgesia improves the patients postoperative ventilatory function. With adequate postoperative analgesia and subsequent early ambulation, the incidence of life threatening complications like DVT can be reduced. Pain relief will help the patient to get adjusted to the new milieu and reduces systemic morbidity and hospital stay and thus reduces the cost also.[1]

Aims and Objectives

Primary objective- To find out whether Hyoscine Butyl Bromide Suppositories are effective for postoperative analgesia.

Secondary objectives- (1) To study the adverse effects of the drugs if any (2).To study the additional advantages of the drug if any.

MATERIALS AND METHODS

The study is a randomized prospective study conducted at Medical College Kottayam to study the effect of Hyoscine Butyl Bromide Suppository (10 mg) for postoperative analgesia. The study included 60 patients who were randomly divided into two groups of 30 each.

Inclusion Criteria

1. Elective repeat caesarean section.
2. Those done under spinal Anaesthesia.
3. Pfannenstiel incision.

Exclusion Criteria

1. Patients with antenatal/intraoperative complications.
2. Patients with cardiac disease.
3. Patients with glaucoma.
4. Patients with myasthenia gravis.
5. Patients sensitive to Hyoscine Butyl Bromide.

Informed written consent was taken from patients. After careful preoperative evaluation spinal anaesthesia was given with injection Bupivacaine 0.5%. Group I patients were given Hyoscine Butyl Bromide suppository (10 mg) perrectally along with injection Tramadol (50 mg) at the end of surgery while group II patients were given only injection tramadol 50 mg. The efficacy of postoperative analgesia was evaluated by using Mc Gills scoring system.[7] According to this subjective rating scale,

Score 0 - No pain
Score 1 - slight pain
Score 2 - Discomfort due to pain
Score 3 - Unbearable pain.
Score 4 - excruciating pain.

Clinical variables like PR, BP were monitored and pain score assessed at 1hr, 2 hrs, 6 hrs and 24 hrs postoperatively. Patients were given repeat dose of injection tramadol 50 mg when the pain score was = 2 and injection pethidine 1 mg/kg when the score is =3. The time of 2nd dose of tramadol and total number of doses of tramadol needed in 24 hrs postoperatively were also noted. Side effects of the drug and additional advantages of the drug were also observed.

Statistical Analysis

The observations were analysed by statistical methods and the software used was Statistical Package for Social Sciences (SPSS). The arithmetic mean and standard deviation of various parameters were calculated. The comparison between the two groups were accomplished using students two sample 't' test whenever applicable. A 'p' value of <0.05 was considered significant. The test of proportion used for statistical analysis was 'z' test.

RESULTS

All the patients in the study had undergone elective repeat caesarean section under spinal anaesthesia and the incision put was Pfannenstiel. None of them had any antepartum or intraoperative complications. Out of the 60 patients included in the study, 4 patients from Group I and 6 patients from Group II were excluded from the analysis as observational variables could not be compared because they received a 3rd drug in the form of sedative

Age in Years	Number of Patients	
	Group I	Group II
20-25	5	4
26-30	12	16
31-35	8	4
36-40	1	0
Total	**26**	**24**

Table 1. Demographic Data

Majority of patients belonged to the age group 26-30 yrs.

Weight in Kilogram	Number of Patients	
	Group I	Group II
50-55	1	0
56-60	13	16
61-65	9	8
66-70	3	0
Total	26	24
Mean	60.64	59.5652
SD	3.9674	2.7107
t value-1.09, P value NS		

Table 2. Weight of Patients

Majority of patients weighed 56-60 kg.

Duration of Surgery in Minutes	No. of Patients	
	Group I	Group II
45-55 minutes	20	19
56-65 minutes	6	5
65-75 minutes	0	1
Total	**26**	**24**
Mean	53.2692	53.2609
SD	5.8210	5.9560
P value –NS		

Table 3. Surgery Duration

Most of the surgeries were completed in 45-55 minutes.

Score	Number of Patients	
	Group I	Group II
1	21	16
2	5	8
3	*4	*6
Total	**26**	**24**
'Z' Value-NS		

Table 4. Pain Score at 6 hrs.

*Excluded from analysis because sedation was given. No statistically significant differences in pain score at 6 hrs.

Time from '0' hr	Number of Patients	
	Group I	Group II
	5	9
6-8 hrs	15	12
≥ 8 hrs	6	3
Total	**26**	**24**
Mean	7.6538	6.9130
SD	1.293	0.9993
't' value-2.46; P value <0.05		

Table 5. Time of 2nd Dose of Tramadol

'P' Value <0.05, which is significant.

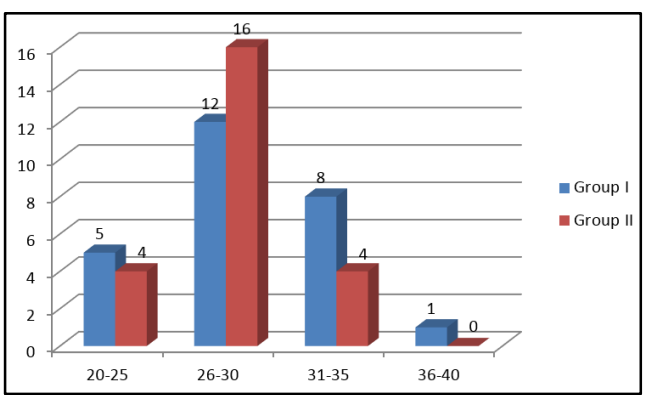

Figure 1. Majority of Patients Belonged to the Age Group 26-30 yrs.

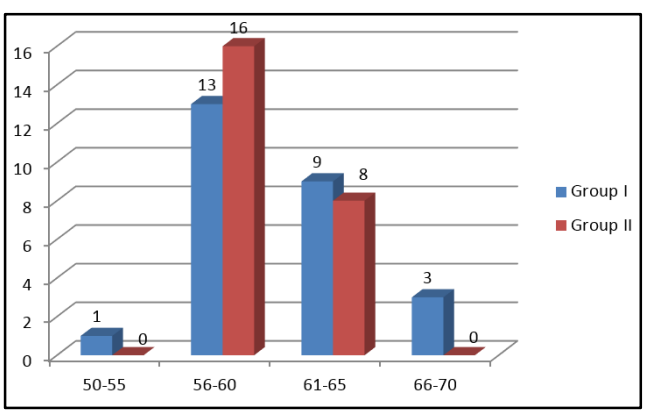

Figure 2. Majority of Patients Weighed 56-60 kg

DISCUSSION

Age, weight and duration of surgery were statistically at par for both groups and thus the two groups were comparable. There was no difference in pain score at 1 hr, 2 hrs, 6 hrs and 24 hrs postoperatively; However at 6 hrs, 21 patients in Group I, had a pain score of 1 while only 16 patients in group II had the same score and 5 patients in group I had a score of 2 while 8 patients from group II had the same score though this was not statistically significant. There was no difference in the total number of doses of tramadol in 24hrs. Habib et al in a "Study of Buscopan for the treatment of pain after laparoscopic sterilization" also concluded that there was no significant differences in pain score and analgesic requirements after its use.[8] The mean interval between the 1st and 2nd dose of tramadol was found to be 7.6538 in group I and 6.9130 for group II patients which was found to be statistically significant. No statistically significant side effects/ additional advantages of the drug noted in the study. One patient in Group I has mild atomic PPH which was controlled with oxytocics. 3 patients in group II had vomiting while no patients in group I had vomiting though this was not significant.

The difference in the interval between 1st and 2nd dose of injection tramadol was statistically significant which means that administration of Hyoscine Butyl Bromide suppository (10 mg) along with injection tramadol 50 mg IM helps the patient to have a longer pain free interval. The rectal route offers an alternate route for analgesia especially in immediate postoperative period where oral drugs cannot be given.[9] This route bypasses liver metabolism, is easy to administer without any harmful effect to mother and infant.

CONCLUSION

The combination of antispasmodic agent and parenteral analgesic has got additive effect. Concurrent administration of Hyoscine Butyl Bromide Suppository (10 mg) and injection Tramadol 50mg IM after lower segment caesarean section offers a longer postoperative analgesia without any increased side effects.

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