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COMPARITIVE STUDY OF EPIDURAL TRAMADOL WITH AND WITHOUT ORAL CLONIDINE AS PREMEDICATION AS POST OPERATIVE ANALGESIA

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KEYWORDS :

INTRODUCTION

Pain is one of the most common symptom for which patients seek medical attention. To provide a common ground for the evaluation and treatment of patients with pain ,the international association for the study of pain (IASP) has proposed the following definition of pain. Pain is an unpleasant sensory and emotional experience associated with either actual or potential tissue damage.

Clinically may present itself temporalily as acute or chronic, physiologically as somatic, visceral or neuropathic and etiologically as pathogenic or psychogenic.

Pharmacological interventions in the management of pain has been with the use of opioid and non opioid drugs including non –steroidal anti-inflammatory drugs.Rescent advances in management of pain include more effective use of standard drug therapy and development of newer drugs for safe and better pain control.The use of opioid drugs in this context has been hampered by two problems-respiratory and cardiaovascular depression and potential of drug abuse.

In order to overcome the handicap tramadol was introduced which successfully bridge the gap between effective analgesia and safety of the patient. However the limitation of Tramadol is its short duration in comparison to morphine and its main side effects nausea and vomiting.

Clonidine ,an aipha 2 receptor agonist by itself has analgesic property in addition,it potentiate the regional analgesia.In addition to its antiemetic effect,has lessen the degree of post operative nausea and vomiting due to post operative analgesia.

Hence this study is undertaken to evaluate the efficacy of oral clonidine in potentiating the post operative analgesia of epidural tramadol and its efficacy in alleviating the common side effect of tramadol –nausea and vomiting .

Aim of the study

1. The study was undertaken to determine and evaluate the efficiency of extra dural tramadol Hcl in providing post operative analgesia following gynecological surgery in particular trial vaginal hysterectomy.
2. To evaluate the efficacy of oral clonidine (dose 5 mcg /kg) a pre anaesthetic medication on the post operative analgesia-Extra dural Tramadol and to study in particular about

Quality of analgesia
Duration of analgesia
Changes in CVS and RS .

Complications in particular nausea and vomiting and their incidence.

Materials And Methods

The study was conducted in a tertiary care hospital. Informed consent was obtained from all patients .The present study compared epidural tramadol with or without oral clonidine as premedication for post operative analgesia in patients undergoing trial vaginal hysterectomy. The study also compared the incidence of side effects such as itching,nausea and vomiting as well as changes in the arterial blood gases during the first 12 hours.

Seventy patients of ASA physical status 1 and 2 scheduled for elective trial vaginal hysterectomy were randomly divided into two groups , Group A and Group B.Group A consisted of 35 patients receiving epidural tramadol with premedication of Inj Diazepam 10 mg and anticholinergic Inj Atropine 0.6 mg .Group B consisted of 35 patients epidural tramadol with oral clonidine 5 mcg per kg as premedication 90 minutes prior to induction of anaesthesia.

On the evening before the day of operation , the patients were informed about the purpose of the study and were introduced to the Visual Analogue Pain Scales.

On the day of surgery ,Group A patients received Inj Diazepam 10 mg and Inj Diazepam and Inj Atropine 0.6 mg as a premedication 45 minutes prior to surgery. Group B patients received Tablet Clonidine 5 mcg per kg (not exceeding the ceiling dose of 300 mcg in any patient) with sips of water 90-120 minutes prior to induction of Anaesthesia.All the vital parameters like Blood pressure ,Pulse rate, Respiratory rate , and SPO2 were recorded preoperatively.

Conduct Of Anaesthesia

In the operating room , an epidural catheter was inserted ,in the lateral decubitus position at L2-L3 or L3 –L4 level. An initial dose of 5 ml of 1.5% lignocaine was injected via the epidural catheter to be followed by an additional 15 ml of 1.5 % lignocaine. All parameters were recorded every 5 minutes initially and then every 15 minutes. Level of sensory and motor blockade was noted. In few cases at the end of 45 minutes to 60 minutes, if the surgery is likely to be prolonged, second dose of 1.5 % lignocaine , half of the initial first dose was injected.

At the end of surgery, after proper positioning ,all the patients in Group A and Group B were given Injection Tramadol 50 mg diluted in 10 ml of normal saline. Initial vital parameters were recorded.

All patients were monitored for 12 hours post operatively in the post operative care unit.All the vital parameters were continuously monitored .The following variables were assessed by a resident who was blind to the study.

Pain Score

Intensity of peri operative pain during the first 24 hours post operatively was assessed every hour using the Visual analogue pain score .0 –denotes No pain while 10 denotes Worst pain imaginable .

Duration Of Analgesia

The duration of analgesia was monitored .This is taken into account till the patient was able to tolerate minimal pain without requirement of next dose .

Side Effects

The other side effects of an opioid narcotics like respiratory depression, itching ,nausea and vomiting during the first 12 hours post operative period was monitored .Although urinary retention is a recognized complication of epidural narcotic ,it was not possible to assess its incidence in our patients who had an indwelling catheter during the first 12 hours.

All the data were presented as mean value ±SD , $P < 0.05$ was considered significant –using student t test chart.

Observation And Results

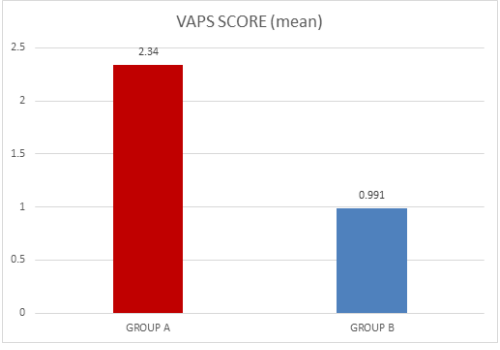
The patient groups were comparable with respect to demographic

variables like age, body weight, height ,ASA status and the resting values of heart rate and blood pressure as shown in **Table -1**

Parameters	Group –A (n=35) mean ±SD	Group B (n =35) Mean ±SD
Age (in years)	34.74 (25 -50)	36.7 (25-50)
Weight (kg)	62.2 ±9.8	70 ±12.6
Height (cms)	165.2 (150-172)	163 (154-172)
ASA status Ⅰ ASA status Ⅱ	25 (71.4 %) 10 (28.6 %)	15 (42.85 %) 20 (57.14 %)
Duration of surgery (minutes)	120 (90-190)	122.8 (90-195)
Base line values Heart rate /min Blood pressure (mm Hg) SBP DBP	81.12 (72-88) 123.12(110-136) 81.04 (70-90)	79.6 (72-84) 122.08 (110-140) 76.76 (70-90)

TABLE 2 -

Groups	VAPS Mean	SD
Group A	2.34	0.3984
GROUP B	0.991	0.3345



The linear analogue pain score in the immediate post operative period of Group A and Group B with mean ±SD are shown in Table 2.

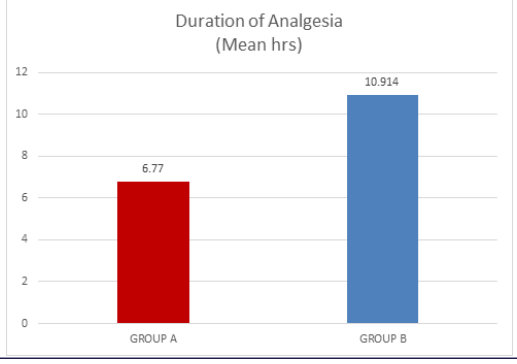
From the table , it is clear that patients in Group B –who were premedicated with oral clonidine had better pain relief than those of Group A. More over , more than 25 patients had excellent pain score < 2 for a period more than 10 hours in comparison to less than 8 patients from Group A ,who had pain score < 2 for a period of 8 hours post operatively.

Duration Of Analgesia

The duration of analgesia with mean ±SD of both the Groups A and B is shown in the table 3.

From the table it is clear that the patients in groups B with oral clonidine as a premedication had good pain relief for longer duration in the post operative period. In this study more than 15 patients had excellent pain relief (pain score < 2) upto 12 hours and more, while only 3 patients had similar pain relief for a period of 10 hours in Group A.

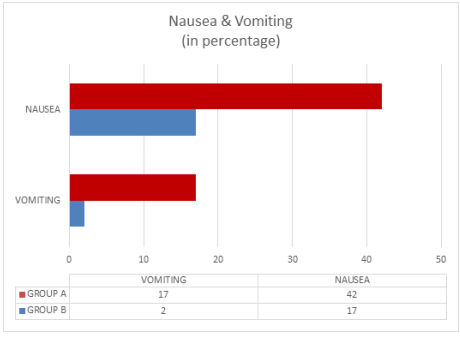
Groups (n=35)	Duration (hours) mean	SD
Group A	6.77	2.23
Group B	10.914	1.539



Nausea and vomiting

The percentage of side effects mainly nausea and vomiting in both groups A and B as shown in the Table 4.

SIDE EFFECTS	GROUP A (n=35) No of pts	percentage	GROUP B (n=35) No of patients	percentage
Nausea	15	42.85	6	17.14
Vomiting	6	17.14	1	2.85



From the table it is clear that for patients in Group B , the incidence of nausea is only 17 %,in contrast to 42 % in Group A and similarly the incidence of vomiting is 17 % in Group A ,while it is only 3 % in Group B. This shows that clear advantage of oral clonidine as an anti emetic , which lessens the degree of nausea and vomiting significantly in the post operative period.

The other side effects are shown in the TABLE 5 .

Side effects	Group A	Group B
Transient fall in BP	1	3
Numbness of legs	-	-
Shivering	-	-
Burning sensation over the body	1	-
Transient numbness of hands	1	_
Retention of urine	1	_
Dry mouth	1	3
Transient double vision	-	2
Dizziness	3	5

$p < 0.05$ between groups A and B .

DISCUSSION

Pharmacological intervention in the management of pain has been with the use of opioid and non opioid drugs including NSAIDS. Recent advances in the management of pain include more effective use of standard drug therapy and development of newer drugs for safer and better pain control.The use of opioid drugs in this context has been hampered by two problems-respiratory and cardio vascular depression and potential of drug abuse.

This fact is well over come by the proven safety of Tramadol as an post operative analgesia.The action of tramadol is probably at the spinal level similar to other opioids like morphine .Our institute lacks the fascilities to estimate serum tramadol level ,hence it is not possible to do so in our study. However chrubasik et al in their study of 21 patients given given epidural tramadol infusion ,found mean plateau serum concentration of around 300 µg/ ml, which were lower than seen with intra venous tramadol treatment.

The draw back of epidural tramadol is that its requirement of higher dosage of better pain relief , which is associated with increasing side effect of nausea and vomiting.

In our present study ,these factors which has the limitation in the usage of epidural tramadol has to be tried to overcome such as to keep the analgesic dose of tramadol to minimum and to alleviate the side effect .The effect of epidural clonidine along with tramadol has been studied by Maser o et al.

In our study ,the main objective was to evaluate the efficacy of oral clonidine on epidural tramadol as a post operative analgesia. It has been previously studied that the clonidine of which ever route has similar effect in potentiating the analgesic property of drugs acting on opioid receptor.

In this study,from the pain score it is well clear that the post operative analgesic of the patient who had received oral clonidine as premedication has good post operative analgesia with $p < 0.05$,in in comparison with the other groups who had received only epidural tramadol.

With regard to the duration of analgesia also,patient with oral clonidine as pre medication ,has shown a longer duration of analgesia with mean duration of more than 10 hours in comparison with that of the other group with $p < 0.05$ which is quite significant .In our study 10 patients with oral clonidine as a premedication has shown no requirement of any sedation for a period of more than 18 hours.

The other parameter such as Respiratory rate , pulse rate ,heart rate & blood pressure were only minimally altered in both the groups. Only 3 patients who had received oral clonidine as a pre medication had shown transient fall in blood pressure & 1 patient showing dry mouth and transient double vision.

With regard to nausea and vomiting , the common post operative complication ,the incidence was very low with only 6 patients with oral clonidine as pre medication ,showing post operative nausea and only one patient had post operative vomiting .This is significant in comparison to the other groups, which had a incidence of 43 % and 17 % of post operative nausea and vomiting .

Although our study has confined to only postoperative analgesia, intra operatively it was found that patient with oral clonidine as premedication has shown a good sedation score and better haemo dynamic stability during the procedure .

CONCLUSION

The result of present study show that a combination of oral clonidine 5 μ /kg as a premedication with epidural tramadol 50 mg as a post operative analgesia has provided better post operative analgesia with only a minimal side effect with good haemo dynamic stability in comparison to epidural tramadol 50 mg alone as a post operative analgesia in ASA Ⅰ and Ⅱ patients.

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