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RESEARCH ARTICLE

Oral pregabalin as preemptive analgesia and reduces the dose of diclofenac consumption during the postoperative period of gynaecological operation under spinal anaesthesia- a randomized, placebo-controlled study

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ABSTRACT

Background: Majority of gynaecological surgeries are performed under spinal anaesthesia because of ease of technique and various side effects associated with general anaesthesia. Multimodal analgesia has been recommended nowadays for perioperative pain. Gabapentinoids are been increasingly being used as preemptive analgesia for postoperative pain management. **Objectives:** The purpose of this study was to assess if preoperative pregabalin had any effect on postoperative analgesic requirement in patients undergoing hysterectomy under spinal anaesthesia. **Methods:** It was a randomized, double-blind, placebo-controlled trial involving 80 women with ASA I and II who were undergoing gynaecological surgeries under spinal anaesthesia and were divided into two groups (n=40). One hour before anaesthesia, group P received pregabalin 75mg and group C received placebo, both in the form of identical gelatinous capsules. The visual analogue scale for postoperative pain, the Ramsay Sedation Scale for sedation, and postoperative nausea and vomiting (PONV) scale were all used in the study. **Results:** In group P, the number of patients with VAS ≥4 at 6, 24, and 48 hours was lower than in group C. At 12 hours, however, the number of patients with a VAS ≥ 4 was higher in group P than in group C. The cumulative diclofenac consumption in the pregabalin group was significantly reduced. Throughout the interval, group P had a slightly higher Ramsay sedation score than group C. PONV was greater in group P after surgery. **Conclusion:** Preoperative administration of 75 mg of pregabalin 1 hr before spinal anaesthesia resulted in a significant reduction of diclofenac consumption after major gynaecological surgeries.

Keywords: Pregabalin, preemptive analgesia, spinal anaesthesia, gynaecological operation.

Pain is defined as unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (IASP: 1979) [1]. Acute pain following surgery is predictable and it is physiological. It corresponds with the extent of tissue damage. Patients are prepared for some degree of pain or discomfort but expect that it will pass over time. Unsatisfactory analgesia increases discomfort of the patient and prolongs hospital stay. Inadequately controlled pain negatively affects quality of life, function, and functional recovery [2]. Postoperative pain management still continues to be a major medical challenge for health professionals. Pain is declared as "The Fifth Vital Sign." by the American pain society in 1996 [3]. Therefore, the evaluation of pain became a requirement of proper patient care as important and basic as the assessment and management of temperature, blood pressure, respiratory rate, and heart rate. Untreated or inadequately treated pain increases postoperative cardiovascular and respiratory complications. It delays wound healing and thus prolongs hospital stay [4]. Untreated

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pain can lead to the development of chronic post-surgical pain (CPSP) which can even more frustrating for both the surgeon and patients. Development of CPSP is primarily due to both peripheral and central sensitization [5-9]. Anaesthesiologist or perioperative pain physician tries to minimize postoperative pain utilizing different modalities like opioids, NSAIDs, α2 agonist, ketamine, magnesium sulphate, dexamethasone, antidepressant and anticonvulsant and different nerve blocks as a part of preemptive and multimodal analgesia [10-12].

Assessment and alleviation of pain have been given a high priority nowadays by medical professionals and health authorities. Improvement in perioperative analgesia is not only desirable for humanitarian reasons but also essential for its potential to reduce postoperative morbidity and mortality. Initially, it was thought that acute postoperative is primarily due to nociception, however recent studies demonstrated that there are some neuropathic components in acute pain due to neuroplasticity [13, 14]. Therefore, acute postoperative pain nowadays is regarded mainly as a mixed type (both nociceptive and neuropathic) in nature. Since the gabapentinoids, pregabalin and gabapentin are widely being used in chronic neuropathic pain over the years, their role in acute pain has been studied recently as part of preemptive analgesia to counter the neuropathic components with mixed results [15,16].

The present study aimed to determine postoperative improvement in analgesia in patients administered pregabalin as preemptive analgesia for gynaecological surgery under spinal anaesthesia, reduction in total postoperative requirements of analgesics and study side effects and complications, if any attributable to the drug.

Materials and methods

The randomized control study was conducted in the gynaecological OT of Tezpur Medical College and Hospital after receiving approval from the institutional and ethical committee (IEC NO-008/2021/TMCH).

Study population: American Society of Anaesthesiologists (ASA) I and II physical status patients posted for various elective gynaecological surgeries of age group 18 -50 years.

Exclusion criteria –

ASA greater than II.

Allergic to the study drug.

Patients contraindicated for spinal anaesthesia.

Hypertension, diabetes mellitus, ischemic heart disease, cerebrovascular disease.

Patients having hepatic or renal disease.

Declined to participate.

Inadequate block or failed block requiring supplemented sedation or general anaesthesia is excluded.

Sample size determination: Sample size was calculated using G-Power 3.1.9.7 statistical software. The sample size required for this study was estimated from a previous study which demonstrated increased time to VAS≥4 with a mean difference of 2.5 [15]. Based on $\alpha = 0.05$, $\beta = 0.20$ and a mean difference of 2.6 in pain score, with an estimated standard deviation of 3.9, a sample size of 36 per group was required. Considering a dropout of 10%, 40 patients in each group were included in this study.

Randomization: Randomization is carried out by block randomization. Patients were divided into two groups (group C and, P). Group C (n=40) received single dose of placebo; group P (n=40) received single dose of pregabalin 75mg.

Parameters used during the study was visual analogue scale for postoperative pain, Ramsay Sedation Scale for sedation and postoperative nausea and vomiting (PONV).

Visual analogue scale (VAS): Pain is measured with visual analogue scale. Rescue analgesic was given if VAS≥4.

Ramsay Sedation Scale:

1 Patient is anxious and agitated or restless, or both.
2 Patient is co-operative, oriented, and tranquil.
3 Patient responds to commands only.
4 Patient exhibits brisk response to light glabellar tap or loud auditory stimulus.
5 The patient responds slowly to a light glabellar tap or a loud auditory stimulus.
6 Patient exhibits no response.

All patients were subjected to routine preoperative assessment and fasting protocols. All patients were visited the night before surgery and explained about the anaesthetic plan and the outcomes. Written and informed consent was taken. All patients were received oral alprazolam 0.5 mg and injection pantoprazole 40 mg in the night before surgery and in the morning on the day of surgery. All participants were explained about the Visual Analogue scale (VAS), PONV intensity score and postoperative anaesthetic plan. During the pre-anaesthetic visit, patients were given a VAS chart and asked to encircle the number according to their pain. 0 means no pain and a score of 10 means the worst possible pain. Written and informed consent was obtained. A pharmacist of our institution prepared both placebo and study drug in the form of a gelatinous capsule whose size and shape was similar. He was not involved in our study.

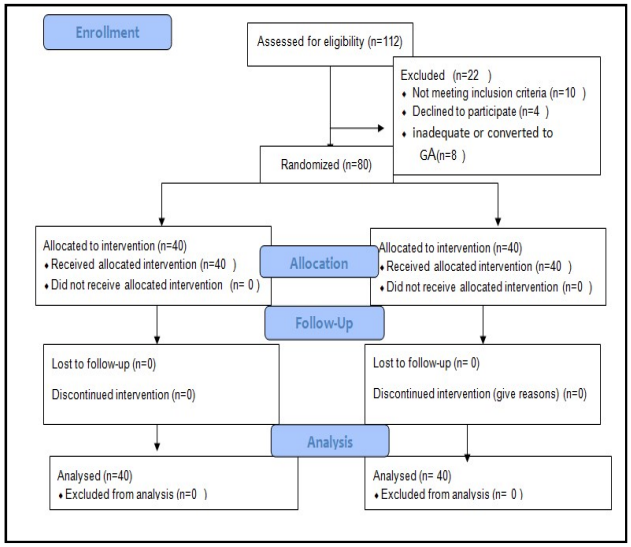

Figure 1: Consort flow diagram

One hour before spinal anaesthesia: Group C - received placebo capsules; Group P - received 75mg of oral pregabalin.

In the operation theatre, an intravenous (IV) infusion line was secured and preloaded with 15ml/kg body weight of ringer lactate solution. Standard monitoring devices measuring Non-Invasive Blood Pressure (NIBP), Percentage Oxygen Saturation (SPO_2) and Continuous Electrocardiograph (ECG) were attached and baseline recordings were taken. Spinal anaesthesia was performed in the left lateral position at L2-L3 interspace using a 25 gauge spinal needle (spinocaine25®G, B Braun, Melsungen, AG, Germany). 3ml of bupivacaine heavy was injected after a free flow of CSF was confirmed. The table was tilted 30-degree immediately in Trendelenburg to achieve a level of a block around T5-T6. The level of sensory block was assessed using the pinprick method with a 26 gauge needle. The Bromage scale was used to record the motor block. Intra-operative heart rate, blood pressure, SpO_2, ECG was monitored at an interval of 5 min. All patients were given oxygen at 3 litres/min via nasal prongs. Fluid administration was continued intra-operatively and a decrease in mean arterial pressure greater than 30% below the pre-anaesthetic baseline value was treated with incremental doses of injection mephentermine 6 mg IV. A decrease in heart rate below 50 /min was treated with incremental doses of atropine 0.3 mg IV. Inadequate levels of anaesthesia or failed spinal blocks were converted to general anaesthesia and were excluded from the study.

Postoperatively, all patients were shifted to the Post Anaesthesia Care Unit (PACU) for monitoring and observation. All patients received rescue analgesia in the form of injection diclofenac 1.5mg/kg intramuscular (IM) if VAS ≥ 4. The patients were subsequently shifted to the ward after 6 hrs.

Patients were assessed at 6, 12, 24 and 48 hrs and recorded the following data.

Time to VAS ≥4

Total number of times VAS ≥4 in 48hours duration.

Total dose of inj. diclofenac administered in 48 hours (in mg).

Incidences of complications such as PONV, somnolence, visual disturbances, headache and respiratory depression were assessed and recorded.

Statistical analysis has been carried out with the help of SPSS (version 20) for the window package (SPSS Science, Chicago, IL, USA). The description of the data is in the form of mean ± SD for quantitative data while in the form of % proportion for qualitative (categorical) data. P-value of < 0.05 was considered significant. For quantitative data, the unpaired student's t-test is used to test the statistical significance of the difference between two independent groups. For comparison of categorical variables (i.e. to examine the associations between qualitative /quantitative variables), a chi-square test was used.

Results

Data presented as mean ±SD or numbers of patients were tabulated and analyzed in Microsoft Excel 7. A total of 112 patients were assessed for eligibility out of which 22 patients were excluded from the study (figure1). 14 patients were excluded in preoperative visits due to not meeting inclusion criteria (n=10), and declined to participate (n=4). 8 patients had an inadequate block or converted to general anaesthesia (n=8) and were therefore excluded from the study. A total of 80 numbers of patients were enrolled in our study, 40 numbers of patients in each group.

Demographic variables, types of surgeries and duration of surgeries were comparable to each group (p value > 0.05) (table1).

Table 1: Demographic variables

Demographic variable	Group P Mean ± SD	Group C Mean ± SD	P value
Age	38.1±5.23	37.87±6.56	0.964
Weight	55.21±6.34	54.67±5.39	1.345
Height	152.92±6.45	154.21±7.12	1.034
ASA I/II	35/5	36/4	1.91

The mean time of onset of sensory block was 2.25±0.46 min and 2.14±0.38 min in group P and group C, respectively. There was no significant difference in the onset of sensory

analgesia between group P and group C (p > 0.1) (table 2). The mean time of onset of motor blocks was 4.46±.67 min and 4.32±.34 min in group P and group C, respectively. There was no significant difference in the onset of the motor block between group P and group C (p value = 0.64200) (table 2).

Table 2: Onset of sensory and motor block, duration of surgery, time to VAS>4, cumulative diclofenac dose and number of complications.

Parameters	Group P	Group C	P-Value
The onset of sensory block	2.25±0.46	2.04±0.38	0.018490
The onset of motor block	4.46±.67	4.32±.34	0.642
Duration of surgery	54.475±10.48	51.325±14.26	0.097846
Time to VAS≥4	2.48±0.82	2.77±0.49	0.046314
Cumulative diclo dose (mg)	280±26.34	350±35.32	0.01361
No of complications	5(12.5%)	0(0%)	<.001

The mean duration of surgery was 54.475±10.48 min and 51.325±14.26 min in group P and group C, respectively. There was no significant difference in the duration of surgery between group P and, group C (p value=0.097) (table 2).

The mean time to VAS≥ 4 was 2.48±0.82 min and 2.77±0.49 min in group P and group C, respectively. There was a significant difference in the meantime to VAS≥ 4 between group P and, group C. (p value=0.046314) (table 2).

No of patients scored VAS≥4 at 6 hr was 31 and 35 at 6 hr, 37 and 33 in 12 hr, 14 and 19 at 24 hrs and 4 and 6 at 48 hrs in group P and group C respectively (figure2).

The cumulative dose of injection diclofenac (mg) was 280±26.34 and 350±35.32 in group P and group C, respectively. There was a significant difference in the cumulative dose of injection diclofenac between group P and group C (p value=0.01361) (table 2).

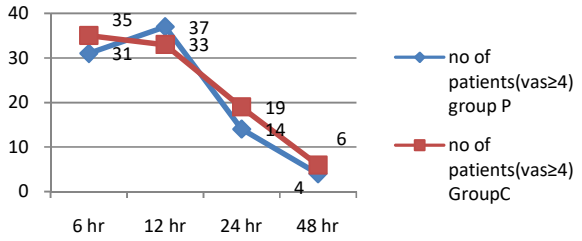

Figure 2: No of patients (VAS>4)

The mean sedation score at 6, 12, 24 and 48 hr were 1.9, 2.075, 2.425 and 2 respectively in group P, while the mean sedation score in group C at 6, 12, 24 and 48 hr were 1.8, 1.975, 2.15 and 2 respectively. There was no significant difference between the groups at 6, 12, 24 and 48 hrs (p > 0.05) (table 3 and figure 3).

There was a statistically significant difference in complications such as nausea, vomiting, and dizziness within 24 hrs in both groups. 5 numbers of patients experienced postoperative side effects within 24 hrs in group p whereas no patients experienced side effects in group C (p value < 0.001) (table 3).

Table 3: Mean VAS, sedation and PONV at 6, 12, 24 and 48 hrs

Parameters	6 hr		p-value	12 hr		p-value	24 hr		p-value	48 hr		p-value
	Group P Mean ±SD	Group C Mean ±SD		Group P Mean ±SD	Group C Mean ±SD		Group P Mean ±SD	Group C Mean ±SD		Group P Mean ±SD	Group C Mean ±SD	
VAS	4.55 ±1.08	4.87 ±1.24	>.01	4.55 ±1.08	4.4 ±1.1	>.01	3.37 ±0.7	3.52 ±1.2	>.01	2.65 ±0.73	2.45 ±0.93	>.01
Sedation	1.9 ±0.44	1.8 ±0.40	<.01	2.07 ±0.65	1.97 ±0.65	>.01	2.42 ±0.59	2.15 ±0.53	>.01	2±0	2±0	>.01
PONV (No of patients)	5	0	<.01	0	0	>.01	0	0	>.01	0	0	>.01

Discussion

Results of our study showed that preoperative oral pregabalin 75 mg as preemptive analgesia, 1hr before surgery significantly reduces the cumulative dose of

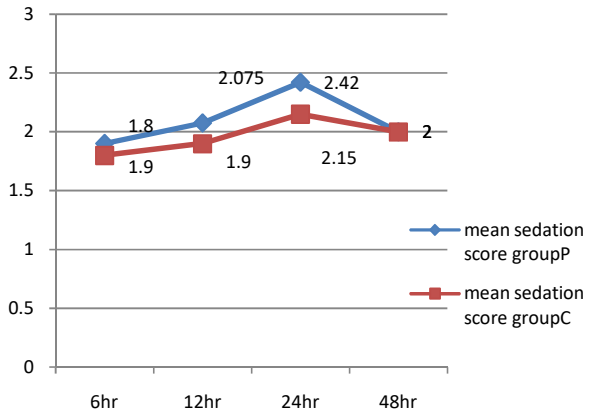

Figure 3: Mean sedation score at 6, 12, 24 and 48 hrs.

diclofenac consumption in the first 48 hrs postoperative period after major gynaecological surgeries under spinal anaesthesia. Pregabalin groups have significantly lower VAS in the first 48 hrs in comparison to the control group. No of patients having VAS ≥4 at 6, 24 and 48 hrs was less in group P than that of the group. However, no of patients having

VAS ≥4 was more at 12 hr in group P than group C. Ramsay sedation score was slightly higher in group P in comparison to group C throughout the interval. 5 numbers of patients experienced postoperative complications such as nausea, vomiting, and dizziness within 24 hrs in the pregabalin group.

Multimodal postoperative analgesia is primarily based on the use of opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol, low-dose ketamine, anticonvulsants, and perioperative local anaesthetic blocks. Multimodal analgesia aims to increase not only the quality of analgesia but also to reduce opioid and other drug-related side effects [10].

Recent studies demonstrated that postoperative is a mixed type of pain having both nociceptive and neuropathic components. Gabapentinoids over a long time has been used for different chronic neuropathic pain conditions. Recently it has been tried preoperatively as preemptive analgesia as a part of multimodal analgesia in acute postoperative pain to counter the neuropathic components [16-18].

Despite the fact that both gabapentinoids are structural analogues of aminobutyric acid, neither of them had any effect on aminobutyric acid receptors. They instead attach to the 2 subunit of presynaptic P/Q-type voltage-gated calcium channels, regulating their traffic and function. The following release of excitatory neurotransmitters from activated nociceptors is hypothesised to be modulated as a result. Pregabalin has been demonstrated to be more effective than gabapentin in treating chronic neuropathic pain. Pregabalin's pharmacokinetics are linear and stable [18].

In a meta-analysis of 16 RCTs (gabapentin group n=8 and pregabalin group n=8), gabapentinoids were associated with reduced pain scores at 6, 12, 24, and 48 hours following spine surgeries. Similarly, gabapentinoids were linked to lower cumulative morphine consumption after 24 and 48 hours. Furthermore, gabapentinoids have been shown to significantly reduce nausea, vomiting, and pruritus. There were no significant differences in the occurrence of sedation, dizziness, headache, visual disturbances, somnolence, or urine retention [17]. In another meta-analysis comprising six clinical trials with 769 patients indicated that pregabalin can decrease the VAS with rest and mobilization. The results indicated that perioperative pregabalin can decrease the cumulative morphine consumption at 24 hr. Moreover; pregabalin can decrease the occurrence of nausea and vomiting but increase the occurrence of dizziness and sedation [19].

Sebastian et al observed that time for rescuing analgesia (VAS score >3) was considerably enhanced in pregabalin groups in a trial utilizing pregabalin 150mg in lower limb orthopaedic surgery. In the 24 hours postoperative period, the total dose of diclofenac required was considerably lower in the pregabalin groups. Pregabalin groups also had higher sedation and patient satisfaction levels [19].

Kohli et al used pregabalin 150 and 300 mg as preemptive analgesia in hysterectomy cases under spinal anaesthesia and found that it caused significantly more sedation than placebo. In the pregabalin groups, first-response analgesia was considerably higher [20]. Saraswat et compared pregabalin 300 mg and gabapentin 1200mg for infra-umbilical surgeries under spinal anaesthesia and found significant prolongation of analgesia, however, duration was more in the pregabalin group. Dizziness and somnolence were the two complications noticed which was in line with our study [15].

Jokela et al used pregabalin 150 as preemptive analgesia and found the prolongation of analgesia but did not reduce the amount of postoperative analgesia after day-case gynaecological laparoscopic surgery [21]. Mathiesen et al demonstrated that a single preoperative dose of pregabalin (300 mg) resulted in an almost 50% reduction in 24-hour postoperative morphine requirements in patients who underwent hip surgery [22]. Mathiesen et al in their study used pregabalin 300 mg and dexamethasone 8 mg in combination with 1000 mg paracetamol 1 hour before anaesthesia for analgesia in patients undergoing abdominal hysterectomy. They reported morphine consumption and pain score was not decreased compared with only paracetamol. The conflict results may be due to differences in the surgical procedure applied in the study [23].

Our study has a few limitations. Single low dose pregabalin has been used whereas maximum pain relief occurs only after 1 week of using gabapentinoids. Sample size of our study was smaller. We have not followed the patients after discharge; therefore the occurrence of post-surgical pain syndrome can't be established.

Conclusions

Preoperative administration of 75 mg of pregabalin 1 hr before spinal anaesthesia resulted in a significant reduction of diclofenac consumption following major gynaecological surgeries.

Conflict of interest: None. **Disclaimer:** Nil.

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