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TO DETERMINE THE DIFFERENCE IN HAEMODYNAMIC PARAMETER OF ORAL 75MG, 150MG PREGABALIN PREMEDICATION AND CONTROL GROUP AMONG PATIENTS UNDERGOING ABDOMINAL HYSTERECTOMY.

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Abstract:
Background: In preemptive analgesia, the analgesic treatment is started before and is operational during the surgical procedure so that the physiological consequences of nociceptive transmission are reduced. Because of this protective effect on nociceptive pathways, preemptive analgesia decreases the incidence of hyperalgesia and allodynia after surgery.
Methods: This Hospital based, prospective, randomized, double blind, comparative study was conducted in Department of Anaesthesiology, Sawai Man Singh Medical College after obtaining approval from Institutional Ethics Committee and Research Review Board and written informed consent from all the patients.
Results: The mean baseline variable i.e. pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were comparable in both the groups. (P value>0.05). Thus we can say that the randomization was done adequately. Hemodynamic variables (pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure) were also comparable during intraoperative period.
Conclusion: Although preemptive use of both pregabalin 75mg and pregabalin 150 mg are effective for prolongation of postoperative analgesia but pregabalin 75mg is superior to pregabalin 150mg as it provides similar postoperative analgesia as compared to 150mg without causing significant change in haemodynamic variables and any adverse effect.
Keywords: Preemptive analgesia, Gabapentin, Rescue analgesic.

Introduction

At present, there are several drugs available that are being used as preemptive analgesics like local anesthetics, opioids, gabapentin, pregabalin, flupirtine, clonidine, NMDA receptor antagonists and their combination (multimodal), in addition to non-steroid anti-inflammatory drugs (NSAIDs) can be used to minimise postoperative pain.[1]

Pregabalin, is a structural analogue of the inhibitory neurotransmitter Gamma-Amino Butyric acid (GABA), but is functionally not related to it. It was introduced in the treatment of epilepsy in 2004, useful in treating neuropathic pain as in diabetic neuropathy, post herpetic neuralgia and reflex sympathetic dystrophy.

Pregabalin is an anticonvulsant drug that has an amino acid substitution at third position, which allows increased lipid solubility and diffusion across blood brain barrier, better pharmacokinetic profile and fewer drug interactions due to the absence of hepatic metabolism.[2]

Pregabalin also reduces movement-evoked pain and this can lead to enhanced functional postoperative recovery.[3]

In view of the above observations, the present study was designed as prospective, randomized, double-blind to compare the efficacy of different doses of pregabalin as preemptive analgesics in abdominal hysterectomy under spinal anaesthesia.

MATERIAL AND METHODS

STUDY DESIGN: Hospital based double blind, randomized control study.

STUDY PERIOD: After approval of the Research Review Board from April 2016 till the desired sample size was completed.

SAMPLE SIZE: The sample size required is 45 in each group at 95% confidence and 80% power to verify the minimum expected difference of 0.50 (±0.76) in VAS at 30 min in all the 3 groups. This sample size is adequate to cover all the other study variables too.

SAMPLING TECHNIQUE: 135 eligible candidates were randomly allocated into 3 study groups using sealed envelope method.

STUDY UNIVERSE: Cases undergoing lower limb surgeries under spinal anaesthesia.

STUDY GROUPS: This study was conducted in the following three groups of patients. Each group consisted of 45 patients.

GROUP A (n=45): Patient received placcebo orally 1 hour prior to the administration of spinal anaesthesia using 20 mg of 0.5% bupivacaine heavy.

GROUP B (n=45): Patients received 75mg pregabalin orally 1 hour prior to the administration of spinal anaesthesia using 20 mg of 0.5 % bupivacaine heavy.

GROUP C (n=45): Patients received 150mg pregabalin orally 1 hour prior to the administration of spinal anaesthesia using 20 mg of 0.5 % bupivacaine heavy.

ELIGIBILITY CRITERIA

INCLUSION CRITERIA:-

✓ ASA grade I and II.

✓ Females between the age 45-65 years.

✓ Body mass index of 18-35kg per mtr sq.

✓ Scheduled to undergo elective abdominal hysterectomy.

EXCLUSION CRITERIA:-

- Refusal to participate in the study.
- Use of anti anxiety drugs.
- History of drug or alcohol abuse.
- History of epilepsy.
- Uncooperative patients.
- The patients with general contraindication for spinal anaesthesia like sepsis, bacteremia, skin infection at the site.
- Severe hypovolemia, increased intracranial pressure, coagulopathy.
- History of convulsion. allergy to the drug used. bleeding disorder, severe neurological deficit.
- Patients not willing to participate in the study.
- Patient with history of hypertension, respiratory, cardiac, hepatic or renal disease (necessitating classification in ASA Class Ill or above)
- History of chronic pain and headache, dizziness or significant post-operative nausea or vomiting after any previous surgery.

STATISTICAL ANALYSIS

Statistical analysis was performed with the SPSS, version 21 for Windows statistical software package (SPSS inc., Chicago, IL, USA). The Categorical data was presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data was presented as mean and standard deviation and were compared bystudents t-test. Probability was considered to be significant if less than 0.05.

RESULTS

Table 1: Systolic Blood Pressure

	Group A		Group B		Group C		Significance (P value)		
	Mean	SD	Mean	SD	Mean	SD	A & B	B & C	A & C
PRE-OP VITALS	125.04	8.85	124.82	10.83	122.82	9.15	0.915	0.346	0.244
0 min	124.77	8.22	122.86	10.01	122.42	8.60	0.325	0.821	0.187
30 min.	125.75	7.77	122.17	10.46	121.29	7.45	0.069	0.643	0.006
60 min.	125.04	7.31	122.00	9.63	121.40	7.32	0.094	0.740	0.0203
2 hrs.	125.42	8.31	121.78	9.88	120.42	8.25	0.061	0.481	0.005
6 hrs.	125.04	6.74	121.98	8.14	121.27	7.20	0.054	0.661	0.011
12 hrs.	124.8	6.07	122.20	9.83	121.56	7.64	0.134	0.729	0.028
24 hrs.	126.11	7.08	122.16	9.26	121.00	6.39	0.025	0.492	0.0005

Table 2: Diastolic Blood Pressure

	Group A		Group B		Group C		Significance (P value)		
	Mean	SD	Mean	SD	Mean	SD	A & B	B & C	A & C
PRE-OP VITALS	73.57	8.64	77.11	9.31	74.02	8.92	0.065	0.111	0.810
0 min	72.71	8.05	75.04	11.39	75.31	7.68	0.265	0.896	0.120
30 min.	73.2	9.61	74.02	9.09	76.16	8.81	0.677	0.261	0.132
60 min.	75.73	8.73	73.62	13.95	77.40	6.28	0.391	0.097	0.289
2 hrs.	73.84	7.79	76.20	8.58	76.07	6.88	0.176	0.935	0.155
6 hrs.	75.33	8.41	74.09	7.88	75.44	7.42	0.470	0.403	0.947
12 hrs.	74.02	7.39	76.71	7.74	75.44	7.08	0.095	0.420	0.353
24 hrs.	70.75	7.65	74.78	7.43	74.56	7.27	0.013	0.886	0.017

Table 3: Pulse Rate

	Group A		**Group B**		**Group C**		**Significance (P value)**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**A & B**	**B & C**	**A & C**
PRE-OP VITALS	81.8	9.25	85.75	9.37	81.58	11.22	0.047	0.058	0.918
0 min	80.91	8.54	85.46	8.52	82.36	10.02	0.013	0.116	0.463
30 min.	81.35	7.94	83.31	8.20	81.16	10.01	0.253	0.266	0.916
60 min.	82.06	8.45	83.28	8.76	81.18	9.28	0.502	0.270	0.636
2 hrs.	81.84	8.11	85.22	8.90	81.24	9.85	0.063	0.047	0.753
6 hrs.	82.84	8.18	83.82	8.24	83.24	8.79	0.573	0.748	0.823
12 hrs.	82.24	7.79	84.02	8.94	81.96	9.38	0.317	0.287	0.874
24 hrs.	81.93	8.07	84.16	6.85	81.33	9.87	0.162	0.118	0.753

Table 4: Respiratory Rate

	Group A		**Group B**		**Group C**		**Significance (P value)**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**A & B**	**B & C**	**A & C**
PRE-OP VITALS	17.02	1.52	15.97	1.82	15.62	2.00	0.004	0.381	0.0003
0 min	17.06	1.49	15.26	1.49	15.69	2.03	0.0003	0.264	0.0004
30 min.	17.02	1.51	15.64	1.58	15.40	1.94	0.0003	0.513	0.0004
60 min.	16.88	1.26	15.71	1.74	15.47	2.00	0.0004	0.537	0.0001
2 hrs.	17.17	1.48	15.73	1.63	15.53	2.02	0.0004	0.606	0.0003
6 hrs.	16.84	1.46	15.56	1.74	15.33	1.78	0.0002	0.551	0.0003
12 hrs.	17.02	1.55	15.60	1.79	15.73	2.11	0.0001	0.747	0.001
24 hrs.	17.15	1.42	15.69	1.66	15.38	1.91	0.0003	0.412	0.0003

Table 5: SPO_2

	Group A		**Group B**		**Group C**		**Significance (P value)**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**A & B**	**B & C**	**A & C**
PRE-OP VITALS	97.35	1.15	97.95	1.34	98.29	0.99	0.025	0.184	0.0003
0 min	97.31	1.12	97.86	1.45	98.18	0.96	0.045	0.234	0.0001
30 min.	97.26	1.11	97.73	1.37	98.09	1.12	0.080	0.182	0.0007
60 min.	97.53	1.03	97.86	1.21	98.16	0.90	0.165	0.204	0.0031
2 hrs.	97.08	1.08	97.42	2.52	97.98	1.10	0.416	0.178	0.0002
6 hrs.	97.17	1.05	97.60	2.17	97.80	0.99	0.242	0.574	0.004
12 hrs.	97.11	0.98	97.51	2.22	97.91	0.87	0.272	0.264	0.0003
24 hrs.	97.13	1.05	97.51	2.30	98.04	0.88	0.319	0.150	0.0003

DISCUSSION

Management of pain in the postoperative period is a major concern. It has to be managed judiciously and adequately. Postoperative pain may delay recovery, increase hospital stay and patient's expenditure. Good analgesic techniques minimizes patient discomfort, facilitates early mobilization and discharge from hospital. It also prevents acute pain developing into chronic pain. Various drugs like opioids, NSAIDs, ketamine, gabapentinoids have been used in multimodal approaches to achieve adequate postoperative analgesia.[4]

Preemptive analgesia is a treatment that is initiated before surgery and thus it prevents establishment of the altered sensory processing resulting from surgical stimuli that amplifies postoperative pain. Various drugs either single or in combinations have been used as preemptive analgesics.[5]

The mean baseline variable i.e. pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were comparable in both the groups. (P value>0.05). Thus we can say that the randomization was done adequately. Hemodynamic variables (pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure) were also comparable during intraoperative period. Trivedi PA et al [6], Rajendran I et al[7] and Kumari A et al[8] also found similar results in their study.

CONCLUSION

Although preemptive use of both pregabalin 75mg and pregabalin 150 mg are effective for prolongation of postoperative analgesia but pregabalin 75mg is superior to pregabalin 150mg as it provides similar postoperative analgesia as compared to 150mg without causing significant change in haemodynamic variables and any adverse effect.

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