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The effect of preemptive administration of IV nefopam versus paracetamol as postoperative analgesia in women undergoing vaginal wall repairs under spinal anesthesia. (A comparative study)

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Abstract
Background Objective: To compare the effect of preemptive administration of IV Nefopam versus Paracetamol as postoperative analgesia in patients undergoing vaginal wall repairs under spinal anesthesia.
Materials and Methods: 120 adult female patients, aged 15-50 years, ASA physical status I and II were scheduled for anterior and posterior vaginal wall repair (APR) and assigned in a randomized manner into three groups after spinal anesthesia. In control group, 50 ml of normal saline had been infused intravenously over 15 minutes. In group (P), an intravenous infusion of 1 g paracetamol had been given over 15 minutes. In group (N), an intravenous infusion of 20 mg nefopam in 50 ml normal saline had been given over 15 minutes. Visual analogue scale (VAS) was take at constant times postoperatively and the total requested postoperative dose of tramadol had been calculate.
Results: Both paracetamol and nefopam groups are associated with a significant longer time to first request of postoperative analgesic treatment (group N > P > C) ($P < 0.05$) with a significant reduction in the total required postoperative analgesics. VAS revealed a significantly lower score in Group N and P, compared to group C.
Conclusion: Preemptive IV paracetamol and nefopam is a good plan to provide an effective postoperative analgesia following spinal anesthesia in patients undergoing vaginal APR.

Keywords: Vaginal wall repair, Paracetamol, Nefopam, preemptive analgesia

Introduction
Pelvic Organ (POP) prolapse mean the herniation of one or more viscera from their normal position, resulting in vaginal protrusion. It is a common gynecological problem, which is of interest in millions of women around the world [1].
Effective postoperative pain control is an essential component of the care of the surgical patient. Inadequate pain control, apart from being inhumane, may result in increased morbidity or mortality [2]. Evidence suggests that surgery suppresses the immune system and that this suppression is proportionate to the invasiveness of the surgery [3]. Good analgesia can reduce this deleterious effect. Data available indicate that afferent neural blockade with local anesthetics is the most effective analgesic technique. Next in order of effectiveness are high-dose opioids, epidural opioids and clonidine, patient controlled opioid therapy, and nonsteroidal anti-inflammatory agents [4].
Postoperative pain (POP) is a major psychological burden and responsible for the triggering a series of physiological changes that increases the rate of morbidity and mortality. Early and adequate treatment of POP enhances early mobilization and reduces the rate of complications and hence cost of hospitalization [5]. Preemptive analgesia immediately before the surgical procedure is an effective measure in the prevention of POP [6]. Paracetamol is an analgesic agent used for mild to moderate pain. It has minimal side effects and it does not interfere with blood clotting. Intraoperative administration of paracetamol before the end of surgery is an effective measure in the management of POP [7]. Nefopam is a centrally-acting non-opioid analgesic. It does not affect COX but it the interrupt of the reuptake of serotonin, dopamine, and norepinephrine. Plasma peak concentrations are reached after 30 min of continuous intravenous infusion and its effect last for 6 hours.

The potency of a 15-30 mg dose is equivalent to 50–100 mg of pethidine administration and considered as a safer, well tolerable agent with fewer side effects [8, 9].

Aim of the study: To compare the effect of preemptive administration of intravenous infusion of Nefopam versus Paracetamol as postoperative analgesia in patients undergoing vaginal wall repairs under spinal anesthesia.

Materials and methods

A comparative study were done in the period from 1st of Jan 2018 to the end of Dec 2018 when 120 adult patients, aged 15-50 years, ASA physical status I and II were scheduled for APR and involved in this study.

Exclusion criteria from this study include: Patients with ASA physical status > II, patients receiving analgesics, allergy to local anesthetics, refusal of the patient, Patients who receive enzyme inducers (carbamazepine, phenytoin, barbiturates, rifampicin) or have a history of alcohol abuse, history of liver or renal diseases, history of bleeding tendency, neuropathies, diabetes mellitus, hypertension, pregnant and lactating women, infection at the site of infection and immune compromised patients.

Method

10 ml of IV normal saline were given to the patients, then by using spinal needles gauge 25 to do spinal anesthesia to them at L3-L4 interspace and administration of 2.5 ml bupivacaine 0.5%. Immediately before starting the surgical procedure (APR), patients were divided randomly into three equal groups. In control group (C), 50 ml of normal saline had been infused intravenously over 15 minutes. In group (P), an intravenous infusion of 1 g paracetamol had been given over 15 minutes. In group (N), an intravenous infusion of 20 mg nefopam in 50 ml normal saline had been given over 15 minutes. POP was assessed by using the visual analogue score (VAS) [10] which is measured every 3 hours during the first 24 hours postoperatively. I.V. administration of 50 mg tramadol was given as a rescue analgesic agent. Time of first rescue analgesic and the total analgesic dose/24 hours were recorded.

Statistical analysis

Statistic were analyzed by IBM-SPSS program, version 25.The qualitative data had been analyzed by using of Chi – square test. The quantitative data were analyzed by using student's paired t-test was used.

Results

Table 1 show that there is no significant difference regarding the age and BMI of the patients between the studied groups. Regarding the duration of surgery, there was a significant difference in group C which is clinically of no applicable importance (81.1±15.4 in control group in comparison with 111.3±30.5 in nefopam group and 99.25±30.60 in paracetamol group).

Table 1: Age, body weight and duration of surgery

Variables	Group (C)	Group (N)	Group (P)	P- value
Age (year)	34.20±8.9	31.0±9.2	32.90±9.77	0.1
BMI	25.2±6.6	26.4±5.8	26.44 ±6.76	0.3
Duration of surgery (minutes)	81.1±20.58	111.3±30.5	99.25±30.60	<0.001

Onset of pain were started earlier in control group than other, mean of VAS was higher in group C > P and N groups. VAS revealed a significantly lower score in Group N and P, compared to group C. there is a highly significant differences between all the studied groups regarding VAS at 6th postoperative hour in control group, while it occurs at 9th postoperative hour in Paracetamol, while there was no significant difference thereafter. Nefopam group has a lower VAS score than Paracetamol group (which is only significant at 9th postoperative hour) (table 2).

Table 2: Comparison of visual analogue score (VAS) between all groups.

	Time (hours)							
Group	**3**	**6**	**9**	**12**	**15**	**18**	**21**	**24**
C (mean ± SD)	1.5± 1	4.5±1.4	3.8±1.5	2.6±0.6	2.4±0.6	2..1±0.3	2.3± 0.6	1.8± 0.8
P(mean ± SD)	1.3±0.8	2.4±1.8	3.1± 1	2.2±0.5	2.1±0.5	1.8± 0.5	2.1± 0.4	1.7± 0.4
N(mean ± SD)	1.2±0.9	2.1±1.1	2.5±0.6	2.8±0.8	2.7±0.6	2.4± 0.2	2.0±0.2	1.6±0.3
P value	NS	<0.001	<0.001	NS	NS	NS	NS	NS

Regarding to the total dose of analgesia, it was found that there is a highly significant increase in group C than that found in both other groups (N and P) (table 3)

Table 3: Total dose of analgesia (tramadol) in milligram / 24 hours postoperatively in studied group

Total dose of analgesic	Group C	Group P	Group N	P value
	86.55± 15.25	37.45± 12.88	30.22± 10.0	< 0.001

Discussion

Analgesia postoperatively in adequate dose to prevent pain is very important for patients care and considered as human right [11]. In our study, we focused on the comparison between IV infusion of paracetamol and nefopam and their outcome on pain control post operatively for APR.

We found that there is a highly significant association between both studied groups regarding VAS at 6 and 9 hours postoperatively, with prolonged duration of postoperative analgesia and a reduced total dose of the analgesic drug in the paracetamol and nefopam groups than in the control group. Paracetamol is widely used to combat moderate postoperative pain [12]. It has an antiprostaglandin (PG) effect with some inhibitory effects of cyclooxygenase [13]. Nefopam exerts its analgesic action through the central mechanism of the opioid action [14]. This study is consistent with the study by S. Zhang and colleagues [15], who found that Nefopam can provide a better and safer analgesic effect than tramadol and may reduce the overall postoperative intake of tramadol. V. Martinez and colleagues concluded that nefopam outperforms most analgesics used alone in terms of reducing morphine intake with control analgesia [16], which works in parallel with this study. Regarding the effect of preventive administration of i.v. Paracetamol, AV Kh. Barazanchi and his colleagues found that preoperative use of paracetamol was recommended for postoperative

analgesia [17].

Conclusion

Preemptive IV Paracetamol and Nefopam is a good plan to provide an effective postoperative analgesia following spinal anesthesia in patients undergoing vaginal APR.

The authors declare that there are no conflicts of interest.

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