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A prospective controlled comparative clinical study of the postoperative analgesia after intraperitoneal instillation and wound infiltration of ropivacaine during total abdominal hysterectomy under general anesthesia

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Abstract
Introduction: Postoperative pain is one of the challenging issues faced by healthcare professionals. Inadequate analgesia or adverse effects associated with analgesics lead to increased perioperative morbidity and delay ambulation.
Objective: to compare duration of analgesia, pain score at analgesic request and hemodynamic changes after intraperitoneal instillation and wound infiltration of ropivacaine:
Study design: Prospective randomized control study.
Method: Sixty female patients of ASA physical status I and II in the age group of 35 – 65 years were enrolled in the study and divided into 2 groups of 30 each. In both the groups 20 ml of 0.2% ropivacaine was given as wound infiltration before closure of the skin. In one group, 20 ml of 0.9% normal saline was given intraperitoneally and in other 20ml of 0.2% ropivacaine was given.
Results: Age, weight and height distribution in both the groups were similar. Difference in Heart rate and Mean arterial blood pressure in both the groups were not statistically significant. Postoperative VAS score was lesser in the group given intraoeritoneal ropivacaine at 60- 120 minutes. The mean duration of analgesia (168 ± 3.68) was also prolonged in the same group vs 140 ± 5.69. The VAS score at analgesic request was also lower in the intraperitoneal ropivacaine group.
Conclusion: Intraperitoneal and wound infiltration of ropivacaine is an effective and cheap method to provide postoperative analgesia without the adverse effects associated with intravenous opioids.

Keywords: Abdominal hysterectomy, intraperitoneal instillation, wound infiltration, ropivacaine, postoperative analgesia, VAS (Visual Analogue Scale)

Introduction

Post- operative pain is usually treated with intravenous opioids which lead to adverse effects like nausea and constipation.

A simple method of analgesia which is rapidly effective with minimum complex equipment would be useful for post-operative patients. Wound infiltration of local anesthetic is a time tested method without adverse effects

It could be supplemented by intraperitoneal instillation of local anesthetic.

Ropivacaine, an amide local anesthetic,which is similar to bupivacaine in potency but less cardiotoxic can be used intraperitoneally.

Studies have been done comparing the duration of post-operative analgesia using local anesthetic solely for wound infiltration and wound infiltration with intraperitoneal instillation.

Methods

Place of study: After obtaining ethical committee clearance study was conducted at KVG Medical College & Hospital from August 2019 to December 2019

Study subjects: Patients undergoing elective total abdominal hysterectomy were assessed for the inclusion and exclusion criteria and were included in the study after obtaining written informed consent.

Study design: Prospective randomized control study.

Sample size: 60 (30 each)

Sample size was calculated using the formula $n=2*\{Z(1-\alpha) + Z(1-\beta) /\delta-\delta 0\}2 *s2$ where n is the sample size, s is pool's standard deviation, δ is mean of group 1,δ0 is mean of group 2,Z(1-α) at confidence interval 95% is 1.96 and Z(1-β) at 20% is 0.8.Sample size calculated was 26 in each group,30 was taken in each group in this study to account for drop outs

Power of study was kept at 80%, levels significance 5% at two tailed test.

Sampling method: Simple random sampling

Statistical tests: SPSS version 16 program were used to enter data and statistical analysis .Continuous data were presented as Mean ± SD and comparison between two groups were performed using Student's t-test. A p value <0.05 was considered statistically significant.

Inclusion criteria

- Patients posted for elective total abdominal hysterectomy

- Patients in the age group of 35 to 65 years
- American Society of Anesthesiologists physical status I and II

Exclusion criteria

- Refusal by the patient to participate in the study
- BMI > 35kg/m2 or < 18kg/m2
- Respiratory, hepatic or renal insufficiency
- Chronic analgesic use
- Patients with cognitive impairment or psychiatric diseases.

Pre anaesthetic examination & preparation

- Pre-anaesthetic check-up was done one day prior to the surgery or as required. Patients were evaluated for co-existing systemic diseases and relevant laboratory investigations were reviewed/ requested. The procedure of general anaesthesia was explained in their understandable language and written informed consent was obtained.
- After obtaining institutional ethical committee clearance, selected patients were randomly allocated into the two groups by computer generated numbers. They were pre-medicated with tab alprazolam 0.5 mg orally the night before surgery. In the pre-operative room, an intravenous line with appropriate gauge IV cannula was secured.
- Preparation of Operation room (OR)
- Anaesthesia machine was checked and prepared. Appropriate size endotracheal tubes, working laryngoscope and blades, stylet and working suction apparatus and emergency drug tray was kept ready before the procedure.
- Procedure
- In the operation room, IV infusion of Ringer's lactate was started at 10- 15mL/kg/hr. Patients were monitored with standard anaesthetic monitoring techniques using non-invasive blood pressure, peripheral oxygen saturation, electrocardiography and end tidal carbon dioxide evaluations. The baseline systolic blood pressure, diastolic blood pressure, heart rate and oxygen saturation were noted.
- Patients were preoxygenated with 100% oxygen for 3 min and induced with Inj .Fentanyl (2µ/kg), Inj. Propofol (2mg/kg) IV. The muscle relaxant was given over 15-30 sec and endotracheal intubation was done using proper size tube ETT (7-7.5 mm). Anaesthesia was maintained with 70% of N2O, 30% ofO2 and isoflourane. The EtCO2 was maintained between 35-45 mm Hg and MAC was kept at 1 with pressure controlled ventilation. Body temperature was maintained between 35 and 37℃ by means of warmed IV fluids and warming blankets (surface body temperature measured via skin probe).
- The study drug was prepared with sterile precautions by an anesthesiologist who is not involved in clinical care or evaluation of trial outcomes.
- Surgery was performed through a Pfannenstiel incision. Blood accumulating into the pelvis was carefully wiped with surgical towels to leave a relatively dry pelvis. When the surgeon was satisfied with hemostasis, the study drug was transferred into a sterile receptacle and drawn up into a sterile 20-mL syringe.
- The operating surgeon then carefully instilled 20 mL of the study drug into each Quadrant of the uterine peritoneum before closure of the parietal peritoneum or fascia. The parietal peritoneum layer was sutured or left open according to operator preference.
- 20 ml of the drug was given as wound infiltration before closure of the skin in group R. In group C, 20 ml of 0.9% normal saline was given intraperitoneally and 20ml of drug was given as wound infiltration before closure of the skin.

Table 1

Study Groups		
		Total volume
Group R	Ropivacaine 0.2% 20 mL wound infiltration 20 mL intraperitoneal instillation	40mL
Group C	Ropivacaine 0.2% 20 mL wound infiltration 20 mL 0.9% normal saline intraperitoneal instillation	40mL

At the end of surgery patients were reversed with inj neostigmine 0.05mg/kg (max 4mg) and inj glycopyrrolate 0.01mg/kg IV. Extubation was done after through oral suctioning.

Assessment of analgesia: Postoperatively quality of analgesia was evaluated with Visual analogue scale (VAS) at every 30 minutes for 1st 2 hours, hourly for next 6 hours and then after 24 hours of surgery.

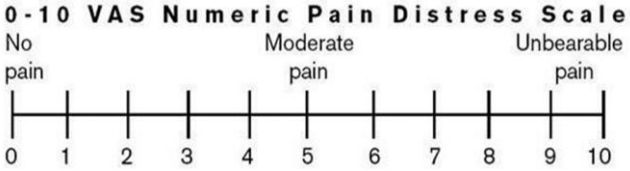

Fig 1

- **Duration of analgesia:** was defined as the time taken from the completion of the injection of the study drug till the patient asked for rescue analgesia.
- **Rescue analgesia:** inj. paracetamol 1g IV infusion was given on patient's demand and 6th hourly thereafter. VAS score when patient demands for analgesia was assessed.
- Hemodynamic parameters like heart rate and blood pressure were recorded at every 30 minutes for 1st 2 hours, hourly for next 6 hours and then after 24 hours of surgery.
- **Follow up:** 24 hours

Results

Table 2: Demographics

	Group R	Group C	P Value
Age	47.2 ±3.32	48.6 ±2.84	0.08
Weight	52.8 ±1.23	53.1 ±3.23	0.6
Height	154.8±2.2	155.4±1.2	0.2

Demographically there is no significant difference were found with respect to age, weight and height

Table 3: Heart Rate

Time	Group R	Group C
Baseline	78 ± 5.2	84 ± 7.6
30 minutes	82 ± 5.4	88 ± 8.3
60minutes	78 ± 2.3	84 ± 7.14
90minutes	76 ± 3.2	82 ± 8.02
120minutes	74 ± 5.11	80 ± 1.23
3 Hours	73 ± 6.12	79 ± 4.24
4 Hours	70 ± 7.84	78 ± 5.27
5 Hours	68 ± 4.15	76 ± 4.22
6 Hours	67 ± 6.1	75 ± 3.18
24 Hours	70 ± 7.1	74 ± 7.8

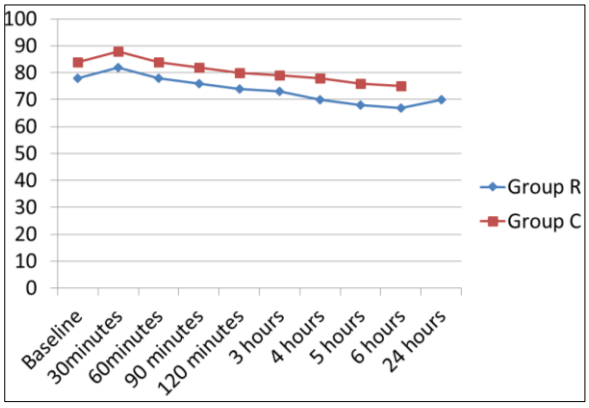

Fig 2

Table 4: Mean Arterial Pressure

Time	Group R	Group C	P Value
Baseline	96 ± 6.79	95 ± 7.79	0.5981
30 Minutes	93 ± 6.71	95 ± 4.05	0.1712
60 Minutes	90 ± 5.66	92 ± 6.81	0.2206
90 Minutes	88 ± 4.68	90 ± 5.78	0.1462
120 Minutes	87 ± 7.54	89 ± 6.12	0.2640
3 Hours	85 ± 4.12	87 ± 6.57	0.1631
4 Hours	80 ± 7.53	82 ± 6.68	0.2810
5 Hours	78 ± 5.33	80 ± 5.99	0.1771
6 Hours	76 ± 6.80	78 ± 4.89	0.1961
24 Hours	73 ± 5.66	75 ± 6.8	0.2206

Hemodynamically,there was no significant difference in heart rate and mean arterial pressure over time in both groups, though both parameters were comparatively lower in ropivacaine group.

Table 5: Visual Analogue Scale

Time	Group R	Group C	P Value
Baseline	1.2 ± 0.7	1.1 ± 0.73	0.5902
30 Minutes	1.53 ± 0.6	1.65 ± 0.5	0.4035
60 Minutes	3.6± 0.8	5 ± 0.8	<0.0001
90 Minutes	2.8 ± 0.3	6.1 ± 1.3	<0.0001
120 Minutes	2.6 ± 0.4	6 ± 0.1	<0.0001
3 Hours	4.8 ± 1.2	5 ± 0.9	0.4681
4Hours	4.6 ± 0.1	4.7 ± 0.6	0.3716
5Hours	3 ± 0.7	3.2 ± 1.8	0.5728
6Hours	2 ± 0.1	2.1 ± 1	0.5878
24Hours	1 ± 0.5	1.2 ± 0.9	0.2917

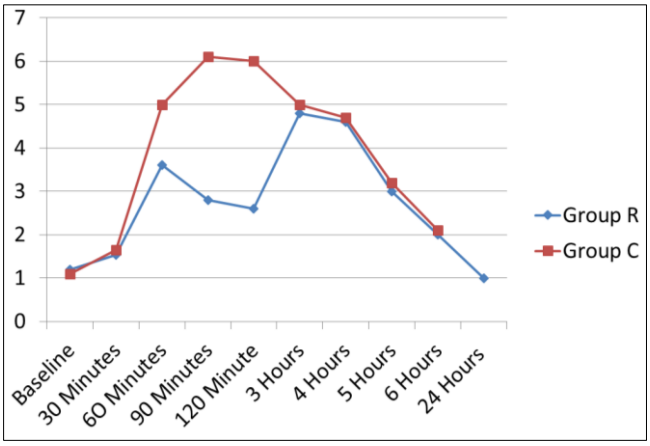

Fig 3

Postoperatively VAS score was significantly lower in group R in the initial time between 60-120 minutes. (P value <0.05)

Table 6: Duration of Analgesia

Group R	Group C	p Value
168±3.68	140±5.69	<0.0001

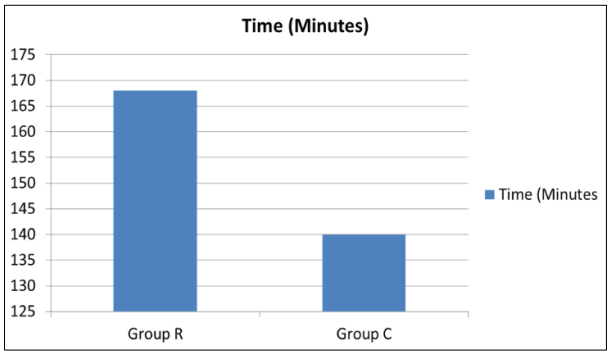

Fig 4

Duration of analgesia was statistically more in Group R compared to Group C.

Table 7: Visual Analougue Scale Score at Analgesic Request

Group R	Group C	p Value
3.4 ± 0.8	4 ± 0.1	0.0001

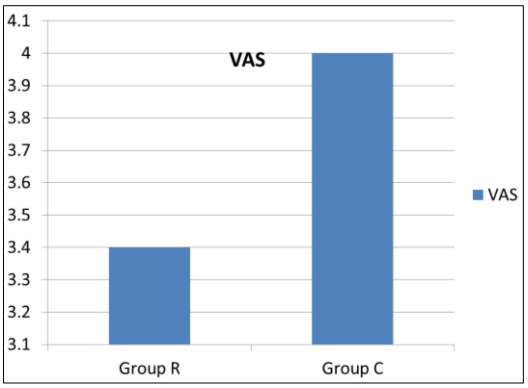

Fig 5

The VAS score at analgesic request was statistically lower in the group given intraperitoneal ropivacaine.

Discussion

Local anesthetics act via blocking voltage gated sodium channels. Local infiltration around the wound site, and even deeper in the surgical cavity, can suppress the generation and propagation of injury-induced discharge during surgical manipulations [1]. They also inhibit phases of inflammation like neutrophil priming, blocking G–protien coupled receptors, protein kinase C, prostaglandin antagonism and lysosomal enzyme release. This reduced inflammation leads to better wound healing due to increased perfusion and oxygenation. [2, 3]. This method of local anesthetic administration is easier with regard to the expertise required. Patients were mobilized earlier with early return of intestinal activity.

Gautam *et al* stated that Injection 0.2% Ropivacaine, 20 ml total volume, given intraperitoneally and as local infiltration produced better post- operative analgesia after cesarean section under spinal anesthesia. [1]. Pacharla *et al* recommended the use of 20 ml 0.2% Ropivacaine intraperitoneally compared to other local anesthetics due to its better cardiovascular safety profile in laparoscoipic surgeries. [2]. Bambigboye *et al* concluded that the use of 30 ml of 0.75% Ropivacaine as infiltration and peritoneal spraying during gynaecological surgeries reduced the postoperative need of opioids. [6]. Fassoulaki *et al* showed that 10 ml of 0.75% ropivacaine used for infiltration after major gynaecological surgery, improved post – operative VAS score. [7].

Conclusion

- Our study shows that 0.2% ropivacaine given intraperitoneally and as wound infiltration produced longer duration of analgesia with lower post-operative VAS scores, compared to ropivacaine given as infiltration alone in total abdominal hysterectomy under general anesthesia.

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