Original Article

Efficacy of Wound Infiltration with 20ml of 0.25% Bupivacaine in Patients Undergoing Hysterectomies in General Anaesthesia

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Abstract

Objectives: To determine the efficacy of local wound infiltration with 20 ml of 0.25% bupivacaine vs. control in post-operative management of pain in Hysterectomies.

Methodology: A randomized controlled trial study was conducted at the Department of Obstetrics and Gynecology, MCH Center, PIMS, Islamabad from 06-11-2017 to 05-04-2018A total of 90 female patients between age 40-60 years undergoing abdominal hysterectomies were enrolled. Forty five women (n=45) were allocated into two groups. Group A (study group) was comprised of those who received infiltration of 20 ml of 0.25% bupivacaine around the wound and surrounding tissues, while Group B patients were infiltrated with 0.9% normal saline and served as a control group. Analgesic consumption was assessed 3, 6, 12 and 24 hours postoperatively. Intravenous diclofenac 75 mg and injection toradol 30 mg was used as rescue analgesia in patients complaining of moderate to severe pain despite receiving initial intervention. Final results were recorded in the form of rescue analgesia requirements every 24 hours and mean VAS at 24 hours in both groups and were compared in both groups for statistical significance.

Results: The mean age in was 47.3 years ± 4.5 SD and 49.8 years ± 5.9 SD in study and control group respectively. In the study and control groups, the mean BMI was 33.7 kg/m2 4.6 SD and 29.2 kg/m2 2.1 SD, respectively. study group, the mean VAS was 2.8 ± 0.77 SD at 24 hours while in control group it was 3.5 ± 0.97 SD (P=0.001).. In study group, mean dose of dicolfenac in 24 hours was 56.7 mg ± 36.3 SD hours while in control group it was 105.1 mg ± 49.1 SD (P=0.001). In study group, mean dose of toradol in 24 hours was 36.7 mg ± 15.5 SD hours while in control group it was 58.1 mg ± 21.6 SD (P= 0.001), implying injection diclofenic and toradol consumption were significantly lower in Bupivicaine group as compared to control group. A similar trend was observed when data was stratified with respect to age and BMI (P<0.05 in all cases).

Conclusion: Pain control at 24 hours after abdominal hysterectomies was significantly better in women who were administered local wound infiltration with 20 ml of 0.25% bupivacaine as compared to women who were administered 0.9% normal saline.

Keywords: Abdominal Hysterectomy, Bupivicaine, Pain control

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Introduction

Pain after any major abdominal surgery is an unpleasant experience and is associated with psychological trauma, delayed mobilization and delayed recovery. Any intervention that leads to pain relief is worthy of further investigation.[1]

Local anesthetic is applied adjuvant to other methods of pain relief,[2,3] however most of the studies are done in non-gynecological patients[4]and the reports on the effectiveness of the strategy are not conclusive. Post op pain is usually managed with opioids in combination with non-narcotics analgesics.

Several studies have been reported on use of preemptive local anesthetic to relieve post-operative

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pain however the results are controversial being beneficial.[5,6]

Besides extra time required for wound infiltration one of the major hindrance in popularity of wound infiltration is the potential risk of side effects ranging from allergy to cardiovascular to CNS effects.[7,8]

The cost implications are the additional concern. If proved beneficial the actual cost of local Anesthetic and additional time for carrying out is justified in view of long term psychological effect of pain and mobility after major surgical procedures.

The current study was conducted to determine the efficacy of local wound infiltration after skin closure in terms of pain relief and need for additional post of analgesia.

Methodology

It was a randomized controlled trial conducted in theDepartment of Obstetrics and Gynecology, MCH Center, Unit-II, Pakistan Institute of Medical Sciences, Islamabad. The study duration was six months from 06-11-2017 to 05-04-2018.

The sample size calculated by using WHO sample size calculator taking level of significance = 5%, power of study 80% and population standard deviation=1.36 taking mean pain score after Local wound infiltration as 1.98+0.91 and 2.8+1.23 in placebo group. Size= 90 (45 in each group).Non-probability. Consecutive sampling technique was used. All patients undergoing hysterectomies under general anesthesia of age, 40-60 yrs. Patients receiving regional (spinal, epidural) anesthesia, undergoing laparoscopic surgeries or having history of hypersensitivity to Bupivacaine were excluded from the study. Approval of the study was taken from hospital ethical committee prior to start the study. The study included 90 women who presented at MCH unit 2. Informed consent was obtained from each patient. Patients were divided into two groups, group A (the study group) and group B (the control group) by using randomized number table. In group A patients (n=45) the wound and surrounding tissues was infiltrated with 20 ml of 0.25% bupivacaine. group B patients (n=45) the wound was infiltrated with 0.9% of normal saline.Analgesic consumption was assessed 3, 6, 12 and 24 hours postoperatively. Intravenous diclofenac 75 mg and injection toradol 30 mg was used as rescue analgesia in patients complaining of moderate to severe degree pain despite receiving initial intervention. Final results were recorded in the form of rescue analgesia requirement in 24 hours and mean VAS at 24 hours in both groups. All the gathered information was entered in the proforma. The calculated data were entered and analyzed by (SPSSv20) statistical package for social sciences. Numeric variables like age, BMI and VAS at 24 hours were measured as mean +/- SD and categorical variables like hysterectomy were presented in the form of frequencies and percentages. Mean analgesia requirement and mean pain score was compared in both group by using independent “t” Test and *P* value ≤0.05 was considered significant.

Pain was defined as highly unpleasant physical sensation caused by illness, injury or something that hurts the body. We will measure it by NUMERIC ANALOGUE SCALE. The visual analogue scale (VAS) is a psychometric response scale for assessment of pain. It is important as it provides assessment of subjective characteristics or attitudes that cannot be directly measured.

No pain	***Mild pain***			***Moderate pain***			***Severe pain***			
0	***1***	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***

Results

The mean age in study group was 47.3 years ± 4.5 SD and in control group it was 49.8 years ± 5.9 SD. Mean BMI in study group was 33.7 Kg/m^2 ± 4.6 SD and in control group it was 29.2 Kg/m^2 ± 2.1 SD. In study group, 75.6% (n=34/45) were in age group 40-50 years and 24.4% (n=11/45) women were in age group 51-60 years and in control group their percentages were 57.8% (n=26/45) and 42.2% (n=19/45) respectively. In study group, 31.1% (n=14/45) were in BMI group <30 Kg/m^2 and 68.9% (n=31/45) women were in BMI group $\geq$ 30 Kg/m^2 and in control group these percentages were 46.7% (n=21/45) and 53.3% (n=24/45) respectively (table I). MEAN VAS AT 24 hours after surgery in study group, was 2.8 ± 0.77 SD at 24 hours while in control group it was 3.5 ± 0.97 SD. *P*-value t-test was found to be 0.001, implying pain control was significantly better in Bupivicaine group as compared to control group. analgesia requirement in 24 hours after surgery in study group, mean dose of dicolfenac in 24 hours was 56.7 mg ± 36.3 SD hours while in control group it was 105.1 mg ± 49.1 SD. *P*-value t-test was found to be 0.001, implying injection diclofenac consumption was significantly lower in Bupivicaine group as compared to control group. In study group, mean dose of toradol in 24 hours was 36.7 mg ± 15.5

SD hours while in control group it was 58.1 mg ± 21.6 SD. *P*-value t-test was found to be 0.001, implying injection toradol consumption was significantly lower in Bupivicaine group as compared to control group (table II).

Table I: Different age and BMI categories in both groups

AGE GROUPS	GROUPS		TOTAL n=90
	Bupivicaine n=45	Control n=45	
40-50 YEARS	34 (75.6%)	26(57.8%)	60(66.7%)
51-60 YEARS	11(24.4%)	19(42.2%)	30(33.3%)
BMI	**GROUPS**		**TOTAL n=90**
	Bupivicaine n=45	Control n=45	
< 30 Kg/m²	14(31.1%)	21(46.7%)	35(38.9%)
≥ 30 Kg/m²	31(68.9%)	24(53.3%)	55(61.1%)

Table II: Mean analgesia requirement in 24 hours (injection diclofenac and toradol) in both groups

	Groups	mean	std. deviation	P-value t-test
Injection diclofenac (mg/24 hours)	Bupivicaine	56.7	36.3	0.001
	Control	105.1	49.1	
Injection toradol (mg/24 hours)	Bupivicaine	36.7	15.5	0.001
	Control	58.1	21.6	

Mean VAS at 24 hours was stratified with respect to different age and BMI groups (table III). Similar trend was observed and pain control was significantly better in Bupivicaine group as compared to control group across age and BMI groups (P<0.05) in all cases.

Mean diclofenac and toradol consumption in 24 hours was stratified with respect to different age and BMI groups (table IV and V). Similar trend was observed and injection diclofenac and toradol consumption was significantly lower in Bupivicaine group as compared to control group across age and BMI groups (P<0.05) in all cases.

Table III: Mean VAS at 24 hours (stratification based on age and BMI)

Age group	Group	Mean VAS 24 HOURS	Std. Deviation	*P*-value t-test
40-50 YEARS	Bupivicaine	2.9	0.82	0.001
	Control	3.5	0.98	
	Total	3.1	0.94	
51-60 YEARS	Bupivicaine	2.5	0.52	0.001
	Control	3.5	0.96	
	Total	3.1	0.96	
BMI GROUP	**Group**	**Mean VAS 24 HOURS**	**Std. Deviation**	***P*-value t-test**
<30 Kg/m²	Bupivicaine	2.3	0.73	0.001
	Control	3.4	0.97	
	Total	2.9	1.03	
≥30Kg/m²	Bupivicaine	2.9	0.71	0.001
	Control	3.5	0.98	
	Total	3.2	0.88	

Table IV: Mean analgesia (injection dicloron) requirement in 24 hours (stratification based on age BMI).

AGE GROUP	Group	DICLORON (mg) Mean	Std. Deviation	*P*-value t-test
40-50 YEARS	Bupivicaine	55.1	38.3	0.001
	Control	103.8	47.8	
	Total	76.3	48.8	
51-60 YEARS	Bupivicaine	61.4	30.3	0.001
	Control	106.6	51.9	
	Total	90.1	49.8	
BMI GROUP	**Group**	**DICLORON (mg) Mean**	**Std. Deviation**	***P*-value t-test**
<30 Kg/m²	Bupivicaine	69.6	35.6	0.001
	Control	103.6	44.2	
	Total	90.1	43.8	
≥30Kg/m²	Bupivicaine	50.8	35.6	0.001
	Control	106.3	53.8	
	Total	75.1	52.1	

Table V: Mean analgesia (injection toradol) requirement in 24 hours (stratification based on age and BMI).

AGE GROUP	Group	TORADOL (mg) MEAN	Std. Deviation	*P*-value t-test
40-50 YEARS	Bupivicaine	36.2	14.4	0.001
	Control	62.3	20.7	
	Total	47.5	21.6	
51-60 YEARS	Bupivicaine	38.2	19.4	0.001
	Control	52.1	22.1	
	Total	47.1	21.8	
BMI GROUP	**Group**	**TORADOL (mg) MEAN**	**Std. Deviation**	***P*-value t-test**
<30 Kg/m^2	Bupivicaine	32.1	14.2	0.001
	Control	61.4	25.9	
	Total	49.7	26.2	
≥30Kg/m^2	Bupivicaine	38.7	15.9	0.001
	Control	55.1	16.9	
	Total	45.8	18.1	

Discussion

It has been observed in routine clinical practice that women who undergo abdominal hysterectomies complain of postoperative pain of moderate to severe intensity. Various interventions are being used peri-operatively to control the associated pain. The present study was planned to evaluate bupivicaine in comparison with control group for pain control in women undergoing abdominal hysterectomies in our settings. The gathered data would help in devising efficient pain control strategies that eventually result in improved quality of life in these patients. Final results were recorded in the form of rescue analgesia requirements at 24 hours and mean VAS at 24 hours in both groups and were compared.

Our results are similar to many other studies. In one study, Hannibal K and colleagues assessed the late and early effects of analgesics on pre-operative wound infiltration with bupivacaine 0.25% (40 mL) versus placebo (NaCl 0.9%, 40 mL) in cases managed with major surgery. They enrolled 41 cases undergoing elective hysterectomy while giving general anesthesia. With identical pain scores in the two groups, the requested total amount of postoperative analgesia was significantly greater in placebo (2.0 [0-5.1] mg) (median and [range]) than bupivacaine group (0.8 [0-2.8] mg) (P < 0.05). We did not estimate the demand for rescue analgesia or the time to first rescue analgesic injection in this current study; however, our pain score results are comparable.[9]

Similarly, in the present study, a lower mean dose of dicolfenac analgesia (56.7 ± 36.3 mg) was required by study group patients in 24 hours while in control group, where it was significantly higher (P=0.001). Similarly, the mean dose of toradol was also lower in the study group when compared with the control group in this study (P= 0.001). This implies that analgesia consumption was significantly lower in Bupivicaine group.

Ige O and colleagues determined the success of a combined subfascial and subcutaneous infiltration of bupivacaine in achieving an opioid-sparing after the abdominal surgery. The study cases got subcutaneous and subfascial infiltration of bupivacaine (40 ml of 0.25%) whereas the control group was given saline (40 ml of 0.9%) given by the surgeon after the closure of the peritoneum. They found that the mean time to first request for analgesia was significantly prolonged (p <0.05) in study group (174 ± 117.6 min) compared to control group (102 ± 84 min). The patients in control group received more morphine, however difference was not statistically significant (p >0.05). They concluded that improved pain scores were achieved by bupivacaine wound infiltration at rest within first 6 hours and pain scores for coughing within first 24 hours after surgery.[10]

Gupta S et al evaluated outcome of local anesthetic on instillation of wound on pain control postoperatively in 100 cases who underwent abdominal hysterectomy with bilateral salpingo oophorectomy. Division of patients was based on wound and non-wound instillation groups with 0.25% bupivacaine 10 ml/hour for 6 hours after 10 ml of basal bolus. Significantly less requirement of rescue analgesic (pentazocine) was found in wound instillation groups when compared with non wound instillation group (P < 0.001). Nausea and vomiting were also greater in non-wound instillation group. Similarly, supine VAS between 4th to 12th hour, VAS leg raising from 3rd to 12th hours and VAS coughing during all time interval was significantly low (P <0.001) in wound instillation group when compared with non wound instillation groups.[11]

Zohar E and colleagues assessed the outcome of local anesthetic wound instillation on somatic and visceral pain in patients who underwent total abdominal hysterectomy and bilateral salpingo-oophorectomy. Patients were administered either bupivacaine 0.25%

or sterile water via a patient-controlled analgesia device, after surgery. Till the time a VAS score of < 30 mm was achieved, rescue morphine IV (2 mg) was given to patients every 10 min after the first 6 hours of surgery. After that, if patient requested, meperidine IM (1 mg/kg) was given as a rescue drug. It was found that less rescue analgesia was required by Bupivacaine group in comparison to the control group (P < 0.001). During the first 6 hours after surgery, rescue morphine was administered in 6 mg ± 4 mg in bupivacaine versus 12 mg ± 6 mg in the control group (P < 0.001). Similarly, rescue meperidine was also required greater by control group compared to bupivacaine group (95 mg ± 36 mg vs 29 mg ± 37 mg respectively) (P <0.001). Moreover, the side effects like nausea and antiemetic drug usage was significantly (P = 0.003) low in Bupivacaine group. In bupivacaine group, patients were found more satisfied (P = 0.04) and decreased requirement of opioids and nausea during first 24 hours after surgery.[12]

Several other studies reported combination of local infiltration of bupivacaine in combination with other agents like epinephrine, clonidine, magnesium sulphate and diclofenac for pain control after abdominal surgeries. Ng A et al studied that whether incisional and intraperitoneal bupivacaine with epinephrine gives analgesic effect after total abdominal hysterectomy. They enrolled 46 patients with ASA I and II who were randomized to either receive 50 mL of bupivacaine 0.25% plus epinephrine 5 microg/mL or normal saline (50 mL). Final outcome showed that movement related pain was significantly more intense in Placebo group than in Bupivacaine group. Higher consumption of morphine was witnessed in placebo group compared to bupivacaine group (P <0.01). It was concluded that combination of intraperitoneal and incisional bupivacaine plus epinephrine intervention gives significantly more morphine-sparing analgesia for 4 hour after total abdominal hysterectomy.[13] Ng A, et al in a subsequent study assessed intra-peritoneal instillation of levobupivacaine plus epinephrine in laparoscopic cholecystectomy cases. Abdominal pain during inspiration was significantly lower in levobupivacaine/epinephrine group [71 (21-129) mm] than placebo [123 (71-179) mm], (P = 0.041).1[4] A study by Rao KG, et al reported that addition of intrathecal clonidine 50 µg to bupivacaine (15 mg, 0.5%) prolongs the duration of sensory and motor block and duration of analgesia and reduce postoperative analgesic requirement.[15] One study witnessed that continuous infiltration of wound with combination of bupivacaine and magnesium sulphate showed an effective analgesic effect after cesarean section and decreased post-operative patient controlled analgesia requirements when compared with continuous wound infiltration with local anesthetics only or placebo.[16] Zohar E evaluated analgesic efficacy of diclofenac given as adjuvant to bupivacaine wound instillation in 90 cases recovering from cesarean delivery. They concluded that bupivacaine wound instillation when given as adjuvant diclofenac has similar postoperative analgesia inducement with that of diclofenac alone.[17]

In summary, there appears to be a clear advantage of local wound infiltration of 20 ml of 0.25% bupivacaine in women having abdominal hysterectomies in terms of pain control and analgesia consumption during 24 hours after the surgery when compared with control. We suggest further randomized controlled trials with larger sample size.

Conclusions

Pain control at 24 hours after abdominal hysterectomies was significantly better in women who were administered with local wound infiltration with 20 ml of 0.25% bupivacaine as compared to women who were administered with 0.9% normal saline.

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