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Original Article

Efficacy of Spinal Epidural Anesthesia and Sub Diaphragmatic Lidocaine with Spinal Anesthesia in Reduction of Pain: A Randomized Clinical Trial

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ABSTRACT

Objective: To determine the efficacy of spinal anesthesia with sub diaphragmatic lidocaine for gynecological laparoscopic surgery at the commencement of the procedure to spinal anesthesia for get pain relief **Methods:** It was a randomized clinical trial conducted at Ali Medical Hospital in Islamabad. A total of 84 patients were given sub diaphragmatic lidocaine spinal anesthesia, only spinal epidural anesthesia and general anesthesia. During procedure, 2, 4, 6 and 12 hours after surgery, and before discharge, patients' pain perception was measured using Visual Analogue Scale (VAS) **Results:** Outcomes showed no significant difference in perception of pain at different time intervals in all three groups. ($F\ 4, 77 = 0.38$, $p = 0.81$). At all-time intervals following surgery, patients' pain levels were similar between groups ($F\ 2, 77 = 0.53$, $p = 0.57$). **Conclusions:** The use of sub diaphragmatic lidocaine at the onset of surgery together with the spinal anesthesia did not result in a prominent statistical difference in patients' postoperative VAS scores when compared to general anesthesia and spinal epidural anesthesia after and prenatal invasive techniques.

INTRODUCTION

Traditionally, women's laparoscopic surgery is performed under general anesthesia and spinal epidural anesthesia has few surgical difficulties [1]. However, spinal epidural anesthesia has convenience, low chance of failure, patient alertness, decreased discomfort after surgery, early release, and avoidance of the hazards of general anesthetic and intubation as well [2]. However, spinal anesthetic is linked to neurological problems like cauda equine syndrome, low blood pressure and bradycardia, headaches, and back and shoulder pain [2, 3]. If a proper dose is chosen, the anesthetic level is regulated and sterilization is followed, the complications will be reduced [4]. Trendelenburg position and pressure on abdomen, which lead to shoulder and neck pain after initiating the pneumo-peritoneum due to diaphragm and phrenic nerve stimulation [5], are the most critical problems with laparoscopy under spinal anesthesia. As a result, patients may develop anxiety [6]. Surgery would be impossible to do since the pain would most likely be uncontrollable [2]. An infiltration of local anesthesia in sub diaphragmatic place before onset of procedure is one of the suggested solutions [7], depending to the pathophysiology of the condition. As far as we know, this procedure has not been reflected. Purpose of this trial is to determine that how efficient spinal anesthesia with sub diaphragmatic lidocaine was at minimizing pain during gynecological laparoscopic surgery compared to spinal epidural anesthesia.

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METHODS

Current trial was conducted as One-Unit, randomized controlled trial (RCT), equivalent group, and controlled-experiment, according to the CONSORT guidelines. Females who were visiting Obstetrics and Gynecology Department for their infertility treatments were enrolled if they matched the below criteria: American Society of Anesthesiologists (ASA) physical standard guidelines were followed, reproductive age between 25 to 45 years and an informed consent form with signature. A total of 194 patients were enrolled between May and August of 2019. Each of the treatment groups received 28 participants out of the eighty-four patients. Exclusion criteria was coagulopathies, cardiovascular disorders, anaphylaxis to local anesthesia, Complications related to abdominopelvic discomfort which may cause misperception of pain directly associated to the process such as endometriosis, prolonged pain syndromes, BMI more than 35, history of abdominal surgery, a history of any mental disorder. A total of 92 patients who did not fulfil the criteria were excluded and 84 patients were included in the trial after obtaining their consents. A random table made up of random numbers generated by computer with a block size of 5 was used to separate women into three categories. Before the patient went into the operation theatre, the therapy was given. A nurse who was not part of the surgery assessed every patient's discomfort and the occurrence of postoperative antagonistic problems. During the trial, pain levels were monitored countinusely by using Visual Analogue Scale (VAS) 100 mm linear: (0 = no pain to 100= utmost agonizing). The agony VAS is a tool for continuous measurement that consists of a horizontal line with linguistic descriptors fixed at both ends. As is standard procedure, each patient was medicated before with midazolam tab 0.05 mg/kg. Standard measurement was carried out during the procedure, which included non-invasive blood pressure readings, oxygen saturation via pulsoximetry and electrocardiography.

Group 1 (only spinal anesthesia) & Group 2 (Pulmonary anesthesia infiltration) (Sub-diaphragmatic Lidocaine spinal anesthesia): Before the spinal block, intravenous (IV) cannula placed in the operation theatre, and a Ringer's lactate solution (10 ml/ Kg) was given through IV. In sitting position 25-G spinal needle was used to puncture the subarachnoid space on the L3-4/ L4-. After confirming Cerebrospinal (CSF) flow, 4 ml of 0.5% hyperbaric bupivacaine was injected at a ratio of 0.1 ml/s into subarachnoid space. The patient was in supine position with a pad beneath right hip to avoid the aortocaval pressure. Using a gentle pinprick method, the level of sensory block was tested and reported. In Group B, 10ml of injections of 1% of lidocaine was given sub-diaphragmatically at the port locations in the beginning of this study.

Group C (General Anesthesia): For endotracheal intubation propofol (1–2.5 mg/kg) Liporo 1% and for an aesthetic stimulation, midazolam (0.02 mg/Kg) was given, the patients were kept anaesthetized with propofol 100–150 g/Kg (B. Broun AG Co., Germany). After every 30 min tracurium 10 mg and fentanyl 50 mg were given. For laparoscopic technique, two-puncture method with carbon dioxide & Filshie clips was used. Through a sub umbilical cut, a trocar of 3mm was introduced straight in peritonium. Micro endoscope 2.9 mm with 0-degree vision (Karl Storz, Germany) was then inserted, and about 2 L of CO_2 was insufflated. After a lateral 3 mm port was inserted with a tiny holder so the other pelvic organs and fallopian tubes were revealed. An intrauterine Foleys catheter was used to provide 30 ml of methylene blue for chromopertubation. The computed sample size was the base end point as the criterion of scoring via VAS. The trial was conducted to get 80% influence so that determine a variance of 35% on score of pain level via visual analogue scale (0.05 of two-sided alpha levels). Each group should include a minimum of 28 people, according to the sample size calculation for independent proportions (a total of 78). Data was analyzed by using SPSS latest version. The descriptive statistics for continuous variables were presented as mean standard deviation (SD), whereas the descriptive statistics for definite variables were presented in form of numbers as percentage. The baseline features of these 3 groups were compared. For continuous variables, *Analysis of Variance Test (ANOVA)* was used while the *Chi-square test* for categorical variables. Repeated measures *ANOVA* was used to investigate the endpoint mean VAS score. Treatment was a constant aspect, whereas parity were variables in the model. All tests were conducted on a 2-sided basis, with a statistical significance threshold of 0.05. All of the analyses were done with the purpose of intention to treat. The trial's methodology and analysis followed the CONSORT criteria from 2010.

RESULTS

Analysis, which was done for basis treatment, which include all those patients which selected randomly. Figure 1 demonstrate the profile of the study. Among all three groups no statistically significance was found in outcomes in term of mean of variables like age, weight, height, parity and leprosopcy indication. Table 1 presents the Pre-values of demographics and clinical variables. Patients felt the intensity of pain at various intervals following procedure is shown in Table 2 and Figure 2. Although there was a difference in pain across the all groups [F 2, 79 = 0.54, p= 0.58], it was not statistically significant. Despite the fact

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that the mean of pain level raised for all three groups throughout the whole course of the trial, within subject effects, repeated measures ANOVA showed no significance, representing that none of the three groups had any significant within-subject effects. During surgery, aching scores in spinal anesthesia with sub diaphragmatic lidocaine were comparable to those in the spinal anesthesia group (Figure 2). In terms of vomiting p=0.94 and analgesic p=0.84 between these three groups no prominent differences observed..

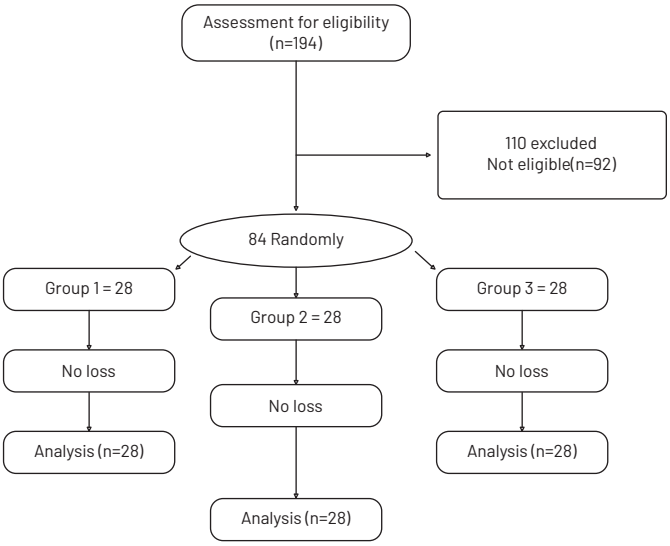

Figure 1: Participants' flow chart for three groups

	Group 1 (n= 28)	Group 2 (n= 28)	Group 3 (n= 28)	p value
Age(year)	28.61 ± (5.48)	26.51 ± (5.03)	29 ± (4.81)	0.88
Pair	0.14 ± (0.9)	0.38 ± (0.78)	0.17 ± (0.49)	0.84
Weight	52.9 ± (12.1)	69.9 ± (10.3)	75.8 ± (0.9)	0.77
Height(cm) Analgesic intake	158.7 ± (5.2)	160.4 ± (5.9)	161.6 ± (2.5)	0.34
Yes	18 (42.86)	10 (35.72)	10(39.29)	0.72
No Vomit	10 (57.14)	18 (64.28)	17 (60.71)	
Yes	8 (28.57)	7 (25)	7 (25)	084
No	20 (71.42)	20 (76)	21 (75)	
Surgery duration Laparoscopy indication	29.88 ± (11.25)	29.65 ± (10.6)	33.88 ± (19.13)	0.5

Table 1: Comparison of secondary outcomes and demographic variables

P value* Pain G1 (n=28), G2 (n=28), G3 (n=28)				
During surgery	-	2.75 ± (3.7)	2.25 ± (2.86)	0.57
After 2 hours	5.18 ± (3.66)	3.07 ± (3.4)	4.34 ± (3.58)	0.08
After 4 hours	4.69 ± (3.01)	3.38 ± (3.16)	4.15 ± (3.04)	0.27
After 6 hours	4.66 ± (3)	4.19 ± (3.13)	5.14 ± (3.02)	0.52
After 12 hours	4.36 ± (3.11)	4.96 ± (3.09)	3.96 ± (2.59)	0.47
prior to discharge	3.3 ± (2.18)	3.65 ± (2.69)	2.62 ± (1.82)	0.24

Table 2: Result for pain feeling during different time interval

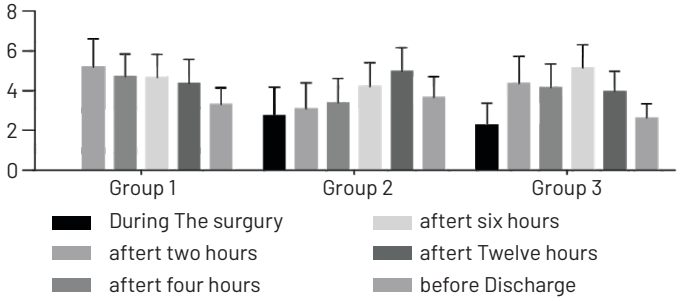

Figure 2: Outcome of feeling of pain for three groups reported experienced the pain at the all Interval

DISCUSSION

The results of this trial revealed that the mean score of pain level of patients in three groups measured instantly post operation at the interval of two. Adding 10 cc of 1% lidocaine to the place lower to the diaphragm at the commencement of operation had no effect on the discomfort level of shoulder, which could be compared to those who were given spinal anesthesia. Instillation of local anesthesia through intraperitoneal was considered to be effective to reduce the intensity of aching after the cholecystectomy & appendectomy in the prior researches [5, 8, 9]. According to a meta-analysis study based on the twenty-four RCTs, local anesthesia into the peritoneal area is statistically significant and effective to reduce the laparoscopic cholecystectomy [8]. On the other hand, local anesthetic peritoneal instillation after laparoscopic procedure is considered to lower the pain. Some studies [10–15] found the pain-relieving approach to be effective, while others did not. Marks et al., published a systematic review in 2012 that comprised seven publications in a meta-analysis. As an inclusion criterion, there was a comparison of the local anesthesia to the placebo group. Overall, the findings displayed that infiltration of local anesthesia into the intraperitoneal is beneficial for the initial 6 hrs afterward the surgical procedure, Anyhow, still no prominent difference found in discomfort twenty-four hours later between the intervention and placebo groups. In each of the seven studies, pain levels were compared between the intervention and placebo groups one and two hours after surgery. There were 220 patients in the therapeutic group and 171 in the placebo group. The interventional group experienced a reduced amount of discomfort as compared to the group with placebo. Three of the seven studies looked at how the intervention affected pain four to six hours following surgery108 patients were assigned to the therapy group, whereas 57 individuals were allocated for the placebo group. Pain was reported to be less in the intervention group as compared to placebo group. (Mean score difference, 2.00; 95% CI: 3.64 -0.35). Further 3 more trials compared the pain level in the two groups 24 hours

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after surgery. In these investigations, 106 people were given therapy and 47 people were given a placebo. Between the two groups, there was no significant difference (mean score difference, 0.26; 95% CI: 0.88-0.35) [16]. Because there was no placebo group in this investigation, local anesthesia effect on reduction of pain level was not determined. In current trial, effect of local anesthesia combined with spinal epidural anesthesia was matched. As a result, no difference between the groups is expected. Because epidural anesthesia is frequently used in women's surgery, neck and shoulder discomfort is the most common complaint [17]. Pain is influenced by a multitude of factors, including local injury from an epidural needle, a high BMI, position of patient during the operation, duration of surgery and time of epidural instillations according to previous study [18]. The three types of pain encountered after laparoscopic surgery are incision discomfort, which escalates to the neck along with pain in shoulder and other visceral pain. [14]. Anesthesia infiltration into intraperitoneal is justified because it chunks the peritoneum's free end: though, absorption from peritoneal surface also provides numbness. While local anesthetics are administered straight to the injured area on the surface of peritoneum, bowel motility returns more quickly. This is because of a lesser neuroendocrine reaction to the operation, as well as, in fact that local anesthetics can be direct administrated in to smooth muscle cells of gut. [19]. Depends on the kind, anesthesia infiltration and its dose, there was no agreement in study on the utility of local anesthetics for pain reduction. Various investigations have proposed gas infiltration of the trocar trajectory, instillation into peritoneal and fallopian tubes prior & post insufflations [20]. The procedure took about 30 minutes in each of the three groups in the current study, and no prominent difference was observed among the groups. Although the exact duration of topical lidocaine's efficacy is uncertain, it is most likely longer than the injectable type's half-life of 2 hours. Given the significant association between an aesthetic dose and an aesthesia severity, a low dose of local an aesthetic was one of the reasons for not detecting the effects of an aesthetic [12]. The dose was high in most research that looked at the favorable benefits of local anesthetics. In comparison to placebo Goldstein et al., discovered that injection (20ml) of 5% bupivacaine or 75% Ropivacaine lower analgesic intake and intensity of pain [21]. In a previous study, Callesen et al., discovered that injecting ropivacaine 50 ml into the spot between the mesosalpinx and peritoneal alleviated pain in eighty patients who got the laparoscopic tubal sterilization to get rid of the infection [22]. When compared the findings of earlier investigations, Current findings were different and unique. A dissimilar pain assessment tool was one of the distinctions. Although VAS was the most commonly used tool in earlier studies, in other investigations, Modified McGill Pain Intensity Scores and the Wong-Baker Faces Pain Rating Scale (WBFS) were used. Measurement error is likely to present in many studies when it comes to the result of pain as a subjective paradigm, and it can be one of the reasons for gaps between recent and previous researches [19]. Researches were conducted at various times, and no search has been conducted since 1980, Effect of advancements in invasive procedures & anesthetic could be the cause of study heterogeneity. Even though most of the research found in the literature suggested that local anesthetic reduced pain after surgery, three RCTs, similar to ours, found that local anesthesia had no effect on pain. Following a comprehensive evaluation by Marks et al., all three RCTs were carried out [16]. In 2016, Collins et al., conducted a study in which 55 women undergoing robotic and robotic gynecologic techniques were allocated to one group: one is placebo and the other one is intraperitoneal ropivacaine. The level of pain was measured post-operatively at the interval of 2, 4, 8 and 12. Though the mean score of pain in the group with placebo treatment was higher than in the Interventional groups and his outcomes did not revealed statistically much significance. [27]. A study conducted by Andrews, on patients undergoing hysterectomy to find out the outcomes of constant intraperitoneal instillation of levobupivacaine, the difference between the placebo and interventional groups on opioid consumption post-operation, stay duration in the hospital, and measure the pain level score did not determined significance [28]. In another RCT, Arden perform laparoscopic hysterectomy on sixty patients, the mean pain score, intake of opioids, and stay duration in hospital while groups placebo (normal saline) and showed similar effects [29].

CONCLUSION

During and after gynecological surgical operations, lidocaine which direct intraperitoneal combined with spinal epidural anesthesia did not show significance in postoperative VAS scores of patients as compared to GA and spinal epidural anesthesia.

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