ORIGINAL ARTICLE

Analgesic Efficacy of Ropivacaine versus Lignocaine in Perineal Tears: A Randomized Controlled Trial

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ABSTRACT

Objective: To compare the analgesic efficacy of Ropivacaine (0.75%) with Lignocaine (2%) in reducing the pain of perineal tears during suturing and postpartum.

Study Design: Randomized Controlled Trial.

Place and Duration of Study: This prospective trial was conducted in Gynecology and Obstetrics department of Kahuta Research Laboratories (KRL) hospital, Islamabad over the period of 3 months from May 2018 to August 2018.

Materials and Methods: In this study 100 patients with singleton pregnancy and vertex presentation undergoing vaginal deliveries were randomly divided into either 2% Lignocaine group or 0.75% Ropivacaine group on the basis of subcutaneous infiltration of the corresponding local anesthetic before perineal repair. Main outcomes studied between the 2 groups include mean pain scores assessed by Visual analogue scoring system (VAS) at the time of suturing and then at 30 mins, 3 hours and 6 hours post partum. The need for additional local anesthetic, on-demand analgesia and side effects were also noted. The outcomes between the two groups were compared and analyzed by SPSS version 23.

Results: A total of 100 women were randomized and equally allocated into one of the two groups. Mean pain score of Ropivacaine was compared with lignocaine and was found to be significantly reduced at the time of suturing (p=0.005), 3 hours (p=0.00) and 6 hours (p=0.001) post partum. But no statistical difference was found in pain score at 30 minutes post partum (p=0.713). The need for additional local anesthetic at suturing (p=0.004) and need for on-demand analgesia (p=0.001) was higher in Lignocaine group. No side effects were noted in both groups.

Conclusion: Ropivacaine was more effective in reducing post episiotomy perineal pain as compared to lignocaine.

Key Words: *Analgesia, Lignocaine, Ropivacaine.*

Introduction

Spontaneous vaginal birth is associated with trauma to the vagina and perineum. This trauma may be in the form of minor/major lacerations or tears occurring spontaneously during vaginal birth or are iatrogenic. The latter term, which includes episiotomy, is defined as a surgical incision or a cut given by the trained mid-wives or obstetrician into the perineum in order to enlarge the vaginal outlet to facilitate the birth of baby.[1,2] Episiotomy is one of the common surgical procedure performed worldwide during spontaneous or assisted vaginal deliveries.[3] The worldwide rates of episiotomies vary due to selective episiotomy recommendation and was found to be 27% overall in WHO report , about 54% for nullipara and 6% for multipara.[4] Some countries are having as low rates as 9.70% such as Sweden whereas others have as high as 100% like Taiwan.[5]

The common problem that affects almost 85–95 % of females includes the post-partum perineal pain for the initial 24 hours. The intensity of pain varies with the degree of the tear/injury.[6] This pain is so arduous that it has negative impact on the mother child bonding like delay in initiating breastfeeding and almost 42 % of these females are not able to carry out the basic activities like sitting, walking, micturition or sleep.[6] About 91% of those with third or fourth degree tears would complain of pain up to 7thpost-partum day.[7]

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Different modalities have been practiced under domain of obstetric analgesia to provide pain relief to laboring females such as epidural analgesia, intra dermal injections of different substances and inhalational agents. Least attention has been given to the post-delivery perineal pain explicitly. Local Anesthetic agents have been widely used to alleviate the pain while suturing the perineal tears. These agents differ on the basis of their chemical structure that in turn affects its efficacy and duration of action.[6] They share same mechanism of action and block the nerve impulse conduction by blocking the sodium channels at the distal nerve free endings and along axon.[6] Traditionally lignocaine, an intermediate acting agent has been used in either 1% or 2% concentration forms. It acts within 1 to 5 minutes after administration and analgesic effect persists for 2 hours.[8] Whereas, long acting anesthetic agents like ropivacaine, bupivacaine and levobupivacaine are now preferred.[7]

Ropivacaine is safer and less cardiotoxic among the three. It has prolonged duration of action and is effective up to 10 hours that can be attributed to its slow reabsorption.[6] Also reduces the peripheral hyperalgesia due to its anti-inflammatory effects.[8] Ropivacaine is generally used for skin infiltration in hemorrhoidectomy and inguinal hernia repair, and has better analgesic effects.[9]

The objective of this study was to compare the effectiveness of 2% lignocaine with the ropivacaine 0.75% in reducing the post episiotomy perineal pain.

Materials and Methods

This was a prospective single blinded randomized control trial conducted over a period of 3 months from May, 2018 to August, 2018. The study participants were consecutively recruited from the labor ward of KRL Hospital Islamabad. Ethical approval was taken from the ethical review committee of the hospital. The sample size was calculated on the basis of WHO sample size criteria by statistician and it came out about 38 patients in each group for statistically significant results.[6] But for better results we have included more patients in both groups.

A total of 100 patients with singleton pregnancy undergoing spontaneous vertex delivery were included on the basis of specific criteria. Women with episiotomy and perineal injury (1st, 2nd and 3rd degrees) were included. While women with fourth degree perineal tear, midline episiotomy, allergy to local anesthetic agent, local infection, and chronic analgesic use before and during pregnancy, drug dependence, major postpartum complications, epidural analgesia, chronic pain syndrome/ neuropathic pain, any comorbid i.e., Diabetes mellitus and Heart disease were excluded.

The patients were randomly allocated into one of the interventional group after explaining the procedure and taking verbal informed consent. Group A was assigned to those receiving 10 ml of 2% lignocaine and Group B to those receiving 10 ml of 0.75% ropivacaine. After negative aspiration, the local anesthetic agent was infiltrated into the vaginal and perineal skin for repairs of mediolateral episiotomy or tears. After infiltration of 5 minutes, the episiotomy or tear was stitched by post-graduate resident using a continuous suture technique for the vaginal mucosa and interrupted suture for the muscle and perineal skin. The patients were familiarized with the visual analogue scoring system. Visual analogue scoring scale is a type of numerical rating scale ranging from 1 to 10 with 1 indicating no pain and 10, the severe pain, as shown in figure 1. The pain assessment was made at the time of suturing and the need for additional local anesthetic agent was noted. In both groups, lignocaine was given as additional analgesia if needed.

All the patients were shifted to postnatal ward, and further pain assessments were made via VAS scoring at 30 minutes, 3 hours and 6 hours post-delivery by the same resident. VAS scoring less than 4 was considered efficacious. Patients with no formal education were assessed for pain by the pictorial presentation of the numerical rating scale.

The need for on-demand systemic analgesia was also noted in both groups. All the patients were observed for side effects and complications. All the data was entered in a performa.

The data was analyzed on the SPSS 23 by using Chi square test. Mean pain scores, age and weight were calculated (mean±S.D) and then independent student t-test applied to compare the two groups. The categorical data was analyzed by applying chi square test and the results were expressed as number or percentages. A p-value < 0.05 was considered statistically significant.

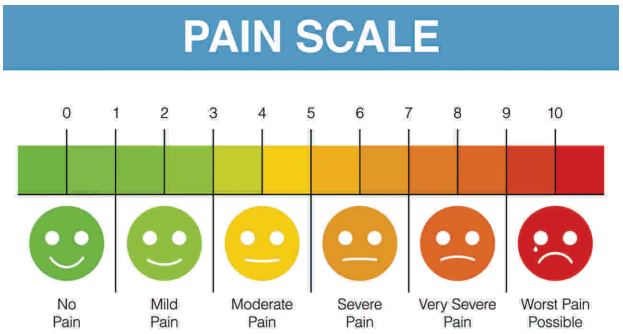

Fig 1: Visual Analogue Scale

Results

Baseline characteristics of 100 study participants are shown in Table I which shows no statistical significant difference in the age, weight, parity, types of delivery and the degree of tear among the two groups.

Based on the results shown in Table II and figure 2, mean pain scores were significantly reduced in the ropivacaine group at the time of suturing, 3 hours and 6 hours post partum. But no significant difference was found at the pain scores at 30 minutes post perineal repair.

Additional analgesic requirement at the time of suturing was greater in lignocaine groups. Most of the patients in lignocaine group complained of pain after 3 hours post delivery. They had greater VAS scores and demanded for oral analgesics as compared to ropivacaine, as shown in Table III.

No side effects were noted in any of the patients in either group. All the patients remained vitally stable post natally, were mobilized, and encouraged to void urine. As per hospital protocol, due to heavy workload the uncomplicated vaginal deliveries were discharged after 6 to 8 hours of delivery therefore, the maternal satisfaction to carry out basic activities could not be assessed.

Table I: Baseline Characteristics of Study Participants

Parameters	Lignocaine	Ropivacaine	P- Value
Age(Mean±S.D)	27.04±3.64	27.58±4.81	0.082
Weight(MEAN±S.D)	68.88±10.25	69.98±10.49	0.59
Parity N (%)			0.42
Primiparous	25(50%)	29(58%)	
Multiparous	25(50%)	21(42%)	
Type of Delivery N (%)			0.832
Spontaneous	33(66%)	34(68%)	
Vaginal Delivery Instrumental	17(34%)	16(32%)	
Type of Tear N (%)			0.539
FIRST DEGREE	9(18%)	6(12%)	
SECOND DEGREE	33(66%)	38(76%)	
THIRD DEGREE	8(16%)	6(12%)	

Table II: Mean VAS Pain Scores

Mean Vas Scores	Lignocaine (MEAN±S.D)	Ropivacaine (MEAN±S.D)	P Value
At The Time of Suturing	4.54±1.84	2.08±1.32	0.005
30 Minutes	3.32±1.03	0.76±1.07	0.713
3 Hours	6.08±1.5	0.64±0.82	<0.01
6 Hours	2.56±1.59	1.56±1.01	0.001

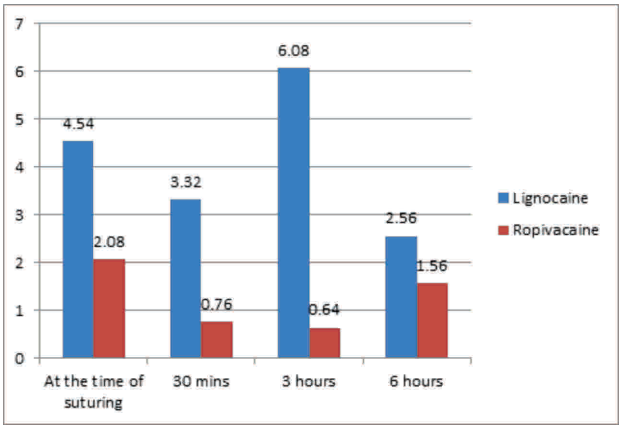

Fig 2: Comparison of VAS Scores between Two Groups

Table III: Need for Additional Local Analgesia at Suturing and on Demand Systemic Analgesia in both Groups

	Lignocaine		Ropivacaine		P-value
	n	%	n	%	
Need for additional Analgesia at the time of Suturing					0.004
Yes	17	34%	5	10%	
No	33	66%	45	90%	
Systemic Analgesics					
Given	20	40%	5	10%	0.001
Yes	30	60%	45	90%	
No					

Discussion

The pain is now considered as a fifth vital sign and it is associated with adverse effects like poor wound healing, wound infection, hypertension, deep venous thrombosis, delayed discharge from hospital and depression.[10] However, persistent perineal pain is most commonly associated with the instrumental delivery. The incidence of persistent perineal pain is documented up to 7% at 6 weeks post partum and 4% at 6 month post partum.[11] The main aim of the current study is to alleviate the post episiotomy perineal pain without further increasing use of systemic analgesics.

In our study the mean pain scores were significantly lowered at the time of suturing, 3 hours and 6 hours post-partum in the Ropivacaine group but non-significant among two groups after 30 minutes of repair. Study by Gutton et al[8] in 2013 showed effective reduction in pain scores at 2, 24 and 48 hours post episiotomy repair in Ropivacaine group and higher maternal satisfaction at 48 hours. The mean pain score was below 4 in Ropivacaine group as compared to Lignocaine group. Similarly, a study conducted by Nagraj et al[6] highlighted that analgesic efficacy of lignocaine and ropivacaine was equal till 4 hours of perineal repair that was in contrast to our study. However, pain scores were higher in lignocaine group after 4 hours that was attributed to the decreased half-life of lignocaine. It was also noted that mean VAS score was less than 1 after 4 hours in ropivacaine group and hence highlighting the greater efficacy of ropivacaine. When compared to our study the pain scores were assessed up to 6 hours, and they were significantly lowered in ropivacaine group, but maternal satisfaction could not be assessed due to early discharge.

About 40% of patients in the lignocaine group required oral analgesics after 3 hours as compared to that of ropivacaine group in our study. In a study by Nagraj et al[6] concluded that the ropivacaine group did not require oral analgesics for 24 hours but the lignocaine group requires analgesics after 4 hours. Similarly, study by Deshpande et al[12] concluded that the time for first analgesic demand was prolonged in ropivacaine group after about average 10.2 hours as compared to 2.2 hours in lignocaine group. Prolonged analgesic effect of ropivacaine for skin surgeries after skin infiltration has also been proven by Moffitt et al[13] which is about 10 hours and for lignocaine it is up to 2 hours. These were similar to our study in which the lignocaine group needed rescue analgesia after 3 hours and can be justified by the shorter half-life of Lignocaine.

In our study, about 90% of patients in Ropivacaine group and 60% in Lignocaine group did not require oral analgesia. Contrary to our results, Schinkel et al[9] in France compared ropivacaine, lignocaine and saline use for perineal infiltration for first 24 hours in patients given epidural analgesia. They concluded that the proportion of patients not demanding oral analgesia were more in lignocaine group about 53% and insignificant among three groups (p=0.09). Whereas about 35% of patients in ropivacaine group did not require analgesia as compared to 90% of patients in our study. This can be explained by the simultaneous epidural infusion and the total 24 hour period taken into account for analgesic consumption.

There were no adverse effects noted in our study participants of either group similar to the other studies by Gutton et al[8] and Nagraj et al.[6] Maternal satisfaction was not assessed in our study due to the early discharge of uncomplicated patients as per hospital protocol. The need for additional analgesia at the time of suturing was not studied in any of the previous studies but it was taken into account in this study.

In clinical use, other drugs have also been compared to lignocaine. Clonidine has been used as an adjuvant to lignocaine and when compared to lignocaine alone, the combined group was significantly lowering the pain intensity and helped the patients to carry out routine activities with ease like squatting, walking, sitting.[14] Similarly another study compared the lignocaine alone with combination of metaclopramide and lignocaine for third degree perineal repairs, and it found significant decrease in mean pain scores after episiotomy for 24 hours.[15] Hypotension and bradycardia were the main side effects noted in the metaclopromide and lignocaine combined group.

The limitation of this study is that the mean pain scores were noted only up to 6 hours due to the early discharge of uncomplicated vaginal deliveries. Blinding of professionals and medical staff was not done.

Conclusion

Ropivacaine is more effective in reducing post episiotomy perineal pain as compared to lignocaine. It can be safely used by the obstetricians as has least side effects and therefore, can replace lignocaine.

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