ROPIVACAINE VERSUS LIDOCAINE FOR EPISIOTOMY-A RANDOMISED DOUBLE BLIND STUDY

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ABSTRACT

BACKGROUND

Episiotomy is a most common surgical procedure for parturients during vaginal delivery. The problem encountered with episiotomy is pain, which is maximum during first 24 hours and may be severe enough to disturb the puerperium. This study aims to compare analgesic efficacy of analgesics, ropivacaine and lidocaine for perineal infiltration during episiotomy.

MATERIALS AND METHODS

We conducted a randomised double blind study for a period one year from August 2013 in a tertiary hospital. 100 parturients were included.

RESULTS

Ropivacaine 0.75% compared to lidocaine 2% did not show any statistical significant changes at suturing and after 4 hours; however, there were great statistically significant changes in VAS scores after 8 hours, 12 hours, 24 hours of episiotomy suturing. Ropivacaine group did not require systemic analgesics for 24 hours, but lidocaine group required systemic analgesics after 4 hours of suturing. Both groups (Ropivacaine and Lidocaine) did not have any adverse effects.

CONCLUSION

Ropivacaine can be used safely for episiotomy wound infiltration thereby reducing the need for systemic analgesia.

KEYWORDS

Episiotomy, Ropivacaine, Lidocaine.

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BACKGROUND

Episiotomy is a most common surgical procedure for parturients during vaginal delivery.[1] In a strict sense, episiotomy is incision of the pudendum-the external genital organs. Perineotomy is incision of the perineum. However, in common practice, the term episiotomy is often used synonymously with perineotomy.[2] Episiotomy rates vary widely worldwide. The worldwide episiotomy rate was 27%, 54% were nulliparious and 6% were multiparous.[3]

Mediolateral episiotomy is currently practised for all vaginal deliveries. Mediolateral episiotomy is a sphincter saving procedure, hencea common practice among primiparous women compared to midline episiotomy.[4,5] The problem encountered with episiotomy is pain, which is maximum during first 24 hours and may be severe enough to disturb the puerperium.[6,7] During delivery, the perineal pain following lacerations or episiotomy is transmitted via pudendal nerves. Epidural analgesia, which is widely used for labour, allows episiotomy to be performed without analgesia. However, severe episiotomy pain is common with resolution of epidural analgesia.[8] Episiotomy pain affects 85-95% of women leading to poor mobility in immediate postpartum period, thereby affecting mother-infant interactions. 42% had at least 1 functional complaint- difficulty in sitting, micturating, walking or sleeping.[7] Obstetric analgesia focuses on pain during labour or after a caesarean delivery whereas analgesia after a vaginal delivery receives less attention.[8] Before episiotomy, analgesia may be provided by existing labour epidural analgesia, by bilateral pudendal nerve blockade, or by infiltration of local anaesthetic. Episiotomy is given during crowning. The analgesic efficacy of infiltration before suturing has been shown in many types of surgeries and the procedure of infiltration is easy. Local anaesthetic injection at the time of episiotomy may be desirable, even in the presence of epidural labour analgesia. Ropivacaine**,** a long acting amide local anaesthetic agent of longer duration when compared to lidocaine, has been used successfully for haemorrhoid surgery, which shares many similarities with an episiotomy. Direct infiltration of local anaesthetic into the subcutaneous layer effectively blocks pain transmission from the free nerve endings located in

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the epidermal and dermal layers.[9] Intradermal injection is also effective but more painful than subcutaneous injection. Local anaesthesia produced by injection of the anaesthetic solution directly into the area of terminal nerve endings. Local anaesthetics reversibly block nerve conduction near their site of administration, thereby producing temporary loss of sensation in a limited area. Nerve impulse conduction is blocked by inhibition of sodium channels at the nerve endings and along the axon. Based on duration of action, local anaesthesia is classified as–short (procaine), intermediate (lidocaine) and long acting(bupivacaine, ropivacaine). The duration of action of the drug is also related to its structure, primarily to the length of the intermediate chain joining the aromatic and amine groups. The protein binding is probably at least as important a determinant of duration of action. Complications during infiltration of local anaesthesia are rare. Avoidance of intravascular injection into major vessels and care not to exceed the maximum total dose of anaesthetic helps to avoid complications. Systemic toxicity, such as of central nervous system (CNS) and cardiovascular system (CVS), is an unusual event, but can occur if the recommended dose is exceeded, if a major vessel is inadvertently injected with a large amount of anaesthetic, or as an idiosyncratic response. Among the local anaesthetics, bupivacaine has the greatest potential for systemic toxicity.[10,11,12] In 1935, lidocaine was first synthesised by 2 Swedish scientists, Euler and Erdtman when they were studying the structure of alkaloid gramine. Later in 1943 it was developed by Nils Lofgren.[13] His colleague Bengt Lundqvist performed the first anaesthesia injection experiments on himself. It was first marketed in 1949 and first reported as an antiarrhythmic drug in 1950.[14] Lidocaine is a moderately long-acting local anaesthetic. It blocks initiation and transmission of nerve impulses at the site of application by stabilising the neuronal membrane. The compound is ultimately metabolised in the liver. Anaesthesia, which persists for 1-3 hours, is induced within 1-5 minutes following mucosal application, infiltration and spinal or dental nerve block, and within 10-15 minutes following other methods of administration. The chemical structure is an aromatic group 2, 6 xylidine, which is coupled to diethylglycine via an amide bond. Half-life (T1/2) – 1.5 hrs. -2 hrs. There is no clinical evidence to suggest that exposure of the mother to lidocaine is harmful to the foetus.[14] Safe use in early pregnancy has not been established. In a recent systematic review, Zaric et al[15] compared the frequency of transient neurologic symptoms and complications after spinal anaesthesia with local anaesthetics. They found that the risk for developing transient neurologic symptoms was higher with lidocaine than bupivacaine, prilocaine or procaine. Lidocaine injection should be kept protected from light and should not be allowed to freeze. Methylene blue may be added to topical formulations for ease of identification. Ropivacaine is a long-acting amide local anaesthetic agent synthesised in 1957 and then released into clinical practice in 1996 in US. It causes reversible inhibition of sodium ion influx and thereby blocks impulse conduction in nerve fibres. This action is potentiated by dose dependent inhibition of potassium channels.[16] Ropivacaine is less lipophilic and less likely to penetrate large myelinated motor fibres. It is extensively metabolised in the liver mainly by aromatic hydroxylation. Peripheral nerve block in orthopaedic surgeries by ropivacaine (0.75%) had significantly faster onset of sensory and motor blockade as bupivacaine.[17] Pre or postoperative wound infiltration with ropivacaine was associated with short-term, dose-dependent relief of postoperative pain in patients.[18] Double blind study by Manolaraki M et al on the effect of local infiltration of the perineum with levobupivacaine versus lidocaine 2% among 100 parturients delivering vaginally with the aid of episiotomy found out that the need of oral analgesia was higher in levobupivacaine than lidocaine 2% group.[19] Study by Schintel et al in his double blind randomised prospective study including 154 patients compared the analgesic efficacy of ropivacaine, lidocaine, saline for perineal infiltration for mediolateral episiotomy who delivered with epidural analgesia. Visual analogue scale scores were low and were not different between the 3 groups (P=0.08). Time to 1st oral analgesic request was comparable between the groups (p=0.104). Patients who did not request oral analgesia were 35%, 54%, 53% respectively (p=0.09).[20] A randomised double blind study by Scott D B et al compared the CNS and CVS effect of ropivacaine and bupivacaine. They observed ropivacaine caused less CNS symptoms. Both drugs increased arterial pressure but no change in cardiac output noted. Hence ropivacaine wasfound less toxic ($p<0.05$).[21] Ropivacaine has been considered to be a safer alternative to lidocaine for perineal infiltration episiotomy suturing by several studies. All studies have showed ropivacaine to be more efficacious than lidocaine in relieving pain and all studies have compared lidocaine 1% with ropivacaine 0.75%. There are no published trials comparing lidocaine 2% and ropivacaine 0.75%. Several studies showed superior analgesic efficacy of ropivacaine, which prompted us to conduct this study.

MATERIALS AND METHODS

100 parturients with singleton pregnancy undergoing vaginal delivery in a tertiary care centre for a period of one year from August 2013 were included for this randomised double blind study. Women with 4th degree perineal tear and those who had analgesic for any other reasons were excluded. Ethical clearance was obtained from the ethical committee of the hospital and informed consent was taken from all subjects. They were assigned randomly to receive ropivacaine 0.75% or lidocaine 2% for local infiltration during mediolateral episiotomy. Randomisation done by computer generated tables. Parturients were blinded to the drug that was administered during episiotomy. The local anaesthesia drugs used in the study were labelled as Drug A and Drug B and decided by third person (neither patient nor investigator). Assessment of Pain score was done by Visual Analogue Scale at the time of suturing, after 4, 8, 12

and 24 hours of suturing. VAS less than 4 considered efficacious. Time needed for first systemic analgesic was noted.

RESULTS

A total 100 patients were recruited for the study. They all were in between age 18 and 37. Their mean age was 26.46 with a standard deviation (SD) of 4.39. Distribution of age between the treatment groups was identical as p value obtained was 0.772. Distribution of parity was observed to be identical between the treatment groups as the p value was 0.841(Table 1to3). Onset of labour distributed similarly between the treatment group; P value 0.585(Table 3). A total of nineteen, thirteen ropivacaine received patients and six lidocaine received patients had risk factors. There was no statistically significant difference in proportion of risk factors between the groups (p value 0.074). Requirement of analgesia was significantly higher in Lidocaine group. (p value <0.001). 60% of patients in Lidocaine group required analgesia compared to 10% in Ropivacaine group (Table 4). None of the patients in both the groups recorded adverse effects. Average VAS score (mean value) at the time of suturing and at 4 hours was similar between ropivacaine and lidocaine (p value 0.353, p value 0.323). But VAS score at 8, 12 and 24 hours was significantly different between ropivacaine and lidocaine (p value <0.001). Average VAS score was high in lidocaine group (Table 5). It was observed that in ropivacaine (R) received patients, the average VAS score decreased gradually from the time of suturing to first day (@ 24 hrs.) and this improvement in pain score between every two consecutive time periods is significant except at 24 hrs. where we got marginal significance (p value 0.073). In ropivacaine received patients, the average VAS score was less than one at each followup after 4 hrs. Whereas in Lidocaine (L) received patients such a trend was not seen. VAS Score at 8 hrs. (2.84) was more than that of VAS Score at 4 hrs. (1.8) and this increase in pain score was significant as p value was <0.001(Table6). After 8 hrs., pain scores decreased after analgesic consumption but not statistically significant (p value 0.177 and 0.280 respectively at 12 hrs. and 24 hrs.). Moreover the VAS Score remained at higher than 2 even after completing a day and consuming more analgesic than Ropivacaine group (P value 0.137). VAS scores were similarly distributed.

DISCUSSION

There were no significant differences between two groups with respect to age, parity, gestational age and onset of labour (Tables 1 to 3). VAS score at suturing did not show significant difference between ropivacaine and lidocaine (p=0.137) Table 7. VAS scores at 4 hrs. also did not show significant difference (p=0.715) Table 8. However, VAS score at 8 hrs., 12 hrs., 24 hrs. showed statistically significant changes in scores (<4). Ropivacaine group had significantly lesser VAS score than Lidocaine; P<0.001, p<0.001, p value 0.003 respectively (Table 9, 10, 11). A study by Gutton et al[22] showed similar results in VAS score at 24 hrs. (p=0.009), VAS score at 2 and 48 hrs. also showed similar result with p value <0.001. Another study by Sillou Set al[23] evaluated ropivacaine infiltration in episiotomy after randomising 62 patients into ropivacaine group and control group. They concluded local ropivacaine infiltration in episiotomy or perineal tear reduced the postpartum perineal pain within first 24 hours (P=0.004). Hence ropivacaine for episiotomy infiltration has been chosen for the research with commonly used lidocaine. Moffitt DL et al[24] in his double blind study compared four concentrations of ropivacaine (1, 2, 5 and 7.5 mg/mL) with normal saline for skin infiltration in skin surgery, and additionally compared with lidocaine 2%+ epinephrine 1:80,000. The results were similar to our study that ropivacaine has a rapid onset and long duration of action. Requirement of analgesic was significantly higher in lidocaine group (p<0.001). 60% of women in lidocaine group required analgesics compared to 10% in ropivacaine group (Table 4). In a randomised trial by Apostolopoulos et al[25] to investigate the safety and efficacy of ropivacaine compared to lidocaine for tonsillectomy under local anaesthesia, pain immediately after surgery was significantly lower. (1.0± 0.4 versus 2.6 ±1.0). Adjuvant analgesics needed was les in ropivacaine group. There were no adverse reactions. They concluded ropivacaine is safe, has longer onset time, more efficient concerning postoperative pain than lidocaine. In our study, it was observed that in ropivacaine (R) received patients, the average VAS score decreased gradually from time of suturing to first day, at 24 hrs. and this improvement in pain score between every two consecutive time periods is significant except at 24 hrs. where we got marginal significance (p value 0.073). In ropivacaine received patients, the average VAS score was less than one at each followup after 4 hrs. where as in lidocaine (L) received patients such a trend was not seen. VAS score at 8 hrs. (2.84) is more than that of VAS Score at 4 hrs. (1.8) and this increase in pain score is significant (p value <0.001) Table6. After 8 hrs., pain scores decreased after analgesic consumption but not by statistically significant margin (p value 0.177 and 0.280 respectively at 12 hrs. and 24 hrs.). Moreover the VAS Score remains at higher than 2 even after completing a day and consuming more analgesia than Ropivacaine group. None of the patients in both the groups recorded adverse effects. Small sample size as well as the fact that Pain score is not evaluated separately among primiparous and multiparous are the limitations of this study.

Age	**Drug**		**Total**
	Ropivacaine	**Lidocaine**	
18-24	19 38.0%	18 36.0%	37 37%
25-30	21 42.0%	19 38.0%	40 40%
>30	10 20.0%	13 26.0%	23 23%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table 1. Age

Distribution of age between the treatment groups is identical as p value obtained is 0.772

Parity	Drug		Total
	Ropivacaine	Lidocaine	
Primi	25 50.0%	24 48.0%	49 49%
Multi	25 50.0%	26 52.0%	51 51%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table2. Parity

Distribution of parity was observed to be identical between the treatment groups (p value 0.841).

Labour	Drug		Total
	Ropivacaine	Lidocaine	
Induced	43 86.0%	41 82.0%	84 84%
Spontaneous	7 14.0%	9 18.0%	16 16%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table 3. Onset of Labour

Onset of labour distributed similarly between the treatment group P value 0.585.

Analgesia	Drug		Total
	Ropivacaine	Lidocaine	
No	45 90.0%	20 40.0%	65 65%
Yes	5 10.0%	30 60.0%	35 35%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table 4. Requirement of Analgesia

Group		Suturing	4 hrs.	8 hrs.	12 hrs.	24 hrs.
R	Mean	2.10	1.58	0.98	0.74	0.58
	Median	2.00	1.00	1.00	1.00	0.00
	SD	1.298	1.052	0.742	0.777	0.673
	Minimum	0	0	60	0	0
	Maximum	6	4	3	4	2
L	Mean	2.34	1.80	2.84	2.40	2.10
	Median	2.00	1.00	2.00	2.00	2.00
	SD	1.272	1.161	2.122	1.852	1.555
	Minimum	0	0	0	0	0
	Maximum	6	5	6	6	6

Table 5. VAS Score

			Paired Differences	Sig. (2-tailed)
Ropivacaine	Pair 1	VAS Score Suturing – VAS 4	0.520	0.001
	Pair 2	VAS 4 – VAS 8	0.600	0.000
	Pair 3	VAS 8 – VAS 12	0.240	0.032
	Pair 4	VAS 12 – VAS 24	0.160	0.073
Lidocaine	Pair 1	VAS Score Suturing – VAS 4	0.540	0.009
	Pair 2	VAS 4 – VAS 8	-1.040	0.001
	Pair 3	VAS 8 – VAS 12	0.440	0.18
	Pair 4	VAS 12 – VAS 24	0.300	0.280

Table 6 Change in VAS Score between Drugs

VAS Score	Drug		Total
	Ropivacaine	Lidocaine	
>/=4	4 8%	9 18%	13 13%
<4	46 92%	41 82%	87 87%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table 7. VAS Score at Suturing

P value 0.137 VAS score distributed similarly.

VAS Score	Drug		Total
	Ropivacaine	Lidocaine	
>/=4	3 6%	5 10%	8 8%
<4	47 94%	45 90%	92 92%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table 8. VAS Score at 4 hours

P value 0.715. VAS score distributed similarly.

VAS Score	Drug		Total
	Ropivacaine	Lidocaine	
>/=4	0 0%	20 40%	20 20%
<4	50 50%	30 60%	80 80%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table 9. VAS Score at 8 hours

P value <0.001. VAS score significantly high in lidocaine group.

VAS Score	Drug		Total
	Ropivacaine	Lidocaine	
>/=4	1 1%	13 13%	14 14%
<4	49 49%	37 60%	86 79%
Total	50 100.0%	50 100.0%	100 100.0%

Table10. VAS Score at 12 hours

P value 0.001. VAS score significantly high in lidocaine group.

VAS Score	Drug		Total
	Ropivacaine	Lidocaine	
>/=4	0 0%	9 9%	9 9%
<4	50 50%	41 60%	91 91%
Total	**50 100.0%**	**50 100.0%**	**100 100.0%**

Table 11. VAS Score at 24 hours

P value 0.003. VAS score significantly high in lidocaine group.

CONCLUSION

Ropivacaine 0.75% compared to lidocaine 2% did not show any statistical significant changes while suturing and 4 hours later; however, there were great statistically significant changes in VAS scores after 8 hours, 12 hours, 24 hours of episiotomy suturing.

Ropivacaine can be used safely for episiotomy wound infiltration thereby reducing the need for systemic analgesia.

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