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A STUDY OF ANALGESIC USE OF LIGNOCAINE GEL IN RELIEVING POST EPISIOTOMY PAIN VERSUS PLACEBO-A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Aim: The aim of the present study was to compare the control of pain using visual analog scale following perineal repair using local lignocaine gel versus placebo at definite time intervals for a period of 48 hours.

Methods: The study was carried out in labor room in BRD Medical College Gorakhpur and 276 patients were included in the study and divided into two groups: Group A- 2% LIGNOCAINE GEL + PLACEBO TABLET, Group B- PLACEBO GEL + ACECLOPARA. The perineal pain was evaluated using the visual analogue scale and pain scale was done at 6, 12, 24 and 48 hours post-episiotomy.

Results: Comparable findings were found in intervention and non-intervention group in terms of socio-economic determinants, maternal determinants (mode of delivery, parity, Hb, TLC) and fetal determinants (birth weight, presentation and foetal outcome) and P value was not found to be significant. The pain score on visual analog scale at immediate post episiotomy repair, at 6 hours, 12 hours, 24 hours and at 48 hours was assessed and Pain score was comparatively less at 24 hours and 48 hours. P value was found to be significant at 24 hours and 48 hours. Intervention group had better pain relief at 24 hours and 48 hours. Pain relief was for more duration in lignocaine gel than aceclopara tablets and also requirement for supplemental analgesic was less with lignocaine gel. Most of the patients performed local gel applications.

Conclusion: This study showed that the use of 2% lidocaine gel for repair of episiotomy after childbirth gives satisfactory results for the women. These are in terms of low pain score on visual analog scale at 24 hours and 48 hours, duration of pain relief and demand for supplemental analgesia by the mother. Also the patients preferred local gel application due to the mode and ease of administration with negligible systemic absorption and minimal side effects.

Keywords: perineal repair, lignocaine gel, visual analog scale, placebo

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

1. INTRODUCTION

Nowadays, different methods are applied to reduce pain during labor and the pain caused by episiotomy.[1] Some of the commonly used methods include non-pharmaceutical methods such as hot packs[2,3], cold water compresses[4], and massage of the perineum[5], and the use of local anaesthetics (lidocaine gel or spray, lidocaine injection with or without vasoconstrictor).[6,7] Although there is no general agreement on the identification of one or more of the methods as the main methods, the most commonly used method is the injection of topical anaesthetic. On the other hand, some other medical specialties have reported that the use of topical products such as sprays[8], gels[9,10], and creams/ointments[11,12] are good alternatives to injectable anaesthetics.

Episiotomy is a common procedure in obstetrics second only to clamping and cutting of the umbilical cord4. Initially, more midline episiotomies were performed in North America but evidence then showed a significantly increased incidence of third and fourth degree tears. As a result, practice again reverted to mediolateral episiotomies. By the 1980s, episiotomy was performed in 64% of American births.[13] Perineal trauma assessment and appropriate care of the perineum are important to reduce associated postpartum morbidities following childbirth.[14,15] Though the role of episiotomy as a protective factor against pelvic floor disorder postpartum has been recognized for many years, its routine use has been hitherto discouraged in the literature.[13] The practice then came under increased scrutiny and study into the purported benefits of the practice. The studies comparing restrictive and routine use of episiotomy, also failed to include any consideration relating to quality of life.[16-18] Episiotomy and other perineal injuries from childbirth are associated with significant perineal pain, infection, haemorrhage, difficulty with micturition, and rarely acute urinary retention.

The aim of the present study was to compare the control of pain using visual analog scale following perineal repair using local lignocaine gel versus placebo at definite time intervals for a period of 48 hours.

2. MATERIALS AND METHODS

The study was carried out in labor room in BRD Medical College Gorakhpur and antenatal women visiting labour room of Obstetrics and Gynaecology department. This hospital serves as a tertiary referral centre for primary and secondary health. 276 patients were included in the study. Patients were divided into two groups: Group A- 2% LIGNOCAINE GEL + PLACEBO TABLET, Group B- PLACEBO GEL + ACECLOPARA.

Inclusion criteria-

1. Primigravida who had normal vaginal delivery with episiotomy at delivery
2. Uncomplicated pregnancy
3. Singleton gestation

Exclusion criteria

1. Women who do not give consent
2. History of adverse reaction to local anaesthetics/ lignocaine
3. Intact perineum
4. Woman with perineal tear
5. Women with previous 3rd or 4th degree perineal tear
6. Woman with postpartum haemorrhage and manual removal of placenta
7. Any medical condition known to be potentially exacerbated by non-steroidal anti-inflammatory drugs

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

8. Instrumental delivery
9. Neurological disease affecting lower extremities

The selection of patients was done by block random sampling following admission into the labour ward.138 subjects were given 2% Lidocaine cream along with calcium tablet while the other 138 subjects were given tablet aceclopara 425mg along with placebo gel for episiotomy pain relief. The patients were commenced on either local lignocaine gel or oral analgesic – tab aceclopara 425mg 4 hourly for 48 hours. This was followed by intramuscular analgesia if required in between 2 doses of local gel or oral tablet. Afterwards the patients were transferred to the postnatal ward for further observation prior to discharge home at least 48hours after delivery if there is no complication.

COLLECTION OF DATA

The perineal pain was evaluated using the visual analogue scale and pain scale was done at 6, 12, 24 and 48 hours post-episiotomy. The maternal demographics, delivery details and perineal trauma characteristics were entered into the proforma sheet. The severity of pain was recorded using the visual analogue scale during repair, six hours, twelve hours, twenty-four hours and at forty-eight hours. The time elapsed between the repair and demand for oral analgesic was recorded, and compared with the severity of pain experienced by patient.

STATISTICAL ANALYSIS

The data and information obtained from this study were processed using statistical package for social science (SPSS) computer software version 16, frequency tables were made and results tested for significance using the chi-square test with the level of significance set at $p \leq 0.05$.

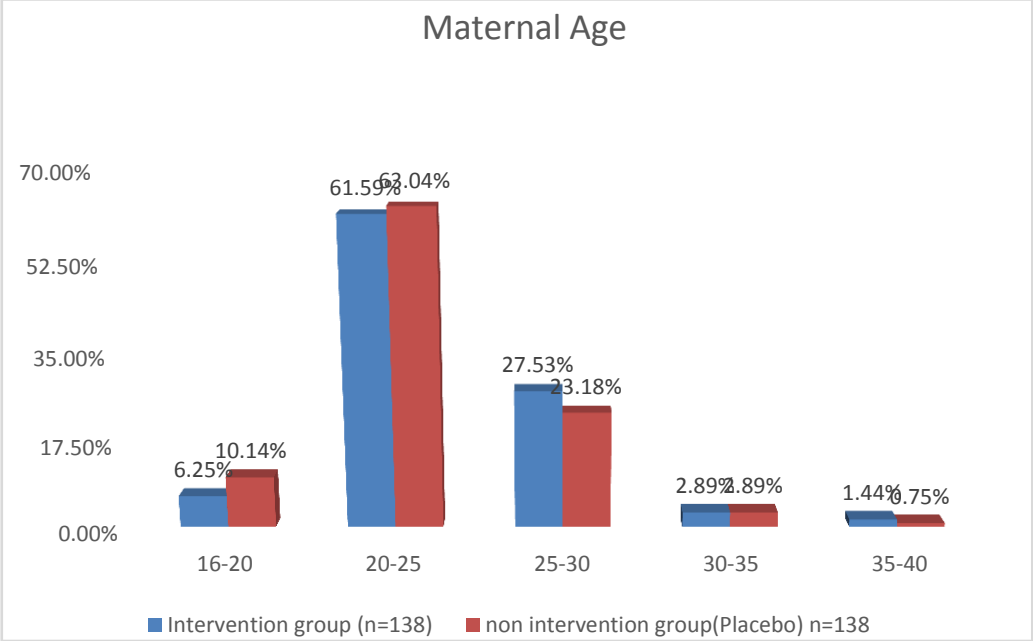
3. RESULTS

Table 1: Distribution of the study participants according to socioeconomic determinants

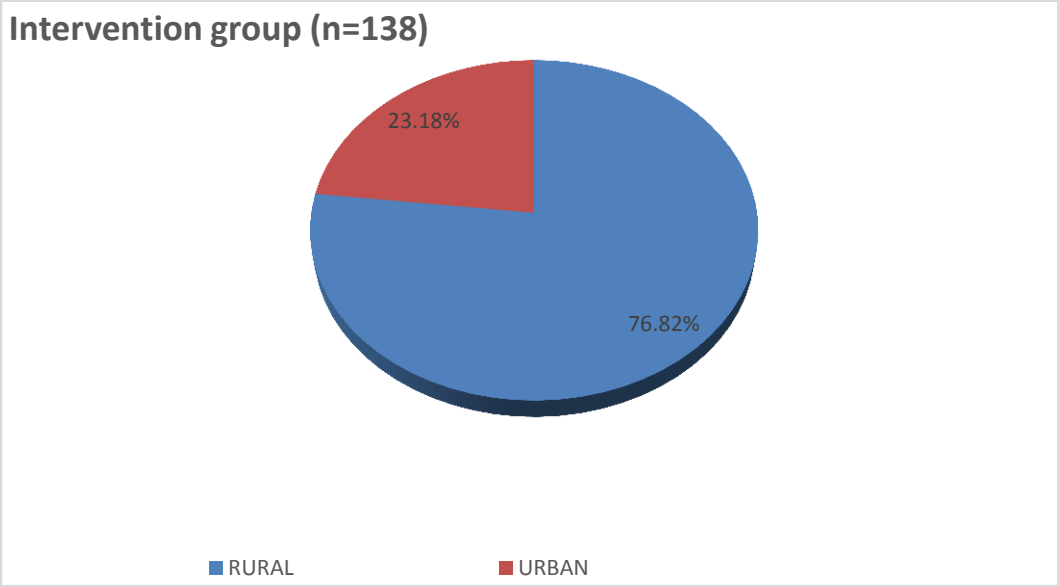
Variables		**Intervention group (n=138)**	**Non-intervention group (Placebo) (n=138)**	**Chi square**	**P-Value**
AGE	16-20	9(6.25%)	14 (10.14%)	1.9578	0.74351
	20-25	85(61.59%)	87 (63.04%)		
	25-30	38 (27.53%)	32 (23.18%)		
	30-35	4(2.89%)	4 (2.89%)		
	35-40	2(1.44%)	1(0.75%)		
PLACE OF RESIDENCE	RURAL	106(76.81%)	94(68.11%)	2.6147	0.10587
	URBAN	32(23.18%)	44(31.89%)		
EDUCATION	ILLITERATE	10(7.24%)	7(5.07%)	4.2942	0.36765

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

	HIGH SCHOOL	78(56.52%)	72(52.17%)		
	INTERMEDIATE	38(27.53%)	44(31.88%)		
	GRADUATE	7(5.07%)	13(9.42%)		
	POST GRADUATE	5(3.62%)	2(1.44%)		

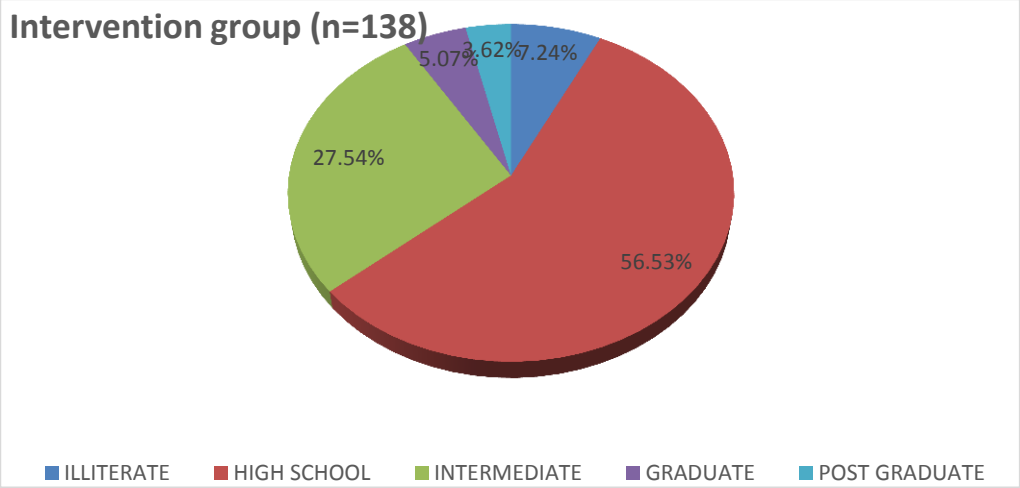


Graph 1A: Distribution according to Maternal Age



Graph 1B: Distribution according to Place of residence

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023



Graph 1C: Distribution according to educational status

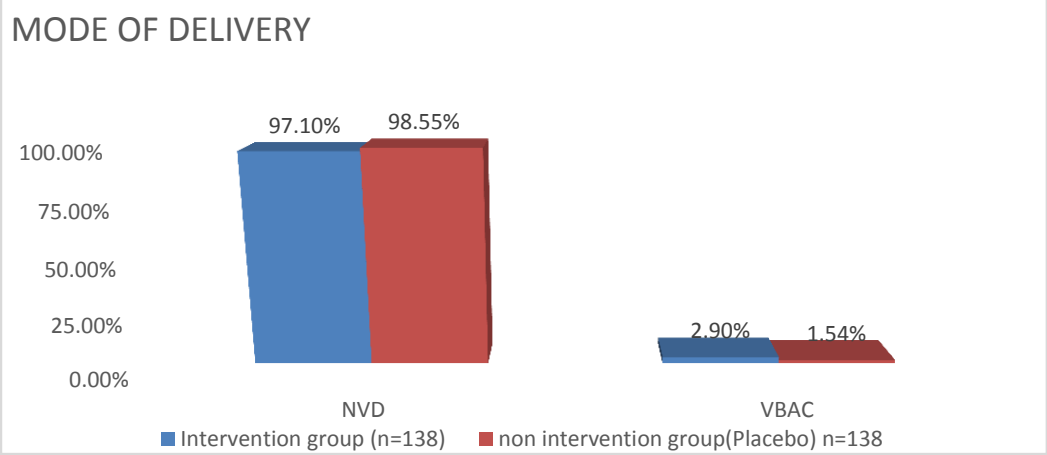
Majority of the cases were found to be in the age group of 21-25yrs (61.59%) in the intervention group and 63.04% in the non-intervention group. Majority of the cases were from rural areas in both intervention (76.81%) and non-intervention group (68.11%). Majority of the participants were high school graduates in both intervention group (56.52%) as well as non-intervention group (52.17%).

Table 2: Distribution of the study participants according to maternal determinants

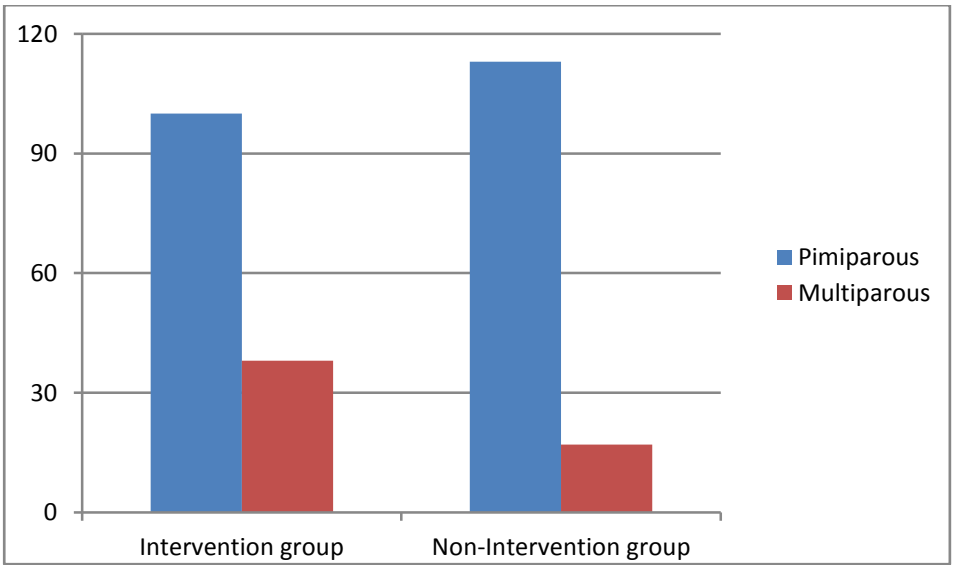
Variables		**Intervention group (n=138)**	**Non-intervention group (Placebo) n=138**	**Chi square**	**P-Value**
MODE OF DELIVERY	NVD	134 (97.10%)	136(98.55%)	0.6815	0.40907
	VBAC	4(2.90%)	2(1.54%)		
Parity	Pimiparous	100 (72.46%)	113(81.88%)	3.615	0.46127
	Multiparous	38 27.54%)	17(12.31%)		
Booking Status	Booked	57(41.30%)	63(54.65%)	0.5308	0.46628
	Unbooked	81(58.70%)	75(54.35%)		
Hemoglobin Range	<7	102 (73.91%)	98 (71.01%)	3.0215	0.38832
	>7	36 (26.08%)	40 (28.98%)		
Total Leucocyte Count Range	4000 TO 12000	53(38.40%)	44(31.88%)	1.532	0.46486
	less than 4000	1(0.74%)	2(1.46%)		

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

	12000 and above	84(60.18%)	92(66.66%)		
Local Complications	none	125(90.57%)	126(91.30%)	0.0628	0.96908
	local infection	9(6.52%)	8(5.79%)		
	episiotomy gape	4(2.91%)	4(2.91%)		

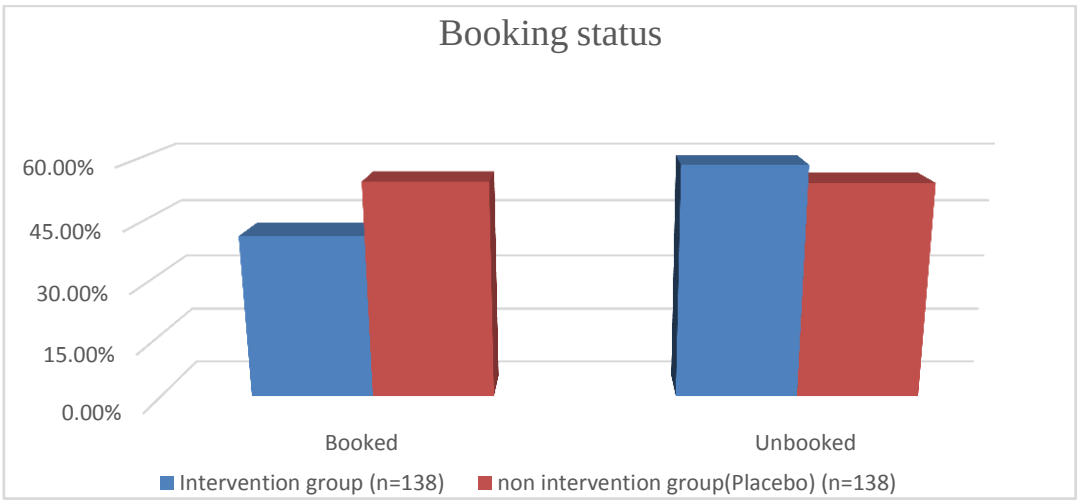


Graph 2A: Distribution according to mode of delivery

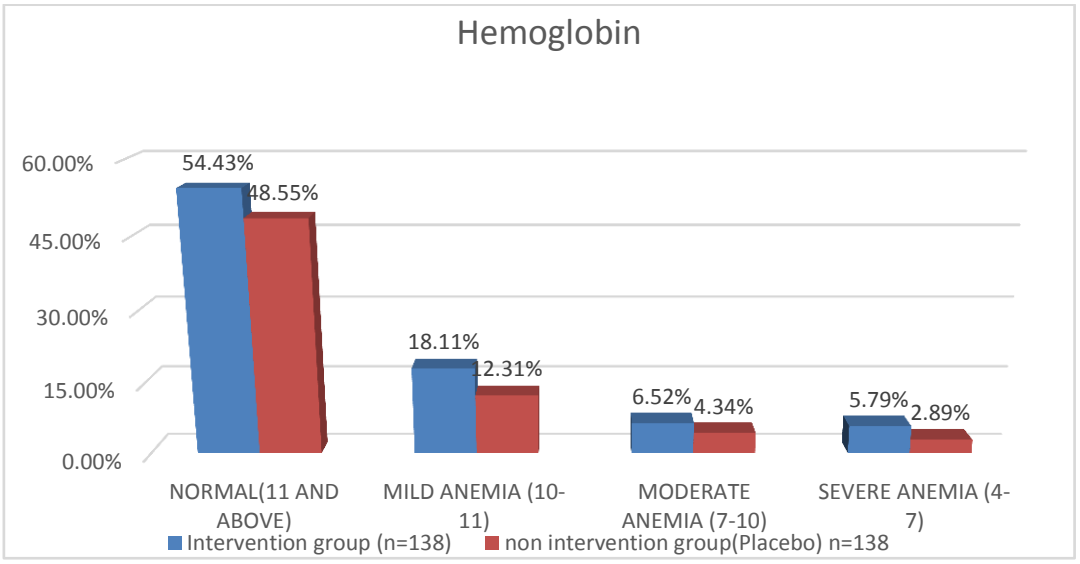


Graph 2B: Distribution according to parity

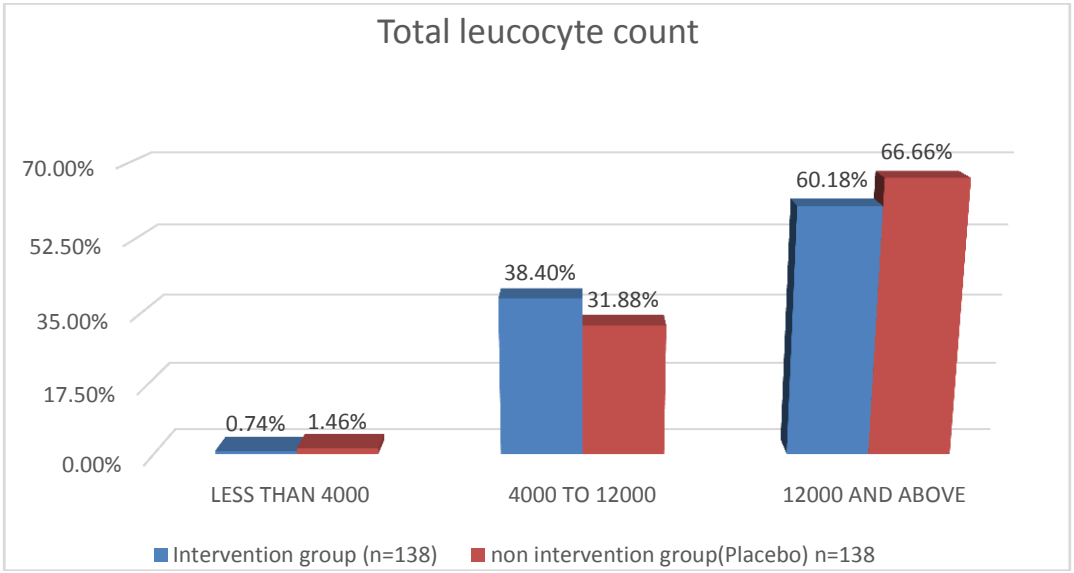
ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023



Graph 2C: Booking status

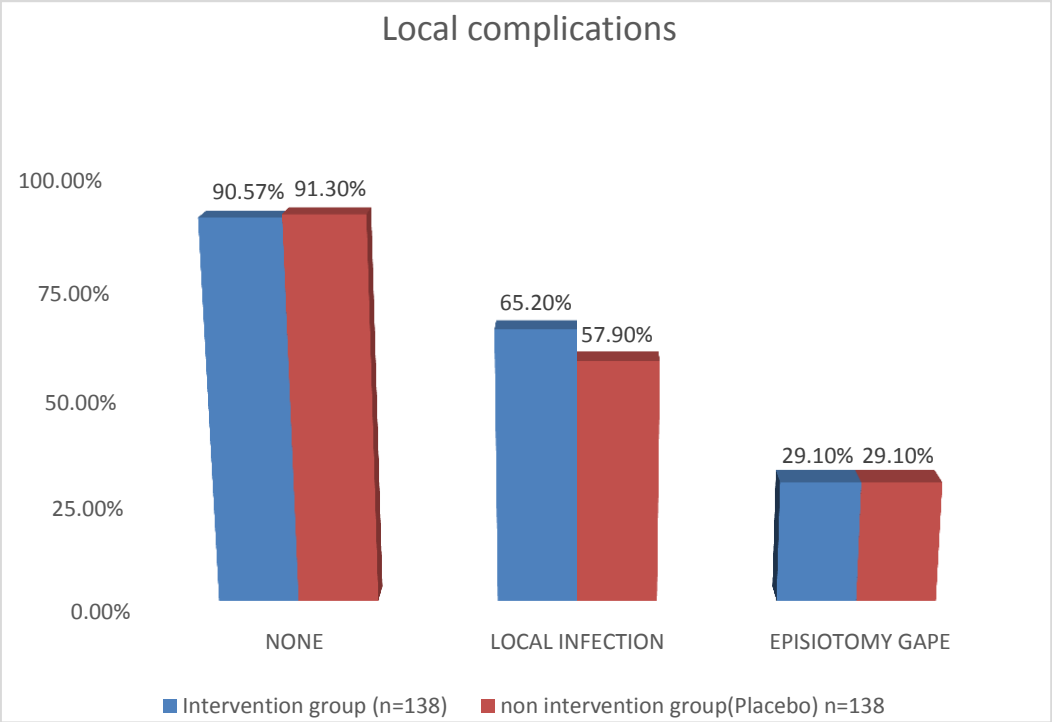


Graph 2D: Distribution according to hemoglobin



Graph 2E: Distribution according to TLC

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023



Graph 2F: Distribution according to local complications

97.10% had normal vaginal delivery in the intervention group. Also comparable findings were found in the non-intervention group with 98.55% cases with normal vaginal delivery and 1.54% only with vaginal birth after caesarean section. 72.46 %were primiparous in the intervention group and 81.88% in the non-intervention group. 58.70% in the intervention group and 54.35% in the non-intervention group were unbooked cases. 73.91% of the cases had hemoglobin <7 g/dl in the intervention group and 71.01% had hemoglobin <7 g/dl in the non-intervention group. Majority of cases (60.18%) had their total leucocyte count more than 12000 cells/mm3in the intervention group as well as in the non-intervention group (66.66%). 90.57% cases in the intervention group and 91.30 % in the non-intervention group did not have any local complications. Local infection was found in 6.52% of the intervention group and 5.79% in the non-intervention group owing to nutritional, socioeconomic and personal hygiene factors.

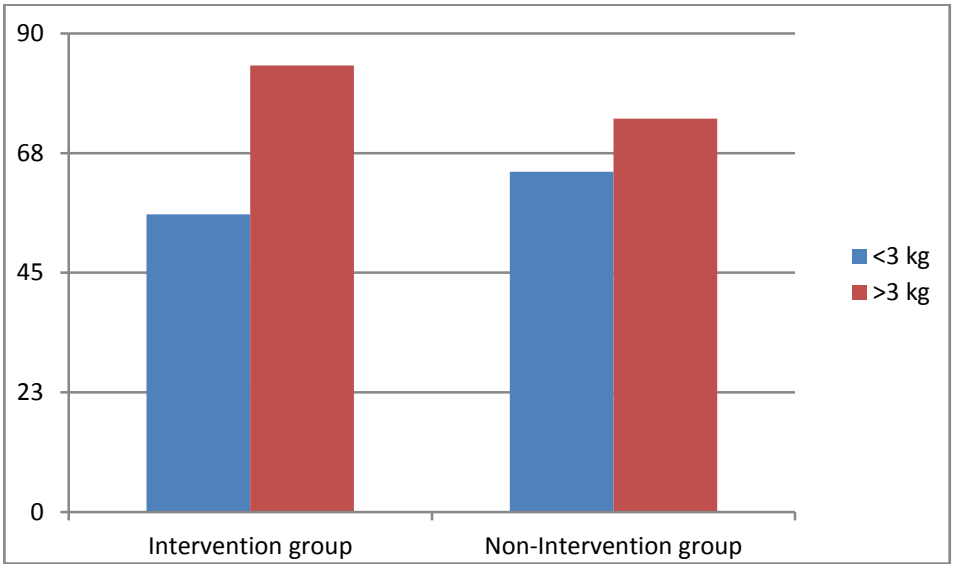
Table 3: Distribution of the study participants according to fetal determinants

Variables		**Intervention group (n=138)**	**Non-intervention group (Placebo) n=138**	**Chi square**	**P-Value**
Birth Weight	<3 kg	56 (40.54%)	64 (46.38%)	7.0049	0.135628
	>3 kg	84 (59.42%)	74 (53.62%)		
Fetal Presentation	Cephalic	129(93.47%)	131(94.92%)	0.2654	0.606445
	Non-Cephalic	9(6.53%)	7(5.08%)		

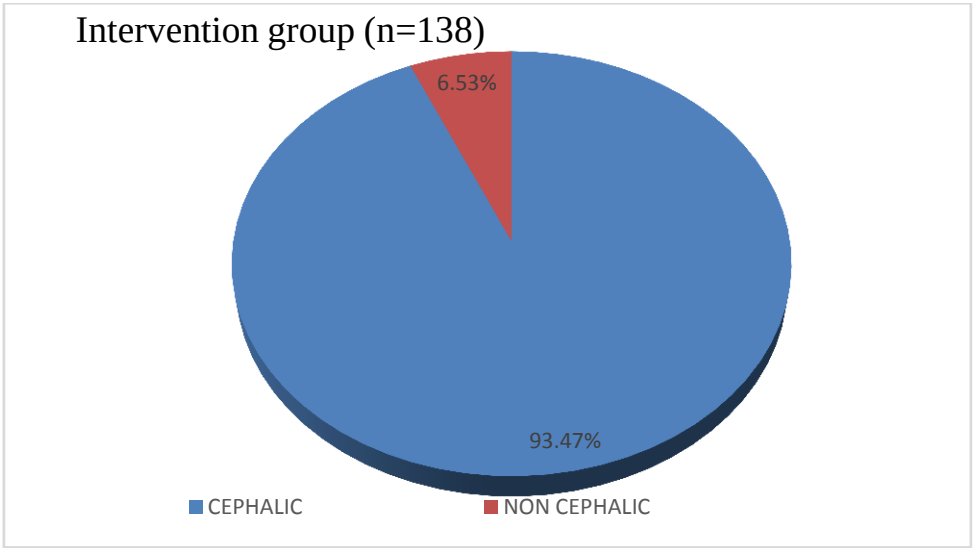
ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

Fetal Outcome	Live Preterm	31(22.40%)	34(24.63%)	1.9822	0.37116
	Live Term	104(75.36%)	97(70.28%)		
	Still Born	3(2.24%)	7(5.09%)		

40.54% had birth weight between <3 kg and 46.38% had birth weight between <3 kg in the intervention group. 59.42% had birth weight between >3 kg and 53.62% between >3 kg in the non-intervention group. P value was not found to be significant. 93.47% in the intervention group and 94.92% in the non-intervention group had cephalic presentation and the rest were non cephalic, most commonly breech presentation. 75.36% in the intervention group and 70.28% had live term babies. 2.24% in the intervention group and 5.09% in the non-intervention group had delivered stillborn babies.

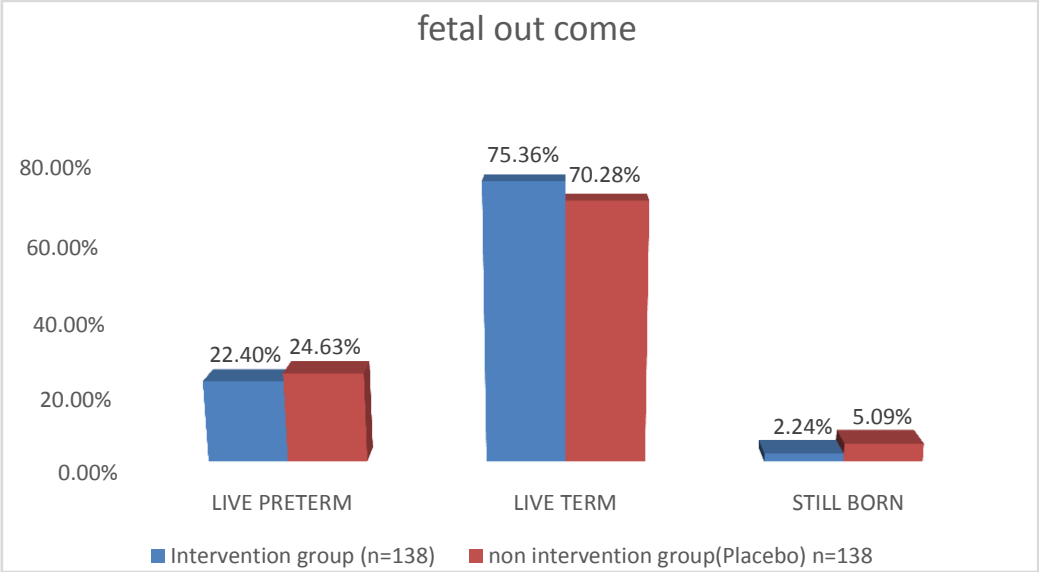


Graph 3A: Distribution according to birth weight



Graph 3B: Distribution according to Fetal presentation

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023



Graph 3C: Distribution according to fetal outcome

Table 4: Distribution of the study participants according to pain score on visual analog scale

Pain score on visual analog scale		**Intervention group**	**Non-intervention group (Placebo)**	**Chi square**	**P-Value**
VAS at 0 hr	Severe	8(5.79%)	7(5.07%)	1.1989	p=0.549119
	Very Severe	108(78.26%)	102(73.91%)		
	Worst Possible Pain	22(15.95%)	29(21.02%)		
VAS at 6 hr	Mild	21(15.21%)	11(7.97%)	3.8768	p=0.275082
	Moderate	92(66.66%)	96(69.56%)		
	Severe	24(17.39%)	30(21.73%)		
	Very Severe	1(0.74%)	1(0.74%)		
VAS at 12 hr	Mild	80(57.97%)	74(53.62%)	0.5288	p=0.46709
	Moderate	58(42.03%)	64(46.38%)		
VAS at 24 hr	Mild	91(65.94%)	70(50.72%)	6.5739	p=0.010348
	Moderate	47(34.06%)	68(49.28%)		
VAS at 48 hr	Moderate	116(84.05%)	99(71.73%)	6.0819	p=0.013657
	Mild	22(15.95%)	39(27.27%)		

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

The pain score on visual analog scale at immediate post episiotomy repair, at 6 hours, 12 hours, 24 hours and at 48 hours. Pain score was comparatively less at 24 hours and 48 hours. P value was found to be significant at 24 hours and 48 hours. Intervention group had better pain relief at 24 hours and 48 hours.

Table 5: Distribution of the study participants according to pain relief and requirement of supplemental analgesic

Pain relief (in HOURS)		**Intervention group**	**Non-intervention group (Placebo)**	**Chi square**	**P-Value**
HOURS	≤2 hour	7(5.06%)	46(33.32%)	62.985	0.00001
	≤4 hours	48(34.77%)	67(48.54%)		
	≤6 hours	83(60.17%)	25(18.14%)		
Requirement of Supplemental Analgesic	YES	10(7.25%)	17(12.32%)	2.0116	0.1561
	NO	128(92.75%)	121(87.68%)		
Supplemental Analgesic Requirement (At Hour)	4^{TH} Hour	3(2.17%)	5(3.62%)	0.0042	0.99791
	5^{TH} Hour	6(4.34%)	10(7.24%)		
	6^{TH} Hour	4(2.89%)	7(5.07%)		

60.17 % cases had pain relief within 5-6 hours of local gel application/ oral formulation in the intervention group whereas 48.54% cases had pain relief within 3-4 hours of local gel application/ oral formulation in the non-intervention group. 92.75% in the intervention group and 87.68% in the non-intervention group did not require supplemental analgesia after local gel application/ oral formulation. In the intervention group, 2.17% required supplemental analgesia at 4th hour post local gel application/ oral formulation and 4.34% required supplemental analgesia at 5th hour post local gel application/ oral formulation followed by 2.89% requirement at 6th hour post local gel application/oral formulation. In the non-intervention group, 3.62% required supplemental analgesia at 4th hour post local gel application/ oral formulation and 7.24% required supplemental analgesia at 5th hour post local gel application/ oral formulation followed by 5.07% requirement at 6th hour post local gel application/oral formulation.

Table 6: Distribution of the study participants according to side effects

SIDE EFFECTS		**Intervention group**	**Non-intervention group (Placebo)**	**Chi square**	**P-Value**
LOCAL GEL	Redness	6(4.34%)	4(2.89%)	0.2105	0.90011

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

APPLICATION	Itching & Pain	2(1.44%)	2(1.44%)		
	Rashes	2(1.44%)	1(0.72%)		
ORAL FORMULATION	Headache	7(5.07%)	4(2.89%)	0.0164	0.991849
	Nausea/Vomiting	5(3.62%)	3(2.17%)		
	Dizziness	2(1.44%)	1(0.72%)		

4.34% cases had local redness, 1.44% had itching and pain and 1.44% had rashes following local gel application in the intervention group. 2.89% cases had local redness, 1.44% had itching and pain and 0.72% had rashes following local gel application in the non-intervention group. 5.07% cases had headache, 3.62% had nausea and vomiting and 1.44% had dizziness following oral formulation in the intervention group. 2.89% cases had headache, 1.44% had nausea and vomiting and 2.89% had dizziness following oral formulation in the non-intervention group.

Table 7: Distribution of the study participants according to patient's preference & predeliction

		Intervention group	**Non-intervention group (Placebo)**	**Chi square**	**P-Value**
Patient's Preference	Local	127(92.08%)	112(81.15%)	7.0225	0.008049
	ORAL	11(7.92%)	26(18.15%)		
Patient's Predeliction	Local	113(81.88%)	104(75.36%)	1.7462	0.186361
	ORAL	25(18.12%)	34(24.64%)		
Rationale	Local	Better Pain Relief	91(65.94%)	105(76.08%)	4.9908	0.082462
		Less Perineal Irritation	36(26.08%)	21(15.21%)		

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

		Simultaneous Cleaning and Application of Gel	11(7.97%)	12(8.69%)		
	Oral	Easy To Take	110(79.71%)	95(68.84%)	4.588	0.100862
		Longer Duration Of Pain Relief	17(12.31%)	29(21.01%)		
		repeated applications after urination	11(7.97%)	14(10.14%)		

92.08% in the intervention group and 81.15% in the non-intervention group preferred local gel application. 81.88% in the intervention group and 75.36% in the non-intervention group predilected local gel application. In the intervention group, 65.94% reported better pain relief, 26.08% reported less perineal irritation and 7.97% mentioned simultaneous cleaning and application of gel as the rationale behind preferring local gel application. In the non-intervention group, 76.94% reported better pain relief, 15.21% reported less perineal irritation and 8.69% mentioned simultaneous cleaning and application of gel as the rationale behind preferring local gel application. In the intervention group, 79.71% mentioned oral formulation to be easy to be taken, 12.31% mentioned longer duration of pain relief with oral tablet and 7.97% mentioned simultaneous applications after urination as the rationale behind preferring oral tablet.

4. DISCUSSION

Perineal trauma following childbirth either spontaneous or episiotomy is an important cause of morbidity for a new mother.[19,20] Most of the time, the perineal pain is one of the most distressing experiences in the immediate post-partum period. This was frequently under reported. In our study, the rate of episiotomy was found to be 46.39%. In some countries, the episiotomy rate has decreased over the years. The episiotomy rate was 60.9% in all vaginal deliveries in 1979 in the United States of America, but the rate decreased to 24.5% in 2004.[21] In our study, majority of the cases were found to be in the age group of 21-25yrs (61.59%) in the intervention group and 63.04% in the non-intervention group. The p value was found to be 0.743515 which was not significant. Majority of the cases were from rural areas in both intervention (76.81%) and nonintervention group (68.11%). In our study, 97.10% had normal vaginal delivery in the intervention group. In our study, 72.46 %were primiparous in the intervention group and 81.88% in the non-intervention group. It is comparable to a study done by P Francis Pebolo et al in 2019 in Uganda where the rate of episiotomy in primiparous women was found to be 73.46%.[22] In our study the incidence of episiotomy was more in unbooked cases (58.70%) than booked cases in intervention group and 54.35% in

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

non-intervention group. 73.91% of the cases had hemoglobin <7 g/dl in the intervention group and 71.01% had hemoglobin <7 g/dl in the non-intervention group. These findings suggest majority of population to be anemic in developing countries mainly due to nutritional factors.

In our study, majority of cases (60.18%) had their total leucocyte count more than 12000 cells/mm3 in the intervention group as well as in the non-intervention group (66.66%). Pain score on visual analog scale was assessed at immediate post episiotomy repair, at 6 hours, 12 hours, 24 hours and at 48 hours. Pain score was comparatively less at 24 hours and 48 hours. P value was found to be significant at 24 hours and 48 hours. Intervention group had better pain relief on visual analog scale. Our findings were similar to study done by Corkill et al[23] who reported that the severity of the perineal pain in women who received lignocaine gel in the first 48 h after childbirth was less than that in the placebo group. Our study showed that pain relief was for more duration in intervention group than nonintervention group. Also, the requirement for additional analgesia was less for intervention group. In our study 4.34% cases had local redness, 1.44% had itching and pain and 1.44% had rashes following local gel application in the intervention group whereas 2.89% cases had local redness, 1.44% had itching and pain and 0.72% had rashes following local gel application in the non-intervention group.

The use of perineal infiltration with local anaesthetics is the most common technique to provide anaesthesia during perineal trauma suturing. Although infiltrative anaesthesia remains a mainstay for pain relief goals during minor surgical procedures, topical anaesthetics in form of gel, sprays ointments have emerged as a reliable alternative. The advantage of using topical anaesthetics include their localized action with negligible systemic absorption, ease of administration, painless application and absence of oedema of the surgical site that distort wounds margin during repair.

5. CONCLUSION

This study showed that the use of 2% lidocaine gel for repair of episiotomy after childbirth gives satisfactory results for the women. These are in terms of low pain score on visual analog scale at 24 hours and 48 hours, duration of pain relief and demand for supplemental analgesia by the mother. Also, the patients preferred local gel application due to the mode and ease of administration with negligible systemic absorption and minimal side effects. We observed that pain score was comparatively less at 24 hours and 48 hours on visual analog scale.

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