



A Study Of The Effectiveness Of Diclofenac Rectal Suppository On Pain Reduction Among Women Under-Going Episiotomy Suturing.

¹Mandeep Kaur, ²Dr. S Sudha Rani, ³Dr. N. Balasubramanian

¹Nursing Tutor, ²Professor cum Vice Principal, ³Dean cum Professor

¹University College of Nursing, BFUHS, Faridkot, Punjab, India, ^{2,3}Malla Reddy College of Nursing, Malla Reddy Vishwavidyapeeth.

Abstract: A significant number of women undergo episiotomy following vaginal deliveries and require stitches. Management of pain during episiotomy suturing is considered as least significant due to more importance is given to the childbirth whereas the pain felt by the mother is ignored. The objectives of the study were to: to assess the levels of pain and behavioural response experienced by women while undergoing episiotomy suturing in both the experimental and the control group, to compare the results of both the experimental group and control group and to assess whether the use of rectal Diclofenac suppository is effective to reduce pain during episiotomy suturing in the experimental group. A quasi-experimental design (Post Test Only) with a sample size (N=60) were selected using purposive sampling technique. The data were obtained by using a baseline Performa, Pain rating scale and BRWES observation checklist. Statistical analysis is done by using descriptive and inferential statistics. There was significant difference in the mean scores of levels of pain in reduction of pain among women undergoing episiotomy suturing between experimental and control group ($T_{58}=2.002$, $P<0.05$). Also, there is significant difference in the mean scores of behavioural responses among women undergoing episiotomy suturing between the experimental and control group ($T_{58}=2.002$, $P<0.05$). Hence, Diclofenac rectal suppository is effective in reducing pain and results in positive behavioural response among women undergoing the procedure of episiotomy suturing.

Keywords: Effectiveness, Diclofenac rectal suppository, Pain reduction, Episiotomy suturing, Behavioural response.

Introduction

Childbirth is a highly joyful experience,¹ an universal and natural phenomenon. It is a transitional event that encompasses pain, emotional stress, exhaustion, vulnerability, possible physical injury, and a permanent role change.² Although labour and delivery are normal physiological events but are not without potential risks for mother and baby. The experience of labour is complex and subjective.³ Several factors affect a woman's perception of labour making each experience unique.⁴

Labour pain is an emotional experience and involves both physiological and psychological mechanism.⁵ The process of normal human childbirth is categorized into three stages of labour: effacement and dilatation of cervix (first stage), descent and birth of the baby (second stage) and expulsion of placenta (third stage). Labour pain being unpleasant for women as well as can have deleterious effects on the baby.⁶ The duration of second stage is difficult to predict with any degree of certainty. The descent of foetal head occurs slowly in initial phase, the pushing exhaust the mother if the head of baby is large or baby is in distress. During these circumstances episiotomy is required.⁷ An episiotomy is the commonest obstetrical procedure,⁸ performed to increase the diameter of the vulval outlet during the last part of the second stage of labour^{9,10}

The WHO recommended use of episiotomy only for selected indications. The indications for episiotomy are foetal distress, shoulder dystocia, face, or breech presentation.¹¹ Episiotomy aid the delivery when the perineum is tight and causing poor progress in the second stage of labour, allow more space for operative or manipulative deliveries. It prevents damage to the baby during delivery. It also helps to shorten the second stage of labour for foetal distress or maternal medical condition.¹²

Worldwide, the rate of episiotomy is on decline in developed countries whereas remains high in developing countries. There is relatively sparse data on episiotomy and perineal trauma from the developing countries as compared to developed countries¹³. In India, the birth rate is very high i.e., 19.3 births/1,000 population.¹⁴ The rate of normal vaginal delivery in India is about 61.5%.¹⁸ Out of which about 63.5% of woman had an episiotomy.¹⁵ Among those midwives performed episiotomies at a lower rate (21.4%) than faculty (33.3%) and private providers (55.6%).¹⁶

Most women think that pain during delivery is part of childbirth, but episiotomy creates fear and apprehension alongside excitement. Pain from episiotomy may be severe which can bring about anxiety. Pain is an unpleasant sensation that can range from mild localized discomfort to agony have both physical and emotional components.¹⁷

Episiotomy is a frequent procedure in which local anaesthetic infiltration of perineum is done. In spite of the local anaesthetic agents, during episiotomy women experiences severe pain. Due to pain odd behavioural responses are exhibited by women. Various studies showed that the pain during episiotomy suturing is severe.¹⁸ Women in labour experience pain of variable intensity, which is affected by psychic (behavioural), mood (motivation), cultural (education) and organic (genetic) factors,¹⁹ and the behavioural response varied during episiotomy suturing related to pain which is expressed through their odd behaviour. The behavioural responses observed during suturing are asking for more analgesia, lifting up the buttocks, crying, grimacing, grasping bed linen or bed rails, bargaining God to reduce pain, taking deep breaths, rebellious to instructions etc. indicating inadequate analgesia given during the suturing procedure.²⁰

The efficacy of Diclofenac suppositories to reduce pain has been significantly proved in various studies. Diclofenac suppositories are inserted as a solid, and dissolve or melt inside the body which is received by the blood vessels that follow the large intestine. The suppository was first used by nursing faculties, administered to elderly patients who were not capable of taking medications.²¹

Diclofenac sodium is a non-steroidal anti-inflammatory drug (NSAIDs) with marked analgesic/ anti-inflammatory properties.²² It is an inhibitor of prostaglandin synthetase (cyclo-oxygenase). The bioavailability of Diclofenac rectal suppository (100mg) is almost immediate ($T_{max} = 1$ hour).²³

To date, there has been little evaluation of the effectiveness of analgesia provided to women undergone perineal repair.²⁴ Many studies have highlighted the role of Diclofenac as a postoperative analgesic,²⁵ but there is no study using Diclofenac rectal suppository as an adjunct to centrally acting analgesic during episiotomy suturing. So, this study is an effort to reduce pain during episiotomy suturing by using additional analgesia, acknowledging the pain management during episiotomy repair. Hence, this study is designed to evaluate the effectiveness of Diclofenac rectal suppository to reduce pain and improve maternal satisfaction with pain relief during episiotomy suturing.

Objectives:

1. To assess the levels of pain and behavioural response experienced by women while undergoing episiotomy suturing in both the experimental and the control group.
2. To compare the results of both the experimental group and control group.
3. To assess whether the use of rectal Diclofenac suppository is effective to reduce pain during episiotomy suturing in the experimental group.

Materials and Methods:

A quasi-experimental design (Post Test Only) with a sample size (N=60) were selected using purposive sampling technique. The data were obtained by using a baseline Performa, Pain rating scale and BRWES observation checklist. Statistical analysis is done by using descriptive and inferential statistics. The independent variable in the study was Diclofenac sodium rectal suppository (100mg) and dependent variables were pain and behavioural responses. The extraneous variables were age, religion, educational status, occupational status, monthly family income and parity.

The sample of 60 women undergoing episiotomy suturing were selected using purposive sampling technique. First 30 samples were considered as the control group and second, 30 samples were considered as the experimental group.

Sampling Criteria:

Women who were:

1. undergoing episiotomy suturing.
2. without antenatal, intranatal and immediate postnatal complications.
3. willing to participate in study.

Development of tools

The tool was developed by the investigator after extensive review, personal experience of investigator, consultation with experts.

The tool was divided into three parts

Part I – Comprised of Socio-Demographic Performa such as age in years, religion, educational status, occupation status, monthly family income in rupees and parity.

Part II – Comprised of standard Wong-Baker FACES Pain Rating Scale. The scale was developed by Donna Wong and Connie Baker. The scale shows a series of faces ranging from a happy face “No hurt”, “Hurts little”, “Hurts little more”, “Hurts even lot”, “Hurts whole” to a crying face “Hurts worst”. The scale was used to assess pain levels in the experimental and the control group based on scoring as follow:

SCORING

Level of Pain	Response	Range	Percentage
No pain	Happy face “No hurt”	0	0%
Mild	Hurts little	1-2	10-20%
Moderate	Hurts little more	3-4	30-40%
Severe	Hurts even lot	5-6	50-60%
Very severe	Hurts whole	7-8	70-80%
Intolerable	Crying face “Hurts worst”	9-10	90-100%

Part III – Behavioural Response of Women Undergoing Episiotomy Suturing (BRWES)

There were several steps involved in the development of this checklist. The steps followed were as follows:

Review of literature: Extensive literature review was done by the investigator. The instruments that were already available to assess the behavioural responses of women while undergoing episiotomy suturing was searched in PubMed, CINAHL, books, reports, articles, periodicals, published and unpublished research studies. However, the investigator found that there was no particular instrument for assessing women’s behavioural response while undergoing episiotomy suturing. Therefore, investigator developed the checklist i.e., Behavioural Response of Women Undergoing Episiotomy Suturing (BRWES).

Item selection: After the extensive literature review pool of items were selected based on the literature, the clinical observation, professional experience, consultation with experts, discussed with women undergone the episiotomy suturing procedure. The 32 statements were developed and stratified into four groups: pain related behaviour, psychological and emotional related behaviour, physiological related behaviour and social related behaviour.

Item construction: After item selection and grouped into four subheadings i.e., pain related behaviour, psychological and pain related behaviour, physiological related behaviour and social related behaviour. The items were carefully grouped under the subheadings. The unwanted and non-related items are taken out. The final tool consists of 20 items.

Scoring: Each item has four responses that is absent, sometimes present, often and always present. Scoring was given as zero for absent, one for sometimes present, two for often and three for always present. The behaviour response was categorised according to scores as follows

SCORING

Level of Behavioural Response	Range	Percentage
Positive	0-20	33.3%
Uncertain	21-40	35%-66.7%
Negative	41-60	68.3%-100%

Content validation: The content validity of this draft tool was established by submitting it to seven experts from the field of Obstetrical and Gynaecological Nursing, One expert from Community Health Nursing and one Graded Specialist, Obstetrics and Gynaecology.

Pretesting: The pretesting was done after taking administrative permission on 10 women undergoing episiotomy suturing. The tool was found to be clear and applicable for observation.

Reliability: The reliability of observation checklist was tested by using split half method with Karl Pearson formula. Reliability of the tool obtained was $r = 0.9$. Hence, tool was found to be highly reliable and feasible to conduct the study.

The pilot study was conducted among 10 women undergoing episiotomy suturing in government hospital, Kharar, Mohali. Five samples were considered as control group and five samples were considered as control group. Formal permission was obtained from the respective authorities of the selected hospital.

The data was collected through the structured observational behavioural checklist and the Wong-Baker FACES pain rating scale from 23.01.2017 to 29.01.2017.

The final data was collected through observation checklist and faces pain rating scale among women undergoing episiotomy suturing at government hospital, Mohali, from 13.02.2017 to 15.03.2017. Informed consent was obtained from the samples after explaining the objectives and purpose of the study. First 30 samples have been considered as control group. No intervention was implemented to them during the procedure of episiotomy suturing. Next 30 samples have been considered as experimental group. Soon after the placental expulsion Diclofenac sodium 100mg suppository was administered rectally. It gives time for the medicine to take effect while uterus exploration and preparation of area takes place for suturing. The action of drug starts within few minutes after administration and has its peak effect in one hour. The post-test was observed by using structured observation checklist to assess the behavioural response of women under-going episiotomy suturing (BRWES) and Wong Bakers FACES pain rating scale to rule out the effectiveness of the suppository in pain reduction during the suturing procedure. Gratitude was expressed by the investigator to the women for their participation and cooperation during the data collection procedure.

Statistical Analysis:

Frequency and percentage were used to analyse the socio-demographic variables. Mean, mean percentage, standard deviation was computed to analyse the pain levels and behavioural response of women undergoing episiotomy suturing. Effectiveness of Diclofenac suppository was assessed by using Unpaired t Test. Karl Pearson's correlation was calculated to analyse the relationship between pain scores and behaviour scores between experimental and control group. Hypothesis were tested at the level of 0.05 level of significance. Chi-square was calculated to find out the association between pain score and behaviour scores with demographic variables.

Results

Part I Sample Characteristics:

In experimental group, highest percentage of women were in below 26 years of age (77%), Hindus (67%), no formal education (30%), unemployed or housewives (97%), income group of Rs 3,000-5,000 (37%) and Rs 5,001–10,000 (37%). Majority of women were multiparous (53%) in experimental group. In control group, highest percentage of women were in below 26 years of age (80%), Hindus (73%), primary school certificate (30%) and middle school certificate (30%). Majority of women were unemployed or housewives (90%), income group of more than Rs. 10,000 and primiparous (63%) in control group.

Part II: Assessment of level of pain among women undergoing episiotomy suturing.

Section A: Assessment of level of pain of experimental and control group among women undergoing episiotomy suturing.

In experimental group level of pain depicts that majority (93.3%) of women had mild pain and only 6.7% of women had moderate pain.

In control group the levels of pain showed that 13.3% of women had severe pain, 83.3% had very severe pain and 13.3% had intolerable pain while undergoing episiotomy suturing.

Section B: Comparison of experimental and control group pain score among women undergoing episiotomy suturing.

In experimental group the women showed only mild and moderate pain. Mild pain shows mean and SD of 1.68 ± 0.48 and moderate pain mean, and SD was 4 ± 0 . In control group the pain varies from severe to intolerable pain. Severe pain shows mean and SD of 6 ± 0 , very severe pain mean and SD of 7.2 ± 0.41 and for intolerable pain of 9 ± 0 .

It is clear from the comparison that Diclofenac rectal suppository had an effect on pain during episiotomy suturing procedure.

Table No. 3: Table showing comparison of experimental and control group mean score, standard deviation and mean percentage among women undergoing episiotomy suturing.

$$N = (30+30) = 60$$

LEVEL OF PAIN	SCORE	EXPERIMENTAL GROUP			CONTROL GROUP		
		MEAN	S.D.	M%	MEAN	S.D.	M%
MILD	1-2	1.68	0.48	16.8	-	-	-
MODERATE	3-4	4	0	40	-	-	-
SEVERE	5-6	-	-	-	6	0	60
VERY SEVERE	7-8	-	-	-	7.20	0.41	72
INTOLERABLE	9-10	-	-	-	9	0	90
OVERALL	1-10	1.83	0.747	18.33	7.10	0.662	71

Part III: Assessment of behavioural response of women undergoing episiotomy suturing.

Section A: Assessment of behavioural response of experimental and control group among women undergoing episiotomy suturing.

After implementation of Diclofenac rectal suppository during episiotomy suturing depicts that in experimental group 100% of them had positive behavioural response and in control group 100% of them shown uncertain behavioural response while undergoing episiotomy suturing procedure.

Section B: Comparison of behavioural response of experimental and control group among women undergoing episiotomy suturing.

There is significant difference between mean percentages of experimental group 13.67 (8.20±2.54) as compared to mean percentage of control group 52.33 (31.40±2.67).

Table No.5: Table showing comparison of mean, standard deviation, and mean percentage of behavioural response of women in experimental group and control group.

$$N = (30+30) = 60$$

Behavioural Response	Experimental Group			Control Group		
	Mean	S.D.	M%	Mean	S.D.	M%
Positive	8.20	2.54	13.67	0	0	0
Uncertain	0	0	0	31.40	2.67	52.33
Negative	0	0	0	0	0	0
Overall	8.20	2.54	13.67	31.40	2.67	52.33

Part IV: Testing of Hypothesis.

To find out the effectiveness of Diclofenac rectal suppository in experimental group among women undergoing episiotomy suturing, a null hypothesis and alternate hypothesis was formulated.

H₀ - There will not be a significant difference between the mean scores of levels of pain and behavioural response between the experimental and control group.

H₁ - There will be a significant difference between the mean scores of levels of pain and behavioural response between the experimental and control group.

The hypothesis was tested using unpaired 't' test, the value of 't' was calculated to analyse the differences in pain scores and behavioural response of experimental and control group among women undergoing episiotomy suturing.

The findings of pain scores shows that there is highly significant difference in experimental and control group ($t_{58}=2.002$, $P<0.05$). Similarly, the findings of behavioural response showed a highly significant difference in experimental and control group ($t_{58}=2.002$, $P<0.05$). There was true difference not by chance. So, the null hypothesis was rejected, and research hypothesis was accepted.

Part V: Association between pain scores of experimental and control groups with selected demographic variables.

Chi-square test was used to calculate the association of demographic variables and levels of pain in a frequency table based on two $\times$ two or more than two contingency table. The levels of pain score were independent of all variables that are age in years, religion, educational status, occupational status, monthly family income and parity in both the experimental and control group.

Part VI: Association between behavioural response of experimental and control group with selected demographic variables.

Chi-square test was used to calculate the association of demographic variable and behavioural response based on two $\times$ two or more than two contingency table. The behavioural response was independent of all variables that are age in years, religion, educational status, occupational status, monthly family income and parity in both the experimental and control group.

Part VII: Correlation of pain scores and behavioural response of experimental and control group among women undergoing episiotomy suturing.

The findings showed that there was positive correlation between variables in experimental group. However, weak correlation was found between variables in the control group.

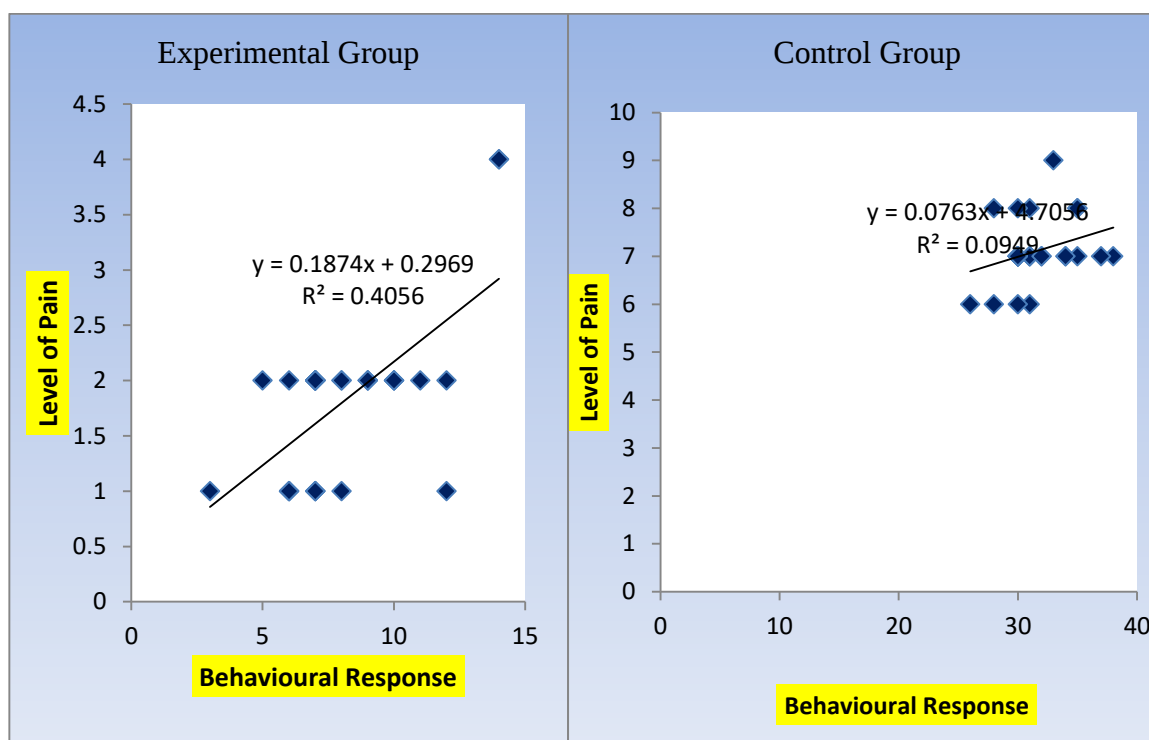


Figure No.12: A scatter diagram showing significant correlation between level of pain and behavioural response in experimental group and control group.

Discussion:

Majority of the women in experimental (77%) and control group (80%) were in the age group of below 26 years. It is more or less parallel to the study of **Breitkreuz L**. Which shows majority of women who underwent episiotomy were in age group of 25 to 29 years of age. Highest percentage of them were Hindus both in experimental group (67%) and control group (63%). It is more or less similar (80.5%) to the census of India (2011), being Hindu dominant country but still variation may be due to Punjab the state if Sikhism (57.69%).

Higher percentages (30%) of women in experimental group were illiterate. Whereas in control group 30% of them were primary school certificate and middle school certificate, respectively. It is contradictory to the findings of census 2011 that literacy rate of females in Punjab is 70.73%. Majority of women in experimental group (97%) and in control group (90%) were unemployed/housewives which is more or less similar to findings of **Anita Sharma (1990)** which shows 90% of women belongs to informal sector and 80% engaged in agriculture. Highest percentage of the women (37%) were in income group of Rs.3,001-5,000 and 5,001 to 10,000 respectively in experimental group. In control group highest percentage of women (53%) were in income group more than Rs.10,000. The findings of socio-economic census 2011 showed that 92% of the households in rural India have an income less than Rs. 10,000 and nearly 75% of them survive on monthly income of less than Rs. 5,000, which is contradictory to the present study. Highest percentage of women were multiparous (53%) in experimental group and primiparous (63%) in control group. The study findings **Breitkreuz L** were parallel to the findings of control group that is 57.3% women were primiparous.

The findings of the present study indicate that significant reduction of pain is observed in experimental group as compared to control group. Hence, it can be concluded that Diclofenac suppository is effective in reduction of pain during episiotomy suturing. No similar study was found whereas there are studies showing effectiveness of Diclofenac rectal suppository in management of post episiotomy pain, pain following hysterectomy and lower segment caesarean section. The findings of **Dasanayake DLW** shows that use of rectal Diclofenac rectal suppository following perineal repair is effective in reducing pain within 24 hours following childbirth. In other findings of **Ali J, Ebrahim, Mozaffar R, Nadia BH and Ali J** shows that a single dose of rectal Diclofenac suppository is effective to provide satisfactory analgesia immediately after surgery.

After implementation of Diclofenac rectal suppository during episiotomy suturing depicts that in experimental group women had shown positive behavioural response and in control group women had shown uncertain behavioural response during the procedure. In a study by **Fernandes V R** the findings shows that the reduction in the pain during episiotomy suturing in women brings out favourable behavioural response.

There was significant difference between mean percentages of experimental group 13.67 (8.20 ± 2.54) as compared to mean percentage of control group 52.33 (31.40 ± 2.67).

The findings of pain scores shows that there is highly significant difference in experimental and control group ($t_{58}=2.002$, $P<0.05$). Similarly, the findings of behavioural response shows a highly significant difference in experimental and control group ($t_{58}=2.002$, $P<0.05$). There was true difference not by chance. Chi-square test was used to calculate the association of demographic variables and levels of pain in a frequency table based on two $\times$ two or more than two contingency table. The levels of pain score and behavioural response was independent of all demographic variables.

The correlation among levels of pain and behavioural response was assessed between the experimental and control group. The findings showed that there was positive correlation between variables in experimental group. However, weak correlation was found between variables in the control group.

Conclusion

From the findings it was clear that there is effective reduction in pain levels and positive behaviour response in experimental group which is highly significant as compared to control group which shows non-significant results. Therefore, it was concluded that Diclofenac rectal suppository is effective in reduction of pain levels and brings out positive behaviour response

Further studies could be conducted to assess the behavioural responses and to assess the experiences and perceptions of women while undergoing episiotomy suturing. To date, there has been little evaluation of the effectiveness of analgesia provided to women undergone perineal repair. There is extensive need for further studies to assess the effectiveness of other pharmacological and non-pharmacological interventions on pain reduction during episiotomy suturing.

Acknowledgement

We sincerely express our gratitude to all the participants to willingly participating in this study and providing us opportunity to conduct this research study.

References

1. Vinlakiv V, Antaniou E. Pain relief and retaining control during childbirth: a sacrifice of the feminine identity. Health Science Journal, 2009, 3(1): 3-9. Available from www.hsj.gr.com
2. Haldorsdotir S and Karlsdottir S I. Journeying through labour and delivery: perceptions of women who gave birth. Midwifery, 1996, 12: 48-61.
3. Simona L, Simon M. The pain of labour. British Journal of Pain. Rev Pain, dec 2008, 2(2): 15-19. Doi: 10.117/204946370800200205.
4. Pirdel M, pirdel L. Perceived environmental stressors and pain perception during labour among primiparous and multiparous women. Journal of Reproduction and Infertility, Oct 2009, 10 (3): 217-223.
5. Simona L, Simon M. The pain of labour. British Journal of Pain. Rev Pain, dec 2008, 2(2): 15-19. Doi: 10.117/204946370800200205.
6. Labar S, Magruire S. The pain of labour: British Journal of Pain, December 2008, 2(2):15-19
7. Milton S H, Isaacs C et al. Normal labour and delivery. Obstetrics and Gynaecology. Available from: www.emedicine.medscape.com.
8. Ogan S F, Mato C N, Eryindah C E. Postpartum perineal pain in primiparous women: a comparison of two local anaesthetics agents. Niger J Med, Jan-Mar 2006, 15(1):77-80.
9. Campell S, Lees C. Obstetrics by Ten Teachers. 17th edition. London: Edward Arnold Publishers Ltd 2002: 282-283.
10. Eryindah C E, Fiebai P O, Anya S E et al. Episiotomy and perineal trauma prevalence and obstetric risk factors. Port Harcourt, Nigeria, Niger J Med, Jul-Sep 2007, 16(3): 242-245.
11. Kim Gibbon. How to perform episiotomy. Midwives magazine, The Royal College of Midwives, 2012: 5. Available from <https://www.rcmorg.uk>
12. Klein M. Rites of passage: Episiotomy and the second stage of labour. Can Fam Physicaian, 1998, 34:2019-2045.
13. Barnabas T A, Amole I O and Olaolorum. Relative frequency and predictors of episiotomy in Ogbomoso, Nigeria: Internet Journal of Medical Update, July 2012, 7(2): 42-45.
14. Indian birth rate-Demographics. Available from: ww.indexmundi.com.
15. Available from: www.quartz.com
16. Episiotomy rates in India. Available from: URL: <http://jpubhealth.oxfordjournals.org>.
17. Medical definition of pain- Medicine net. Available from: ww.medicinenet.com.
18. Fernandes V R. Effectiveness of breast crawl on the intensity of episiotomy pain and behavioural response among women during episiotomy suturing. Muller Journal of Medical Sciences and Research, 8(1), 2017, 24-30.
19. Keevar K J, Sheperd P. The use of music in labour- the pain perception. Gorgetown University, 267985 pdf: 1-36

20. Brisco L, Lavender T, O'Brien, Campbell M, MC Gowan L. A mixed method study to explore women and clinician response to pain associated with suturing second degree perineal tears and episiotomies. [PRAISE]. Midwifery PubMed, April 2015, 31 (4): 464-472.
21. Chico D, Grabnar I et al. Correlation of in vitro and in vivo paracetamol availability from layered excepiant suppository. IJP, 1999, 189: 147-160.
22. Voltarol suppositories- summary of product characteristics. Available from: <https://www.medicines.org.uk>.
23. Voltaren GuildLink. Available from www.guildlink.com.au.
24. Sanders J, Campbell R and Peters Tim J. Effectiveness of pain relief during perineal suturing. BJOG: An International Journal of Obstetrics and Gynaecology. September 2002, vol. 109; 1066-1068.
25. Scott RM, Jennings PN. Rectal diclofenac analgesia after abdominal hysterectomy. Australia, NZ Journal of Obstetrics and Gynaecology, 1997, 37(1): 112-114.

