

Original Article

ORAL VERSUS RECTAL DICLOFENAC SODIUM EFFICACY IN PAIN CONTROL AFTER PERINEAL REPAIR IN A PRIMIPARA

Uzma Altaf, Alia Zaineb Asad, Shazia Ashraf and Muhammad Tayyab

Objective: To compare oral with rectal route of diclofenac sodium pain control after repair of an episiotomy in a primiparous patient.

Methods: This study was carried out in Jinnah Hospital, Lahore. The duration of the study was six months. It was a prospective case control study. 100 patients were enrolled; 50 in each group. Group-A was given rectal suppositories, and group-B was given oral drug. The sampling technique was non-probability convenience sampling. A simple visual analogue pain (VAS) scoring was used to assess extent of pain after 24 hours of delivery in both groups. Results were tabulated by SPSS 20.

Results: Age, gestational age and BMI were comparable in both groups. Regarding parity distribution, all mothers were primigravidae. Mean pain score on VAS in group-A was 2.08 ± 0.96 and in group-B 5.92 ± 1.08 ($p < 0.001$).

Conclusions: Rectal route was found to be more effective than oral diclofenac.

Keywords: episiotomy pain control, diclofenac sodium.

Introduction

Episiotomy is a surgical procedure facilitating SVD. It is essentially a cut in the skin and muscles of perineum.¹ After its initial frenzy, various randomized control trials were carried out, and a restrictive use of episiotomy is now being advocated. Episiotomy or a perineal tear during delivery can cause considerable discomfort and pain. MacArthur and MacArthur reported perineal pain in 75% of women who deliver without episiotomy and 97% in women delivering with episiotomy.² Severity of pain is also directly proportional to the extent of trauma. Over one-third of women with episiotomy report it as distressing or worse on "present pain intensity" PPI scale of the McGill pain questionnaire on Day one. Albers et al reported these findings,³ among other researchers.⁴

Subjective assessment of post episiotomy pain by Reading et al⁵ showed that 63% of women reported this pain as discomforting and 10% as distressing, and 7% deemed it horrible.

Effective pain control during labor and after delivery is a basic right of all women. Control of the pain can be done by various modalities including intravenous, intra-muscular, oral and rectal drugs.⁶⁻⁸ As epidural is not freely available in government hospital setups, amongst the various modalities available for episiotomy repair pain control, NSAIDs are the most easily available and cost-effective modality without causing undue

side-effects. However, oral diclofenac is best avoided on an empty stomach. Labour of primiparous women can extend easily up to 12 to 14 hours, and food intake is minimal during this time. To avoid delay, therefore, rectal route will be more suitable. Various trials have shown that rectal suppositories are effective up to 24 hours.⁹ It has also been shown that absorption through rectal route avoids the first pass liver effect, and a greater dose of the drug is available in a shorter time.

Some studies have shown the pain score to be zero after 24 hours of the drug.⁶ In comparison, oral diclofenac showed lesser pain control.¹⁰ Rationale of this study is to compare the route of diclofenac sodium most suitable for episiotomy repair pain control. Further studies are required to equate patient acceptability and cost effectiveness and may divert pain management from oral to rectal route.

Methods

Prospective cohort study was carried out in department of Obstetrics and Gynaecology, Jinnah Hospital, Lahore. Study was carried out over a period of six months from 14-07-2015 to 13-01-2016. Sample size of 100 cases; 50 cases in each group was calculated with 80% power of test, 95% confidence level and taking expected mean \pm SD. Sampling was non-probability convenience. Inclusion criteria was females of age 18-40 years were recruited, Primigravidae presenting at gestational ages \geq 37 weeks who underwent delivery for singleton,

Cephalic fetus (on USG) and required episiotomy repair. Those excluded were females with medical diseases like PIH (BP > 140/ 90 mmHg), preeclampsia (PIH with proteinuria +1 on dipstick method), gestational diabetes (BSR > 186 mg/ dl), anemia (Hb< 10 mg/ dl), or severe asthma (on medical record and history), Gastric or duodenal ulcer (on medical record and history), major postpartum haemorrhage (blood loss > 1000 mL), or who required manual removal of placenta or emergency caesarean section. Mothers with macrosomic babies (weight >4000gm) were also excluded. Approval from hospital ethical committee was taken. primigravidas undergoing episiotomy repair in labour room of Unit-III of Obstetrics and Gynaecology, Jinnah Hospital, Lahore, were enrolled in the study. Informed consent was obtained. Demographic data (including name, age, gestational age, and parity) were also recorded. After delivery, the women were

divided in two groups by using non-probability, convenience sampling. In group-A, females were given rectal Diclofenac in 100mg dose, while females in group B were given oral Diclofenac in 100 mg dose. Dose was given immediately after delivery. Then they were followed up in ward for 24 hours. After 24 hours, they were asked for perineal pain by using visual analogue scale (VAS) and pain was assessed. All the information was collected on a specially designed proforma. All the collected data was entered and analyzed through SPSS version 20.0. Quantitative data like age, gestational age and pain score on VAS was presented as mean and standard deviation. Data like parity was presented as frequency. Independent sample, T-test was applied to compare mean pain score in both groups taking p value ≤ 0.05 as significant. Data was stratified for age, gestational age parity and BMI to address effect modifiers. Post stratification independent sample t-test was applied to check the significance with p value ≤ 0.05 as

Table-1: Distribution of cases by age, gestational age and BMI.

Age (in years)	Group-A Rectal Diclofenac		Group-B Oral Diclofenac	
	Frequency	Percentage	Frequency	Percentage
Age (years)		27.40 \pm 3.74		29.32 \pm 4.44
20-30	41	82.0	91	67.41%
51-80	09	18.0	135	100%
Gestational age (Wks)		38.66 \pm 1.28		38.74 \pm 1.13
37-39	37	74.0	35	70.0
40-41	13	26.0	15	30.0
BMI		22.80 \pm 1.93		22.90 \pm 1.72
= 25	47	94.0	49	98.0
>25	03	06.0	01	02.0

Table-2: Comparison of mean VAS scores.

Age (in years)	Group-A Rectal Diclofenac Mean \pm SD	Group-B Oral Diclofenac Mean \pm SD	P-value
VAS Score Total	2.08 \pm 0.96	5.92 \pm 1.08	< 0.001
Age (yrs.) 20-30	2.07 \pm 1.01	5.65 \pm 1.01	<0.001
31-40	2.11 \pm 0.78	6.37 \pm 1.06	
Gestational age (Wks)			
37-39 (Weeks)	0.03 \pm 0.92	5.83 \pm 1.17	<0.001
40-41	2.23 \pm 1.09	6.13 \pm 0.83	
BMI			
= 25	2.09 \pm 0.97	5.88 \pm 1.05	<0.001
>25	2.00 \pm 0.00	8.00 \pm 0.00	

Results

A total of 100 females (50 in each group) were included in this study during the study period of six months from 14-07-2015 to 13-01-2016. Group-A received rectal diclofenac while Group-B was given oral diclofenac. Mean age of the patients was 27.40 ± 3.74 and 29.32 ± 4.44 year in group-A and B, respectively. Mean gestational age was 38.66 ± 1.28 weeks in group-A and 38.74 ± 1.13 weeks in group-B. In group-A, mean BMI was 22.80 ± 1.93 and in group-B mean BMI was 22.90 ± 1.72 kg/m² (Table-1). Regarding parity distribution, all females were primigravida. Mean pain score on VAS in group-A was 2.08 ± 0.96 and in group-B 5.92 ± 1.08 ($p < 0.001$). Stratification with regard to age, gestational age and BMI was carried out and presented in (Tables 2).

Discussion

Perineal pain can cause psychological as well as physical symptoms like urinary retention, decreased mobility and inadequate care of the newborn.¹¹

NSAIDs are the most easily available and commonly used drugs. Diclofenac sodium when given orally has a major first-pass effect. It can also cause gastric mucosal irritation, essentially requiring a full stomach before taking the drug. Some studies show that the rectal absorption is better and first-pass effect is avoided so a greater amount of drug is available sooner in the blood, allowing quicker pain relief and prolonged action of treatment.^{11,12} Assessment after 24 hours shows significant improvement of pain control when the drug is given rectally.¹³ These results were

comparable to our study.

In the current study, mean age of the patients was 27.40 ± 3.74 and 29.32 ± 4.44 years in suppositories group and oral group respectively. Naz et al reported mean age of the patients 24.38 ± 6.23 . In a study by Corkilla et al,¹⁴ the mean age was 28 years. Rectal use of suppositories resulted in lesser requirement of analgesia.¹⁵ There appears to be a clear advantage in using rectal NSAIDs. According to Jane A. Searle¹¹, the mean pain score assessed at 12, 24, 48 and 72 hours after delivery were significantly reduced in rectal diclofenac suppositories group as compared to the control group.¹⁶ This has also been reflected in our study when scoring was done at 24 hours so requirement of oral NSAIDs were reduced in patients initially treated with rectal group. In the current study, mean pain score with oral versus rectal diclofenac after childbirth through normal vaginal delivery with episiotomy was 2.08 ± 0.96 and 5.92 ± 1.08 respectively. There was statistically significant difference between the two groups. A similar result was found in the study of Dodd et al¹³ which showed that rectal diclofenac was more potent in reducing perineal pain. Searle et al¹¹ studied 45 post-episiotomy women who were given 100 mg of diclofenac rectal suppositories and found statistically significant pain relief at 24, 48 and 72 hours after giving birth.

Conclusion

Rectal use of diclofenac was found to be a simple and effective modality of reducing the post-natal pain experienced by women after normal vaginal delivery with episiotomy.

Department of Obst. & Gynaecology

References

- Cunningham F, Leveno K, Bloom S, Spong CY, Dashe J. Normal labor and delivery, editors. Williams Obstetrics 23rd ed. New York NY: McGraw Hill Professional; 2010.
- Sheiner E, Sarid L, Levy A, Seidman DS, Hallak M. Obstetric risk factors and outcome of pregnancies complicated with early postpartum hemorrhage: a population-based study. J Matern Fetal Neonatal Med 2005;149-54
- Albers L, Garcia J, Renfrew M, McCandish R, Elbourne D. Distribution of genital tract trauma in childbirth and related post-natal pain. Birth 1999;26:11-7.
- Declercq E, Cunningham DK, Johnson C, Sakala C. Mothers' reports of postpartum pain associated with vaginal and cesarean deliveries: results of a national survey. Birth 2008;35:16-24.
- Reading AE, Sledmere CM, Cox DN, Campbell S. How women view postepisiotomy pain. Br Med J 1982;284:243-6.
- Acharyapota V, Titapant V. Relieving perineal pain after after perineorrhaphy clinical trial. J Med Assoc Thai 2008;91:799-804
- Habib L, Manzar S. Postoperative analgesic effect of diclofenac suppository versus diclofenac injection. Pak J Surg 2004;20:11-15
- Suhrabi Z, Tughinejad H. A comparative study on the efficacy of ibuprofen and celecoxib on the intensity of perineal pain following episiotomy: a randomized clinical trial. Iran Red Crescent Med J 2013;15:e9980.
- Hedayati H, Parsons J, Crowther CA. Rectal analgesia for pain from perineal trauma following childbirth. Cochrane Database Syst Rev 2003;3:CD003931.
- Lim SS, Tan PC, Sockalingam JK, Omar SZ. Oral celecoxib versus oral diclofenac for post-perineal repair analgesia after spontaneous vaginal birth: a randomized trial. Aust N Z J Obstet Gynaecol 2008;48:71-7.
- Searles JA, Pring DW. Effective analgesia following perineal injury during childbirth: a placebo controlled trial of prophylactic rectal diclofenac. BJOG 1998;105:627-31.

- Larrouture D, Tuleu C. Rectal route in the 21st century to treat children. *Advanced drug delivery reviews*. 2014 Jun 30;73:34-49.
13. Dodd JM, Hedayati H, Pearce E, Hotham N, Crothew CA. Rectal analgesia for the relief of perineal pain after childbirth: a randomized control trial of diclofenac suppositories. *BJOG* 2004;111:1059-64.
14. Naz S, Maimon NY, Sattar A, Baloch R. Diclofenac rectal suppository: an effective modality for perineal pain. *J Pak Med Assoc*. 2016 Aug;66(8):1005-8.
15. Cheung YW, Hopkins LM, Coughy AB. How long is too long: Does a prolonged second stage of labour in nulliparous women affect maternal and neonatal morbidity? *Am J Obstet Gynecol* 2004;191:933-8.
16. Glazener CN, Abdalla M, Stroud P, Naji S, Templeton A, Russell IT. Postnatal maternal morbidity: extent, causes, prevention and treatment. *Br J Obstet Gynaecol* 1995;102:282-7.
17. Facchinetti F, Casini ML, Costabile L, Malavasi B, Unfer V. Diclofenacpyrrolidene versus ketoprofen for relief of pain from episiotomy: a randomized control trial. *Acta Obstet Gynaecol Scand* 2005;84:951-5.

Medical News

FIBER-FERMENTING BACTERIA IMPROVE HEALTH OF TYPE 2 DIABETES PATIENTS



Fig-1: This is gut bacteria in culture.

Promotion of a select group of gut bacteria by a diet high in diverse fibers led to better blood glucose control, greater weight loss and better lipid levels in people with type 2 diabetes, according to research published today in *Science*.

The study, underway for six years, provides evidence that eating more of the right dietary fibers may rebalance the gut microbiota, or the ecosystem of bacteria in the gastrointestinal tract that help digest food and are important for overall human health.

"Our study lays the foundation and opens the possibility that fibers targeting this group of gut bacteria could eventually become a major part of your diet and your treatment," said Liping Zhao, the study's lead author and a professor in the Department of Biochemistry and Microbiology, School of Environmental and Biological Sciences at Rutgers University-New Brunswick.

Type 2 diabetes, one of the most common debilitating diseases, develops when the pancreas makes too little insulin -- a hormone that helps glucose enter cells for use as energy -- or the body doesn't use insulin well.

In the gut, many bacteria break down carbohydrates, such as dietary fibers, and produce short-chain fatty acids that nourish our gut lining cells, reduce inflammation and help control appetite. A shortage of short-chain fatty acids has been associated with type 2 diabetes and other diseases. Many clinical studies also show that increasing dietary fiber intake could alleviate type 2 diabetes, but the effectiveness can vary due to the lack of understanding of the mechanisms, according to Zhao, who works in New Jersey Institute for Food, Nutrition, and Health at Rutgers-New Brunswick.

In research based in China, Zhao and scientists from Shanghai Jiao Tong University and Yan Lam, a research assistant professor in Zhao's lab at Rutgers, randomized patients with type 2 diabetes into two groups. The control group received standard patient education and dietary recommendations. The treatment group was given a large amount of many types of dietary fibers while ingesting a similar diet for energy and major nutrients. Both groups took the drug acarbose to help control blood glucose.

The high-fiber diet included whole grains, traditional Chinese medicinal foods rich in dietary fibers and prebiotics, which promote growth of short-chain fatty acid-producing gut bacteria. After 12 weeks, patients on the high-fiber diet had greater reduction in a three-month average of blood glucose levels. Their fasting blood glucose levels also dropped faster and they lost more weight.

Surprisingly, of the 141 strains of short-chain fatty acid-producing gut bacteria identified by next-generation sequencing, only 15 are promoted by consuming more fibers and thus are likely to be the key drivers of better health. Bolstered by the high-fiber diet, they became the dominant strains in the gut after they boosted levels of the short-chain fatty acids butyrate and acetate. These acids created a mildly acidic gut environment that reduced populations of detrimental bacteria and led to increased insulin production and better blood glucose control.

The study supports establishing a healthy gut microbiota as a new nutritional approach for preventing and managing type 2 diabetes.

(ScienceDaily)