Comparison of Diflunisal and Paracetamol for the Relief of Post-Episiotomy Pain

EPİZYOTOMİ AĞRISININ GİDERİLMESİNDE DIFLUNISAL VE PARASETAMOL'ÜN ETKİNLİĞİNİN KARŞILAŞTIRILMASI

A.Aydın ÖZSARAN*, M.Coşan TEREK**, İsmail M.İTİL***, Sermet SAĞOL***, M. Sait YÜCEBİLGİN****, Ucar ASENA****

* Yrd.Doç.Dr.,Egc Üniversitesi Tıp Fakültesi Kadın Hastalıkları ve Doğum AD,
** Asist.Dr.,Ege Üniversitesi Tıp Fakültesi Kadın Hastalıkları ve Doğum AD,
*** Uzm.Dr.T.ge Üniversitesi Tıp Fakültesi Kadın Hastalıkları ve Doğum AD,
**** Prof.Dr.,Ege Üniversitesi Tıp Fakültesi Kadın Hastalıkları ve Doğum AD, IZMIR

Summary

Objective: *To compare the analgesic efficacy of diflunisal and paracetamol in women requiring pain relief after episiotomy in a randomized study.*

Institution: *Ege University Faculty of Medicine, Department of Obstetrics and Gynecology, Izmir.*

Materials and Methods: *A total of 100 women requiring pain relief after episiotomv were enrolled in the study. The patients were randomized into two groups to receive either 1.5 g of paracetamol divided in equal three doses or lg of diflunisal divided in equal two doses daily. Pain intensity was assessed with pain relief scores 2, 6, 24, and 36 hours after the procedure and the mean pain score was calculated.*

Results: *The difference between the pain scores of patients taking paracetamol or diflunisal related to hours after the procedure was found to be statistically insignificant ([)>().05). The difference between the mean pain scores of patients taking paracetamol or diflunisal related to hours after the procedure was also found to be statistically insignificant (p>0.05).*

Conclusion: *Diflunisal was found to be as effective as paracetamol at this dosage regimen in the treatment of posl-episiotomy pain. Adverse reactions were rare, and acceptable with both drugs.*

Key Words: Paracetamol, Diflunisal, Episiotomy, Pain

T Klin J Gynecol Obst 1999, 9:233-236

Özet

Amaç: *Epizyotomi sonrası ağrının sağaltımında diflunisal ve parasetaınol'ün analjezik etkinliklerinin randomize çalışına biçiminde karşılaştırılması*

Çalışmanın Yapıldığı Yer. *Ege Üniversitesi Kadın Hastalıkları ve Doğum Aıiabilim Dalı, İzmir*

Materyal ve Metod: *Çalışmaya epizyotomi sonrası ağrısı olan 100 hasta alındı. Hastalar randomize olarak 50 hastalık iki guruba ayrılarak günde 1.5 g paracetamol üç eşil doza bölünerek veya günde 1 g diflunisal iki eşit doza bölünerek peroral verildi. Ağrı şiddeti ağrı skoru ile 2, 6, 24, 36. saatlerde değerlendirildi ve ortalama ağrı skoru hesaplandı.*

Bulgular: *Paracetamol veya diflunisal alan hastaların işlem sonrası saatlere göre hesaplanan ağrı skorları arasında istatistik olarak anlamlı fark saptanmadı(p>0.05). Parasetamol veya diflunisal alan hastaların işlem sonrası saatlere göre hesaplanan ortalama ağrı skorları arasında da istatistik olarak anlamlı fark saptanmadı(p>0.05).*

Sonuç: *Bıı sağaltım dozunda diflunisal ağrının giderilmesinde parasetamol kadar etkilidir. Yun etki her iki ilaç ile de düşük ve kabul edilebilir oranda görülmüştür.*

Anahtar Kelimeler: Parasetamol Diflunisal, Epizyotomi, Ağrı

T Kİin Jinekol Obst 1999, 9:233-236

Nonsteroidal anti-inflammatory drugs (NSAID) were used for more than 25 years to treat rhcumatologic diseases, were then introduced to relieve pain after tooth extraction, and finally about 10 years ago for postoperative analgesia. NSAIDs have been increasingly used over the past ten years in the treatment of postoperative pain, such that they now play an important role in the management of postoperative analgesia, either alone or combined with opioids (1). When used alone, they arc effective in relieving minor or moderate pain such

Geliş Tarihi: 29.12.1998

Yazışma Adresi: Dr.A. Aydın ÖZSARAN
Gime Bulv. No : 26/12 Eser Apt.
35530 Karşıyaka. İZMİR

as that seen after maxillofacial, minor orthopedic, or some ambulatory surgical procedures, and postpartum pain (episiotomy). In these indications, the main benefit as compared with opioids is the lack of respiratory 'depression, nausea and vomiting. Since these side effects delay discharge from the hospital, the use of NSAIDs may result in faster recovery and earlier discharge. Because of the ceiling effect of NSAIDs, their efficacy as sole agents is usually insufficient to treat pain after major surgery. NSAIDs should then be combined with opiods(2).

In this study the analgesic effect of two NSAIDs were compared with respect to relieving the post-episiotomy pain.

Method

A randomized trial was carried out in 100 women suffering from postepisiotomy pain in Ege University Faculty of Medicine Obstetrics Department between the dates of March 1997 and June 1998 to compare the analgesic efficacy of diflunisal and paracetamol. A hundred patients presenting with mediolateral episiotomy after the vaginal delivery were recruited. There were no other criteria for inclusion. The criteria for exclusion were unwillingness of the patient to participate, sensitivity to paracetamol or diflunisal, lacerations other than the episiotomy and episiotomy incision larger than 5 cm. The study was approved by the hospital's Ethics Committee and all patients gave written informed consent.

A total of 100 patients were enrolled in the study. The patients were randomized according to their hospital record number into two groups to receive either 1.5 g of paracetamol (Minoset-Roche) daily divided in equal three doses (Group A, n=-50), or 1 g of diflunisal (Dolphin-Sanovel) daily divided in equal two doses (Group B, n=50). Pain intensity was assessed with pain relief scores 2, 6, 24, and 36 hours after the procedure. In pain scale 0 stands for no pain, 1 for mild pain, 2 for moderate pain, and 3 for severe pain (3).The mean pain scores for both drugs were calculated as described by Bitsch et al (3). The obstetrician and the nursing staff caring for the patients postoperatively were unaware of which patients had received paracetamol or diflunisal. No other medication for analgesia was given to either group of patients. The side effects of the drugs were recorded. Pain scores related to hours and the mean pain scores were compared between groups using a Chi-Square test accepting PO.05 as significant.

Results

The number of patients according to the pain level and hours after the procedure for the drugs paracetamol (Group A) and diflunisal (Group B) were summarized in Table 1. The mean pain scores of patients taking paracetamol or diflunisal related to hours after the procedure was summarized in Table 2 and shown in Figure 1. The difference between the mean pain scores of patients taking paracetamol or diflunisal related to hours after the

Table **1.** Number of patients in pain scale related to hours after the procedure for paracetamol (Group A) and diflunisal (Group B)

	Group A				Group B			
pain scale	2nd hour[1]	6th hour[2]	24th hour[3]	36th hour[4]	2nd hour[1]	6th hour[2]	24th hour[3]	36th hour[4]
0	0	0		24	0	0	0	27
1	0	25	31	24	0	18	38	23
2	34	24	17	2	35	32	12	0
3	16	1	0	0	15	0	0	0

X-
ip=0.83
[2]P=0.20
[3]P=0.45
4P=0.44

Table 2. The mean pain scores related to paracetamol and diflunisal after the procedure

Hours after the episiotomy	Group A Paracetamol	Group B Diflunisal
2	2.30	2.32
6	1.64	1.52
24	1.24	1.30
36	0.46	0.56

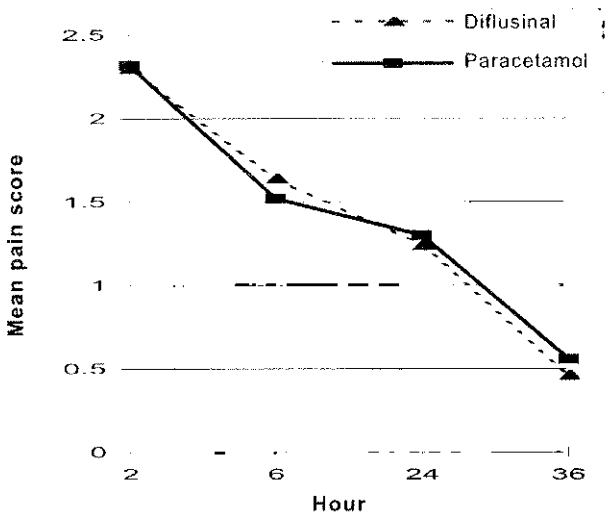

Figure 1. Mean pain sores of patients taking paracetamol or diflunisal related to hours after the procedure

procedure was found to be statistically insignificant (p>0.05). Nausea and vomiting was recorded in 6 patients using diflunisal and in 4 patients using paracetamol.

Discussion

Episiotomy is one of the most common surgical procedures performed by the obstetricians. The relief of post-episiotomy pain should necessarily be provided for the patient comfort and for the rapid return of patients to daily living. The incidence of pain after vaginal delivery or vaginal termination of pregnancy was also increased by the routine use of oxytocic agents for the involution of uterus, which should be discriminated from the episiotomy pain (4). In our study the location of the pain was asked to the patients with respect to the somatic nature of the episiotomy pain.

Van Winzum et al. (5) studied 740 patients complaining of pain after oral or orthopedic surgery or episiotomy comparing efficacy and safety of diflunisal with that of acetylsalicylic acid, glafenin or placebo and they found diflunisal to be effective in relieving postoperative pain in 75-85% of patients. No serious drug-related clinical or laboratory adverse experiences were encountered in their study.

Buck et al.(6) performed a double-blind study in women with post-episiotomy pain to compare the efficacy of 500 mg diflunisal twice daily, 65 mg dextropropoxyphene plus 650 mg paracetamol 3-times daily, and placebo. Their results as assessed by descriptive rating scales, showed that all three treatments were equally effective in relieving pain. De-Vroey et al.(7) carried out a double blind randomized trial in 161 primiparous women suffering from moderate to severe post-episiotomy pain to compare the analgesic efficacy of single doses of diflunisal (125 mg, 250 mg, of 500 mg), aspirin (600 mg), and placebo. The results of pain rating assessments made before and at hourly intervals after drug administration showed that both the active drugs were more effective than placebo and produced similar pain relief over the first 4 hours. The analgesic efficacy of aspirin tailed off after 4 hours but pain relief with 500 mg diflunisal was still evident after 8 hours. Over 65% of patients in the diflunisal group had effective relief of pain after 8 hours whereas there was no significant difference between the aspirin and placebo-treated groups by the seventh and eighth hour. Yalcin et al.(8) studied the efficacy of diflunisal in cancer pain and compared to dipyrone. Diflunisal was given at the dosage of 500 mg perorally twice a day, and dipyrone was given at the dosage of 500 mg perorally three times a day in 50 patients. Pain intensity was assessed by 10-point visual analog scale. Diflunisal reduced the pain score by a mean of 4.65+3.10, whereas dipyrone reduced the pain the pain score by a mean of 3.25 (p<0.001).

The finding of insignificant difference (P<0.05) between the mean pain scores of paracetamol and diflunisal related to hours after the procedure in our study shows diflunisal to be as effective as paracetamol in women with episiotomy pain. A twice day dosage schedule seems to be clinically adequate, 500 mg twice daily to be equally

effective as paracetamol 500 mg three times daily providing better patient compliance. However, regarding the cost; diflunisal is three times more expensive than paracetamol m our treatment regimen.

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