Original Article

The effect of diclofenac sodium and paracetamol on active and passive range of ankle motion after sprains

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ABSTRACT

Lyrtzis C, Papadopoulos C, Natsis K, Noussios G. The effect of diclofenac sodium and paracetamol on active and passive range of ankle motion after sprains. *J. Hum. Sport Exerc.* Vol. 6, No. 1, pp. 40-48, 2011. The purpose of this study was to evaluate the effect of a NSAID, Diclofenac sodium, and an analgesic, Paracetamol in the reduction of pain and in the passive and active range of ankle motion of severe sprains. Ninety patients, 18 to 60 years old, with severe acute ankle sprain were randomized in two groups. Group A (45 patients) were given Diclofenac sodium tabs 75 mg 2 times a day for the first 10 days. The patients in group B (45 patients) received Paracetamol tabs 500 mg, 3 times daily for the pain. The patients had no significant differences concerning their baseline values ($p>0.05$). The restriction of active and passive ankle range of motion was significant decreased in both groups on the 10th day in comparison to the arrival day ($p<0.05$). There were no significant differences found between the two groups ($p>0.05$). The pain decreased in both groups on the third day and the tenth day ($p<0.001$). According to these results, both Diclofenac sodium and Paracetamol had the same effect on pain reduction, on passive and active range of ankle joint motion after sprains during the first 10 post traumatic days. **Key words:** DICLOFENAC, PARACETAMOL, ANKLE RANGE OF MOTION.

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INTRODUCTION

Ankle sprains are common musculoskeletal injuries. The sprains of the lateral ligament account approximately 25% of all time lost from competition (Ashton-Miller et al., 1996). They are classified in three types according to injury severity, clinical symptoms and integrity of collateral ligaments. The symptoms vary among the three types from slight annoyance and edema (type I) to intense hematoma and pain accompanied with loss of function of the leg (type III) (Ivins, 2006). Rest, ice, compression with a bandage and elevation (RICE) still remain the treatment of isolated and uncomplicated cases.

The ankle sprain causes quite subtle joint stiffness and restricted range of motion (Beynnon et al., 2001; Denegar et al., 2002; Green et al., 2001). Ankle sprain causes significant pain and functional limitations. A normal range of motion is necessary before starting an aggressive strengthening, or returning to sport and old activities. As a consequence various treatment modalities have been applied for ankle sprains between institutions, but also among physicians of the same institution. The use of NSAID or Paracetamol are accepted in the treatment of ankle sprains with good results and bibliographic documentation (Edwards et al., 1984; Colville et al., 1999; Kayali et al., 2007).

While there are several studies that show a good effectiveness of NSAID against pain in ankle sprains, their effect on ankle range of motion after a sprain in the acute posttraumatic period has not been evaluated. The current study aimed to assess the influence of Diclofenac and Paracetamol on the restriction of passive and active ankle range of motion and additionally their influence on sprained ankle pain. To our knowledge, there are no similar studies in recent literature.

MATERIAL AND METHODS

In order to achieve our purpose we initiated a randomized control trial to 90 patients, mean age 34.7 (range, 18 to 60 years old) with unilateral severe acute type II sprains of the lateral collateral ligaments, who came to the emergency departments of our hospital within 24 h since the injury. All patients fulfilled the inclusion criteria. They did not receive analgesic drugs after the injury and their pain with the VAScale was measured more than 45 of 100. They had no fractures other injuries or preexisting ankle problems on both feet. They did not refer renal or hepatic insufficiency and they had not a medical history of gaster ulcus, lower limb thrombosis, diabetes mellitus, osteoporosis, chronic alcohol consummation or toxic. We did not include pregnant and psychiatric patients in our research. All patients were informed about the study and they gave their consent. The trial was in accordance with the ethical principles of Helsinki's Declaration.

Immediately after their arrival in our hospital, the patients were randomized in two groups with the assistance of a randomization computed program, concerning their treatment with Diclofenac sodium (group A) or with Paracetamol (group B). The drugs were given to the patients and they were instructed not to use other drugs during the treatment protocol. Additionally, all the patients were treated with the RICE protocol. Ankle bandage was applied and non weight bearing was proposed for 10 days to all patients, as well as elevation of the leg for the first three days (Wolfe et al., 2001). The bandage was removed provisionally on the third day for the measurements. The patients were encouraged to start walking after ten days. In group A (45 patients) for the first 10 days received Diclofenac sodium tabs 75 mg was prescribed, 2 times daily for the first 10 days. The patients of the group B (45 patients) received Paracetamol tabs 500 mg, 3 times daily. All patients were blinded to treatment group. Written instructions were given to the patients about the use of the drugs, the RICE protocol and the follow up period.

Three patients who were treated with Diclofenac sodium had stomach-ache and interrupted their treatment protocol within the first 3 days. One patient from group B was lost to the final follow-up, as well. Finally, 42 patients constituted the group A and 44 patients constituted group B. In follow-up period of the two groups we evaluated the difference of the ankle joint range of passive and active motion in comparison with the non sprained ankle in degrees between the fibula head, the lateral malleolus and the head of the fifth metatarsal, as well as the pain of the joint with the Visual Analogue Scale (VAScale). The above parameters were evaluated in the two groups at the time of patients' admission and at the 3rd and 10th posttraumatic day.

The ankle joint range of motion was measured in degrees between the fibula head, the lateral malleolus and the head of the fifth metatarsal. These landmarks were marked by using a black permanent pointer. We measured the ankle range of motion in maximal active and passive, plantar and dorsal flexion, on both feet. The patients were in supine position with their knees in 90 degrees flexion. The passive and active range of motion from plantar to dorsal flexion, of the sprained ankle was performed in both positions. The passive range of motion was measured, when the patient felt pain. Still images were recorded in these positions, on a tripod-mounted digital photo camera located perpendicular to the subject, approximately 2 m away from the ankle. They recorded images of both ankles. We analysed later the angle between the landmarks with the use of angle analysis triangular screen MB-Ruler-4.0 software, which helps to measure distances and angles on a screen (Figure 1).

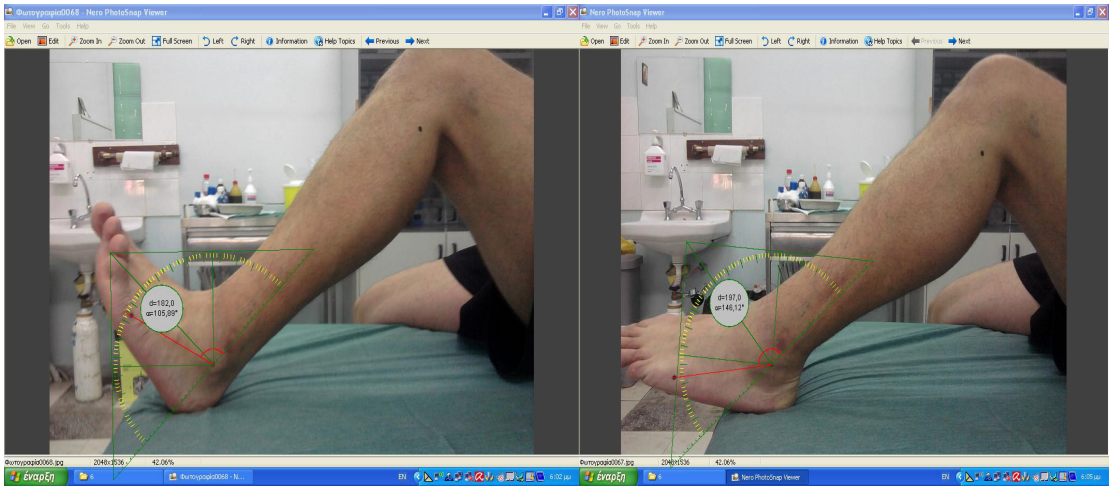

Figure 1. *Measurement of the angle in active dorsal and plantar flexion.*

The VAS is a scale which is used to evaluate pain. We asked patients to evaluate their pain on a scale between 0 and 100 (Boonstra et al., 2008). The evaluation of the pain with VAScale was performed during patient's fullweightbearing on both feet.

The measurements were performed by the same person, who didn't know about the participant's treatment group. All data were calculated with the statistical program SPSS 17.0. The variables had normal distribution and their comparisons were made by the use of parametric tests. The level of statistical significance for all tests was set at $p<0.05$. The characteristics of the patients of the groups before treatment were compared with the use of parametric Student's t-test. The same test was used to determine the significance of differences in restriction of ankle passive and active range of motion and VAScale at the third and tenth posttraumatic day. The parametric Paired sample student's t-test was used to determine the significance of differences between the baseline values and the values of the third and the tenth post traumatic day.

RESULTS

Eighty six patients completed strictly our treatment protocol. Finally, group A and group B constituted from 42 and 44 patients, respectively. Their age ranged from 18 to 60 years old (mean age, 35.17 years). The time period between the trauma and the arrival at the hospital ranged from 1 to 17 hours (mean time, 3.19 hours). The two groups had no significant differences concerning their baseline values (Table 1).

Table 1. *Patients baselines values.*

	Diclofenac sodium group	**Paracetamol group**	**p value**
Patient number	42	44	-
Age (mean)	35.67	34.75	0.393
Males (%)	66.6	61	0.642
Time to hospital (mean)	3.07	3.38	0.641
Ice use before arrival (%)	53.8	48.2	0.656
Range of active sprained ankle motion (°)	51.1	50.7	0.489
Range of active non sprained ankle motion(°)	67.3	67.2	0.898
Range of passive sprained ankle motion(°)	56.3	56.5	0.865
Range of passive non sprained ankle motion(°)	70.2	71.1	0.642
Pain (VAScale)	70.2	72.5	0.568

In two groups, the pain measured with the VAScale exhibited a significant difference from the baseline value at the third day *(*p<0.000) and at the tenth day after the injury (p<0.000) with the Paired sample student's t-test (Table 2).

Table 2. *Parameters values of two groups in different time intervals.*

		Injury/3rd day (p value)	Ingury/10th day (p value)
Restriction of active ankle range of motion	Diclofenac	16.2/14.6 (p=0.167)	16.2/3.8 (p=0.011)
	Paracetamol	16.5/14.8 (p=0.134)	16.5/4.1 (p=0.017)
Restriction of passive ankle range of motion	Diclofenac	13.9/10.2 (p=0.158)	13.9/2.5 (p=0.027)
	Paracetamol	14.6/10.8 (p=0.151)	14.6/2.9 (p=0.029)
VAScale pain	Diclofenac	70.2/20.05 (p<0.000)	70.2/6.92 (p<0.000)
	Paracetamol	72.5/22.30 (p<0.000)	72.5/5.12 (p<0.000)

In two groups, the restriction of the passive and active ankle range of motion did not exhibit significant differences from the baseline value at the third day *(*p>0.05), but significant at the tenth day after the injury (p<0.05) with the Paired sample student's t-test (Table 2).

The comparison of the restriction of the ankle passive range of motion measured in degrees at the 3rd posttraumatic day between the two groups resulted in non statistical significant differences. More specifically, the comparison of this variable at the 3rd day with the Student's t-test showed no significant differences between the two groups (p=0.341). Also, the comparison of the same variable at the 10th day with the same statistical test resulted in non statistical significant differences between the two groups (p=0.374) (Table 3).

The comparison of the restriction of the ankle active range of motion measured in degrees at the 3rd posttraumatic day between the two groups showed no significant differences. The comparison of this variable at the 3rd day with the Student's t-test showed non statistical significant differences between the two groups (p=0.560). The comparison of the same variable at the 10th day with the same statistical test resulted in non statistical significant differences between the two groups (p=0.335) (Table 3).

We also compared the two groups for the pain improvement. The Student's t-test was used for the comparison of this variable at the 3rd day (p=0.934) and at the 10th posttraumatic day (p=0.301). According to these results, we concluded that Diclofenac sodium had the same influence on the reduction of the posttraumatic pain and on the restriction of the passive and active range of motion of an ankle joint sprain with Paracetamol (Table 3).

Table 3. *Comparison between groups in ankle pain, restriction of the passive and restriction of active range of motion.*

		Diclofenac Group (Sd)	Paracetamol Group (Sd)	p value
Restriction of the active range of ankle motion	3rd day	14.6 (3.8)	14.8 (4.3)	0.560
	10th day	3.8 (2.8)	4.1 (2.7)	0.335
Restriction of the passive range of ankle motion	3rd day	10.2 (2.1)	10.8 (2.1)	0.341
	10th day	2.5 (1.7)	2.9 (1.5)	0.374
VAScale pain	3rd day	22.05 (12.81)	22.30 (14.41)	0.934
	10th day	6.92 (8.32)	5.12 (6.83)	0.301

DISCUSSION AND CONCLUSION

Ankle sprains constitute common injuries. The most frequent type is caused by inversion trauma. The sprains of the lateral ligament account approximately 25% of all time lost from competition (Ashton-Miller et al., 1996). There is lack of evidence as far as the treatment is regarded. The treatment of acute ankle sprain aims to immediately decrease pain and swelling and to protect ankle ligaments from further injury (Safran et al., 1999).

RICE protocol is the most effective treatment choice for ankle sprains. It seems that the use of NSAID or analgesics in acute ankle injury has satisfactory results, as well (Slatyer et al., 1997; Boyce et al., 2005). However, there are no studies that evaluate the effect of NSAID on the improvement of the restriction of the ankle passive and active range of motion following ankle sprain. Inadequate treatment of ankle sprains can lead to chronic problems such as decreased range of motion, pain, and joint instability (Wolfe et al., 2001).

The principal aim of our study is to evaluate the effect of Diclofenac sodium and Paracetamol in the improvement of the restricted passive and active ankle range of motion and pain following ankle sprains. Our results showed that Diclofenac sodium tabs 75 mg, 2 times a day, wasn't more effective in reducing the pain to the patients suffering from ankle sprains than paracetamol at the 3rd and 10th post-traumatic day. This study constitutes the first randomized clinical control trial which evaluates the influence of these drugs not only on the pain, but also the improvement of the restricted ankle range of motion the third and tenth day after the injury.

NSAID have anti-inflammatory, analgesic, and antipyretic effects and inhibit thrombocyte aggregation (Gotzsche., 2000). Their action mechanism caused by the blocking of prostaglantins production from arachidonic acid. This results to the decrease of inflammatory response. They are also effective on the healing of ligaments (Dahners et al., 1988). Their negative effects are the tissue damage through leukotriene increase, the hypertension, the altered renal function, the symptoms from gastrointestinal tract, increased blood clotting times, because of reduction on platelet aggregation and the increased percentages of myocardial infraction (Bahamonde & Saavedra, 1990; Schafer, 1995; Garcia-Rodriguez et al., 1998; Paolini & Orchard , 2005; Hippisley-Cox & Coupland, 2006).

The indication of NSAID in acute ligament sprains is for short term use and for analgesia. Other studies showed that NSAID had the same influence on the reduction of the posttraumatic pain of ankle joint sprain with the paracetamol (Dahners et al., 1988; Ogilvie Harris & Gilbart., 1995). Paolini and Orchard (2005), found that Paracetamol has similar effect with NSAID in soft tissue injury and it is cheaper for the treatment of soft tissue injuries. Other non steroid antiinflamatory drugs, like Cyclooxygenase selective inhibitors, Ibuprofen and acetaminophen were found to have similar effect in ankle sprains treatment (Andersson et al., 1983; Yepes et al., 2002; Nadarajah et al., 2006). On the other hand, Bahamonde and Saavedra (1990), found that diclofenac sodium has stronger effect than piroxicam and paracetamol in the reduction of pain in patients with ankle sprain.

In our study we measured the restriction of the sprained ankle joint range of motion, in comparison with the non sprained ankle. In many studies the authors used the measurement of the ankle dorsiflexion (Nield et al., 1993; Pellow & Brantingham, 2001; Fryer et al., 2002). Moselay and Adam (1991) used a photographic still for the angle measurement. Although goniometers are the simplest tool available, it is established that photography significant increased accuracy of measurement compared to a goniometric method (Fish & Wingate, 1985). In our study the improvement of the ankle passive and active range of motion was similar in both groups.

Kayali et al. (2007) observed increase of the ankle range of motion, but on the 6th week. Slatyer et al. (1997) compared Piroxicam with placebo after ankle sprains and they found a decrease of the range of motion in patients treated with Piroxicam. Dalton and Schweinle (2006) evaluated acetaminophen and ibuprofen for the treatment of ankle sprains, but the range of motion and other parameters were similar.

According to the results of our study, Diclofenac sodium had not any significant difference in comparison to Paracetamol in relieving the acute pain and in improving the restriction of the passive and active range of motion following ankle injury. Furthermore, the improvement of the restricted passive and active range of motion was similar to the patients who were treated with Diclofenac sodium and the patients who were treated with Paracetamol. Our results refer to the early posttraumatic period and can not be generalized for the posttraumatic restriction of ankle range of motion at the late posttraumatic period.

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