Efficacy of Diclofenac in Lateral Epicondylitis of the Elbow Also Treated With Immobilization

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Objective: To evaluate the efficacy of an oral nonsteroidal anti-inflammatory drug in the treatment of lateral epicondylitis.

Design: Multicenter double-blind randomized controlled trial in which the following hypothesis was tested: whether diclofenac sodium provided a 20% or greater improvement over rest and cast immobilization in the response rate to treatment of lateral epicondylitis beyond and over rest in an experimental group compared with a control group after 4 weeks of treatment.

Setting: Recruitment from urban general practices and referrals to 4 university hospitals.

Subjects and Methods: During a 1-year period, 206 subjects aged 18 to 60 years with lateral epicondylitis were recruited from the clientele treated by family physicians. Thirty subjects refused to participate and 47 presented with exclusion criteria, leaving 129 subjects who entered the study. One subject withdrew after 21 days.

Interventions: The experimental group was treated with a daily dose of diclofenac sodium (150 mg) for 28 days, while the control group received a placebo during the same period. In addition, both groups were immobilized in a cast for 14 days and were told not to perform repetitive movements of the involved limb for 21 days.

Main Outcome Measures: Measuring instruments consisted of grip strength measurements with a squeeze dynamometer, a visual analog pain scale, a visual analog function scale, and an 8-item pain-free function index.

Results: A statistically and clinically significant reduction of pain was associated with treatment with diclofenac, but no clinically significant difference in grip strength or functional improvement could be detected between the 2 groups. Secondary effects (diarrhea and abdominal pain) were significantly more frequent in the diclofenac-treated group.

Conclusion: Taking into account the limited improvement noted over rest and cast immobilization and the number of associated adverse events, it is difficult to recommend the use of diclofenac in the treatment of lateral epicondylitis at the dosage used in this study.

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LATERAL epicondylitis (LE) or "tennis elbow" is a common clinical syndrome and has a significant impact in terms of morbidity and financial cost both for the health care system and the patient. In Sweden, the prevalence rate ranges from 1% to 3%, increasing up to 19% for men between 40 and 50 years of age.[1] The disease (or syndrome) occurs mainly among people whose occupation requires repetitive movements of the forearm and hand. For example, 7.4% of industrial workers and 40% to 50% of tennis players in the United States are at some time in their lives affected by the disease.[2]

An impressive number of studies have been published on LE, since the first clinical description of its pathological features by Runge[3] in 1873. Review articles have reported more than 40 different treatments of LE used either alone or in combination (eg, anti-inflammatory medications, steroid injections, various methods of physical therapy, cast immobilization

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or orthoses, surgery, and less conventional methods [radiotherapy, acupuncture, and vitamins]). In a critical review[4] of the English and French medical literature on the treatment of LE, we concluded that because of the poor quality and contradictory results of the randomized

SUBJECTS AND METHODS

INCLUSION CRITERIA

To study a valid sample of the general population afflicted with LE, all subjects included in the study were recruited from urban general practices. A letter that asked for collaboration with the project was sent to all family physicians (N=2000) of the metropolitan area of Montreal, Quebec, at the beginning of the trial. Subsequently, during a 13-month period, we received 1 or more referrals from 60 family physicians. The study protocol was approved by the ethics committees of all participating institutions. We included all subjects aged between 18 and 60 years who presented with a painful lateral elbow syndrome with the following characteristics: (1) pain on palpation of the epicondyle and/or the common extensor mass of the elbow, (2) pain elicited by the dynamic test of wrist pronation and dorsiflexion against resistance with the elbow in extension, (3) pain reproduced by static stretching of the pronated wrist in palmar flexion with the elbow in extension, and (4) normal anteroposterior and lateral x-ray films of the elbow.

EXCLUSION CRITERIA

All subjects who presented with 1 or more of the following problems were excluded from the study: (1) a history of polyarthralgia in the month that preceded recruitment, (2) any history of cervical or cervicobrachial pain, (3) any wound or skin lesion on the lateral side of the involved elbow, (4) a history of steroid intake in the 6 weeks that preceded recruitment, (5) a history of NSAID intake in the 3 weeks that preceded recruitment, (6) any limitation in the range of motion of the elbow, (7) paresthesia in the territory of the superficial radial nerve, (8) bilateral epicondylitis, and (9) any contraindication to NSAID intake.

THERAPEUTIC INTERVENTION

Each potential subject referred by a family physician was evaluated within 3 days by an orthopedic surgeon at 1 of 4 collaborating hospitals in the Montreal area. Inclusion and exclusion criteria were verified at the initial visit, and an informed consent form was signed by all volunteers. A log that was devoid of any confidential information was kept with the reasons for rejection of all eligible subjects who were excluded or unwilling to participate. All subjects were evaluated at 14 (visit 2), 21 (visit 3), and 28 (visit 4) days after the baseline evaluation (visit 1).

The experimental group received the following treatment: (1) immobilization of the involved upper limb with a long-arm cast that maintained the elbow at 90° flexion and the forearm and wrist in a neutral position for 14 days and (2) a daily dose of diclofenac sodium (150 mg) in a slow-release form for 28 days (Voltaren, 75 mg twice daily). The control group received the following treatment: (1) cast immobilization as for the experimental group and (2) a placebo given twice daily for 28 days. The medication and the placebo were available as pills of identical shape, taste, and color prepared by the manufacturer and delivered in identical containers of 56 pills that were identified only by a code number. The key to the code numbers was kept by the manufacturer, and a sealed copy was available to 1 investigator (R.G.) for emergency purposes. The collaborating orthopedists, the subjects, and the research assistant did not know what type of medication was being given to the subjects. Allocation of the subjects to the experimental or control group was done by block randomization in 4 groups (ie, 1 for each participating hospital). The order of allocation was preestablished with a table of random numbers.

All participants were kept away from any activities that involved repetitive movements of the wrist or elbow during the first 3 weeks of treatment. Cast immobilization was removed at 14 days when the subjects were instructed to resume activities of daily living but to avoid "at-risk" activities. Subjects were not allowed to take any other medication for LE, and the ingestion of medication for other purposes was recorded and taken into account in the statistical analysis. At each visit, all variables were monitored by an independent research assistant who was not involved in the treatment process and, as stated above, completely blinded as to the subject's treatment group.

and controlled trials that have been reported so far in the literature, there has not been sufficient scientific evidence to favor any particular type of treatment of LE.

The purpose of this study was to evaluate the efficacy of an oral nonsteroidal anti-inflammatory drug (NSAID), which is one of the most frequent types of treatment prescribed for LE. Diclofenac sodium was arbitrarily chosen to represent an NSAID because of its current popularity among physicians, its single dosage recommended for all patients by the manufacturer, and its availability in a slow-release form. The following hypothesis was tested with a multicenter double-blind randomized trial: diclofenac provides a 20% or greater improvement in the response rate to treatment of LE beyond and over rest and cast immobilization compared with a control group after 4 weeks of treatment.

A 20% improvement of the response rate to treatment was considered to be sufficient to justify its clinical use, taking into account the possible side effects and complications of the medication by the group of orthopedic surgeons who collaborated on this trial.

RESULTS

A total of 206 subjects were referred for evaluation at 1 of the participating hospitals. Thirty subjects declined participation in the trial for the following reasons: 25 subjects did not want cast immobilization, 4 could not come back for the scheduled visits, and 1 subject refused treatment with an NSAID. A further 47 subjects were excluded because 1 or more exclusion criteria were detected, leaving 129 subjects to be included. A total of 128 patients completed the study, and 1 subject withdrew at 21 days because of secondary side effects.

The sample included 59 women and 69 men, with a mean age of 43.7 years (age range, 22-59 years), a mean

MEASURING INSTRUMENTS

All measuring instruments that were utilized in this study have been previously validated for LE[5,6] and were used at each visit as follows:

1. The maximum pain-free grip strength (MPFGS) was expressed in kilograms, as measured by a squeeze dynamometer (JAMAR, TEC, Clifton, NJ) with the elbow at 90° of flexion. The mean of 3 trials at 20-second intervals was kept.
2. The ratio of the MPFGS of the affected side over the normal side (ie, the MPFGS ratio) was determined. This ratio allows normalization of raw values to eliminate variations due to sex, weight, height, and similar covariables.
3. The maximum grip strength (MGS) was expressed in kilograms, as measured by a squeeze dynamometer (JAMAR) with the elbow at 90° of flexion. The mean of 3 trials at 20-second intervals was kept.
4. The ratio of the MGS of the affected side over the normal side (ie, the MGS ratio) was determined.
5. A vertical analog pain scale of 100 mm was used, on which subjects were asked to rate their pain level (scale range, 0 [no pain] to 100 [maximal pain] mm).
6. A vertical visual analog function scale of 100 mm was used, on which subjects rated the functional level of their upper limb (scale range, 0 [no function] to 100 mm [normal function]).
7. An 8-item pain-free function index measured the presence or absence of discomfort in the following activities of daily living: dressing, eating, washing, cleaning the house, opening a door, lifting an object, working, and practicing sports or normal activities.

The MPFGS was chosen as the prime indicator of treatment efficacy since it has been shown to be the most sensitive instrument to change, as well as being a relatively stable measure.[6] Finally, information on the number of days missed from work and on recurrence of symptoms was obtained from a telephone interview 3 months after the end of treatment.

STATISTICAL ANALYSIS

The trial was ended when a sample of 128 subjects completed the study. It had been calculated that a sample size of 126 (63 per group) would be necessary to detect a mean difference of 5 kg in the MPFGS between the 2 treatments, with a statistical power of 80% and a type I error of 0.05. The difference of 5 kg was chosen for the following reasons: First, it is greater than the reported interrepetition (repeated measurements obtained at the same session) and interoccasion (measurements obtained on different days) reliability of the measurement method.[6] Second, according to the data reported by Stratford and colleagues,[7] this difference in favor of the experimental group would be necessary to raise the success rate by 20% between the 2 groups—a change that was considered to be sufficient to justify the prescription of an oral NSAID, taking into account the known side effects due to the medication. The following independent variables were considered in the analysis: age, sex, weight (kilograms), height (centimeters), treatment, hospital, duration of symptoms (acute vs chronic), dominance, side that was affected, practice of a racket sport, history of a work-related accident, presence of another disease, other medication, accurate or inaccurate guessing of the medication that was taken, type and frequency of side effects, and the number of pills that was taken. Standard univariate analyses were performed on the independent variables, on the 7 previously listed measuring instruments, both at baseline and at 28 days, and on the change (difference) in the values of these measuring instruments between baseline and 28 days. Clearly, this change for each instrument constitutes the set of outcome variables. The relationship between independent variables (eg, treatment) and outcome was studied first by a series of bivariate analyses with the use of the Student t or χ^2 test, as appropriate. Furthermore, to correct for potential confounders, each outcome (change) was treated as the response variable in a stepwise ordinary regression, including the following covariables: treatment, values at baseline of the measurement instrument (forced in), and the other previously listed independent variables. This is equivalent to a repeated-measures analysis of variance with covariable adjustment. Stepwise logistic regression was also used to build a prediction model for the occurrence of side effects.

weight of 70 kg (weight range, 42.6-104.3 kg), and a mean height of 167.2 cm (height range, 139.7-191 cm). On entry in the trial, 55 subjects (43.3%) presented with acute LE, which was defined as having symptoms for less than 6 weeks; 56 (44.1%) presented with chronic LE, which was defined as having symptoms for more than 6 months. Eighty-nine percent of the sample were right-handed and the dominant side was affected in 72%. The majority (81.2%) of the subjects were not involved in racket sports. A work-related accident was reported by 37% of the subjects, and another disease was present in 25% of the sample. Thirty-nine subjects were taking 1 or more medications at entry in the study.

Sixty-four subjects were randomized to each treatment group. The randomization process was successful since we could not detect any significant difference between the 2 groups for any of the previously mentioned dependent and independent variables, except for the visual analog function scale values for which a significant (P=.03) difference was found. For this variable, the experimental group was slightly more affected than the control group (mean±SD, 43±24 vs 53±27 mm). **Table 1** and **Table 2** provide the mean values with SDs for all dependent variables that were measured in the study.

MAXIMUM PAIN-FREE GRIP STRENGTH

The MPFGS improved significantly for all subjects by 5.9 kg after 28 days (P<.001). There was no statistically significant difference in improvement between the diclofenac-treated (7.2 kg) and placebo-treated (4.6 kg) groups. When controlling for other covariables in a multiple linear regression, diclofenac and male gender were associated with a greater improvement, whereas chronic LE, a history of a work-related accident, and adequate guess-

Table 1. Results of Measurements for Dependent Variables*

Variable	Mean±SD			P
	Baseline	28 d	Difference	
Maximum pain-free grip strength, kg	20.8±12.9	26.8±13.6	5.9±10.0	<.001
Ratio of maximum pain-free grip strength	0.59±0.29	0.73±0.24	0.15±0.27	<.001
Maximum grip strength, kg	28.6±14.0	31.3±13.6	2.6±7.8	<.001
Ratio of maximum grip strength	0.80±0.26	0.86±0.20	0.06±0.23	<.05
Visual analog pain scale	59.8±22.0	36.6±28.1	−23.0±27.6	<.001
Visual analog function scale	48.0±25.8	68.2±24.9	20.2±28.3	<.001
Pain-free function index	6.9±1.5	4.0±2.8	−2.8±2.8	<.001

**Results are given for dependent variables at baseline, 28 days, and the difference between the 28-day and baseline values.*

ing of group allocation were associated with less improvement.

MPFGS RATIO

This variable displayed a significant improvement of 14% between baseline and 28 days for the entire sample ($P<.001$). Bivariate and multiple linear regression analyses did not reveal any significant difference in improvement between the diclofenac- and placebo-treated groups.

MAXIMUM GRIP STRENGTH

For the entire sample, the MGS increased significantly at 28 days by an average of 2.6 kg. A comparison of the diclofenac- and placebo-treated groups revealed no significant difference. However, with multiple linear regression, LE involvement of the dominant side, heavier patients, and diclofenac were significantly associated with greater improvement.

MGS RATIO

There was a significant improvement of this ratio in the entire sample from a baseline value of 0.8 to 0.86 at 28 days ($P<.05$). As presented in Table 2, there was also a significant difference with respect to treatment, with the diclofenac-treated group presenting an average increase of 10% compared with 2% for the control group ($P<.05$). This was further supported by findings from the multiple linear regression analysis, with the diclofenac-treated group and LE involvment of the dominant side displaying greater improvement.

VISUAL ANALOG PAIN SCALE

For the entire sample, this variable significantly decreased by 23.0 mm from 59.8 mm at baseline to 36.6 mm at 28 days ($P<.001$). The decrease in pain was significantly greater in the diclofenac-treated group at 28 days ($P<.005$) than for the placebo-treated group (29.9 vs 16.0 mm). This was confirmed by results of the multiple linear regression analysis in which treatment was the only significant variable that was identified to explain the variance observed between the 28-day and baseline values.

Table 2. Results of Differences Between Values*

Variable	Treatment Group, Mean±SD		P
	Placebo	Diclofenac Sodium	
Maximum pain-free grip strength, kg	4.6±10.1	7.2±9.8	.20
Ratio of maximum pain-free grip strength	0.11±0.27	0.18±0.26	.12
Maximum grip strength, kg	1.3±7.2	3.9±8.2	.30
Ratio of maximum grip strength	0.02±0.21	0.10±0.24	<.05
Visual analog pain scale	−16.0±27.4	−29.9±26.3	<.005
Visual analog function scale	21.8±27.6	18.5±29.1	.10
Pain-free function index	−2.4±2.8	−3.3±2.8	.52

**Results of differences between values at 28 days and baseline for the 2 treatment groups.*

VISUAL ANALOG FUNCTION SCALE

A significant improvement was found for the entire sample from 48.0 mm at baseline to 68.2 mm at 28 days ($P<.001$). On the other hand, there was no difference in improvement with respect to treatment after 28 days ($P=.10$). This finding was confirmed by use of the multiple linear regression analysis, which did not reveal any significant variable.

PAIN-FREE FUNCTION INDEX

This index significantly improved ($P<.001$) from 6.9 at visit 1 to 4.0 at 28 days, with a score of 8 meaning no function and a score of 0 denoting full function for activities of daily living. This improvement was not significantly different between the 2 treatment groups ($P=.52$), and multiple linear regression analysis revealed only 1 significant factor that explained some of the variations observed between 28-day and baseline values, with the presence of a work-related accident being associated with a smaller improvement.

The number of days missed at work because of LE, at 3 months following the end of treatment, was 23 days. There was no significant difference ($P=.35$) between treatment groups with respect to this variable. Fifty subjects in the population presented with a recurrence of symptoms at this period (23 in the experimental group and 27 in the control group); this was a nonsignificant difference ($P=.52$).

One or more adverse events were noted in 55% of the population at 14 days, 35% at 21 days, and 30% at 28 days. **Table 3** details the type and number of adverse events at 14 days. Two were encountered with

a surprising frequency: abdominal pain and diarrhea. One subject who was treated with diclofenac withdrew from the study at 21 days because of diarrhea. Stepwise logistic regression analysis revealed that the odds ratio (OR) (relative risk) for a subject to present with diarrhea at 14 days was 2.99 in the diclofenac-treated group compared with the placebo-treated group (confidence interval [CI], 1.34-6.71). For abdominal pain, the OR was 3.73 for subjects who were treated with diclofenac at 14 days compared with the control group (CI, 1.53-9.13).

In general, 52% of the sample ingested all 56 pills at the end of the study and 80% of subjects ingested 50 or more pills. The average number of noningested pills per patient was 3.2 (range, 0-34 pills). There was a significant difference ($P=.02$) for the number of noningested pills at 28 days between the placebo-treated group (1.9 pills) and the diclofenac-treated group (4.6 pills [7.4]). Compliance to cast immobilization was 100%.

Table 3. Type and Number of Patients With Secondary Effects at 14 Days in the 2 Treatment Groups*

	Treatment Group, No. of Patients	
Variable	Placebo	Diclofenac Sodium
Headache	4	2
Vertigo	0	3
Visual problem	0	2
Palpitations	0	1
Abdominal pain	6	19
Diarrhea	13	25
Itching	5	2
Urticaria	0	2
Other	16	18

*No patient had jaundice, bloody stools, or asthma.

COMMENT

To our knowledge, only 3 controlled studies that compared oral NSAIDs in the treatment of LE have been reported in the literature. None of these revealed any significant differences among the various NSAIDs that were examined. More specifically, Adelaar et al[1] compared naproxen with diflunisal in 18 patients, Rosenthal[8] studied piroxicam vs flurbiprofen in 50 subjects, and Saartok and Eriksson[9] compared naproxen with steroid injections in 21 patients. Only the study by Rosenthal[8] demonstrated a significant difference ($P<.001$) in outcome before and after the anti-inflammatory treatment. Taking into account, the small sample size of these studies and the absence of any published placebo-controlled trial, we thought that the therapeutic value of an oral NSAID was presently unknown.

The sample included in our study represented the general population affected by LE in a large urban community since recruitment came from general practices and not from a clientele referred to second- or third-line specialists. Voluntary recruitment in the trial was good, with only 1 withdrawal and 30 refusals, of 206 eligible subjects. The sample size (n=128) was sufficient to verify our hypothesis with a statistical power of 80%. The randomization process was successful, and both treatment groups were similar for baseline values. The double-blind trial was also strictly respected, and the research assistants, collaborating orthopedists, and patients were not informed of the medication that was received during the trial. The measuring instruments have all been previously validated and shown to be both sensitive and stable.[5] Observance to treatment was adequate although there were significantly fewer pills ingested in the experimental group than in the control group, possibly reflecting the greater incidence of abdominal pain and diarrhea in the experimental group. Although these side effects might have potentially revealed the treatment group to some subjects, it should be noted that they were also present in the placebo-treated group in a significant number of cases and that the correct guessing of the treatment received was not significantly different in both groups.

With these considerations in mind, is dicolfenac a valuable therapy for LE? First, it should be reiterated that for all variables measured between baseline and 28 days, there was a highly significant improvement noted whatever the treatment received. This improvement can only be explained by a placebo effect, by the natural history of the disease that tends to improve with time and rest, and by the therapeutic effect of cast immobilization. It should be remembered that our study protocol reflects the effect of diclofenac over and above rest and cast immobilization.

For the most part, our hypothesis has not been verified since we have not detected a 20% improvement (a 5-kg increase) in the response rate to treatment of MPFGS, which was our primary outcome variable. Although treatment with diclofenac was identified as a significant variable that explained the changes observed between baseline and 28 days, the difference of 2.6 kg between the 2 groups is not clinically significant, considering that the normal average values of grip strength in women and men are, respectively, 25.5 and 49 kg in the age group between 40 and 44 years.[10] The same findings and arguments can be applied to the other measures of grip strength. Although the improvement noted in the experimental group compared with that in the placebo-treated group is statistically significant, the changes observed are still too small to be of clinical significance.

On the other hand, the improvement in pain that was noted with the visual analog pain scale is both statistically and clinically significant. It is twice as large as that in the experimental group, and it is a 30% improvement magnitude over baseline values. This analgesic effect of diclofenac is certainly valuable in the treatment of LE, but it is not sufficient to produce a significant improvement in the function of the affected limb as measured by the visual analog function scale or the pain-free function index. Whether the observed effect of diclofenac on pain is mediated through an anti-inflammatory effect or is simply analgesic remains to be determined.

As a secondary indicator of functional status, there was no change in the number of days missed at work be-

tween the 2 treatment groups, 3 months after the end of the trial. Finally, we have no explanation for the higher frequency of abdominal pain and diarrhea in the experimental group. It is not known if this effect is dose-related since a single dosage was used for all patients in this trial, as suggested by the manufacturer.

CONCLUSIONS

A number of interesting conclusions can be drawn from this trial that has studied the benefits of diclofenac over rest and immobilization in the treatment of tennis elbow: (1) Diclofenac produces a significant reduction in pain when compared with a placebo. (2) Diclofenac does not produce a clinically significant improvement of grip strength or function of the involved upper limb when compared with a placebo. (3) Diclofenac does not significantly decrease the number of days missed at work, 3 months after the end of treatment. (4) There is a time-related significant improvement in pain, grip strength, and function of the upper limb that is independent of the treatment received. This improvement can only be explained in 3 ways: it can be due to a placebo effect, to cast immobilization and rest, or to the natural history of the disorder associated with rest.

Based on these findings and on the number of side effects noted during the trial, we do not recommend the use of diclofenac in the treatment of LE at the dosage prescribed in this trial. Use of a smaller dose may be worthwhile to provide analgesia in LE, but not for functional improvement. Finally, we strongly suggest the pursuit of other clinical evaluative studies on the currently used different treatments of LE.

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Clinical Pearl

Vitamin E supplements were associated with decreased progression of known heart disease for those patients receiving other lipid-lowering therapy (*P*=.02). (*JAMA.* 1995;273:1849-1854.)