

# Acute Low Back Pain

## Symptomatic Treatment with a Muscle Relaxant Drug

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**Abstract:** The aim of this work was to evaluate in a double-blind controlled study the effect of a pure muscle relaxant drug (dantrolene sodium) in the symptomatic treatment of uncomplicated acute low back pain in 20 patients. The one capsule daily dosage (25 mg) was given for 4 days. Patients treated with dantrolene sodium obtained an improvement of muscle contracture ( $p < 0.001$  versus placebo), VAS pain measurement, and pain behavior (both  $p < 0.001$  versus placebo). The electromyogram (EMG) parameters (i.e., the antalgic reflex motor unit firing) improved in the treated group ( $p < 0.01$  versus placebo). Data show the possibility of treating uncomplicated acute low back pain with a pure muscle relaxant. Some basic physiopathological aspects of low back pain are also discussed. **Key Words:** Dantrolene sodium—Low back pain—Muscle relaxant.

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Statistical studies carried out in Europe and America have shown that 80% of the population have experienced one or more episodes of acute low back pain during their lifetime, consequently emphasizing the social relevance of this pathology (1-5). Nevertheless, the fact that there are so many different approaches to the treatment of low back pain can be justified by the great number of therapeutical failures that there have been (6). These include physical therapy and rehabilitation (7-12), various types of psychological therapy [for a review article of these studies see Turk and Flor (13)], transcutaneous electrical nerve stimulation (TENS) (12,14-16), vibration (17), acupuncture (15,16), local injection (18-20), surgery (21-23), and pharmacological methods (24-28). Of these therapeutic methods, drugs are the most widely used (29). Pharmacological treatments are fundamentally based on analgesic-anti-inflammatory and antispasmodic

drugs because of their speed of action. However, these are not widely studied in controlled trials, and results obtained by different authors are scarce (30).

### AIM

Our aim was to evaluate in a double-blind controlled trial the effect of a pure antispasmodic drug in the symptomatic treatment of acute low back pain in hospitalized patients, without evidencing other disorders, e.g., as shown by tomographic or neurophysiological signs of root compression.

The drug chosen was dantrolene sodium, the antispasmodic properties of which work because of a specific inhibitory mechanism on the  $Ca^{++}$  release at the level of the sarcoplasmic reticulum of the striated muscle (31,32). This level of action therefore avoids any direct effects on pain, such as those of diazepam and baclofen.

### PATIENTS

The study encompassed 20 patients, whose characteristics are shown in Table 1 and who were all

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**TABLE 1.** Characteristics of the patients admitted to the study dantrolene sodium (25 mg daily) versus placebo and homogeneity comparison between the two groups

	Dantrolene	Placebo	Homogeneity comparison
Sex			
M	7	8	
F	3	2	NS
Age (years)			
Mean $\pm$ SEM	46.70 $\pm$ 2.3	47.10 $\pm$ 2.2	NS
Min-max	37-58	38-56	
Duration of illness (day)			
Mean $\pm$ SEM	12.4 $\pm$ 2.2	14.7 $\pm$ 1.2	NS
Min-max	5-30	7-20	
Examined joint			
Knee	6	7	
Hip	4	3	NS
Examined muscle			
Ischio-tibialis	3	5	
Gluteus medius	3	3	
Flexor of lower limbs	2	2	NS
Abducent muscle	1	—	
Quadriceps	1	—	

over age 16, suffering from chronic low back pain in the acute phase, i.e., there was no tomographic or neurophysiological evidence of radicular compression. They had all been previously seen (at least once) for the same problem. On that occasion we asked them to avoid all drugs in case of a successive relapse and to contact us immediately for a within-the-day hospital admission. This permitted us to avoid any form of "classical" wash-out. We arbitrarily considered a "relapse" to be an acute pain state that occurs after at least 2 months of relief without any pharmacological or physical therapy.

Patients suffering from renal failure, liver disease, severe respiratory disease, pregnancy, or other neurological pathologies, both concomitant with or resulting from the case history, were banned from the trial.

#### METHODS

A daily dosage of 1 capsule was given for 4 days running, and the patients were randomly assigned to one of two treatments: Group A, 25 mg dantrolene sodium; group B, placebo. The blinding form was prepared and coded by courtesy of Boots-Formenti Italy in an indistinguishable form (both were confectioned in the same size white capsules). The daily dosage of 25 mg of active drug was chosen based on our previous experience (25) and because of pharmacological studies on its lowest active dosage (33).

During this period, by-treatment with sedatives, anxiolytics, hypnotics, other antispasmodic and anti-inflammatory drugs was avoided. From day 0 to day 4, the following daily evaluations were performed within 3 h of taking the tablet. (A) Evaluation of articular motility, active and passive, measured in angular degrees at the level of the knee joint (flexion-extension) and hip joint (abduction, extension, and flexion) (34). (B) Evaluation of muscle spasm (expressed in 5<sup>+</sup>) by means of manual semiotic maneuvers (deep pressure, lifting of skin layers, pinching-rolling, evaluation of demography) (35,36). (C) Assessment of pain behavior (4-point scale) based on mimic expression, posture, night decubitus, and degree of self-sufficiency (37). (D) Evaluation of the muscle force at the knee and hip joints (4-point scale) (38).

On days 0 (baseline), and 4 (end of treatment), pain and EMG activity were assessed. The pain provoked by joint movement against maximum resistance was measured by Scott and Huskinsson's visual analog scale (VAS), which was filled out by the subjects before and after such movements (39). The EMG activity was measured during a maximum voluntary effort and during the period following this maximum voluntary contraction. This assessment and EMG methodology has previously been described (40). In short, the recording was performed using a Medelec MS6 electromyograph with four channels of acquisition, and the EMG's signal was

detected using a needle electrode commonly used in neurophysiological routine.

The myoelectric activity at maximum voluntary effort was assessed according to the parameters proposed by Buchtal (41). The persistence of involuntary myoelectric activity due to delayed relaxation after a maximum voluntary effort was measured in seconds, and the period of myoelectric silence was defined as an interval of complete absence of the motor unit's firing activity lasting 10 s (Figs. 1 and 2).

The muscles examined are reported in Table 1. Laboratory tests [complete hematology, bilirubin, serum glutamic-oxaloacetic transaminase (SGOT), serum glutamic-pyruvic transaminase (SGPT), alkaline phosphatase, gamma-GT, azotemia, and urinalysis] were performed at the beginning and end of the study.

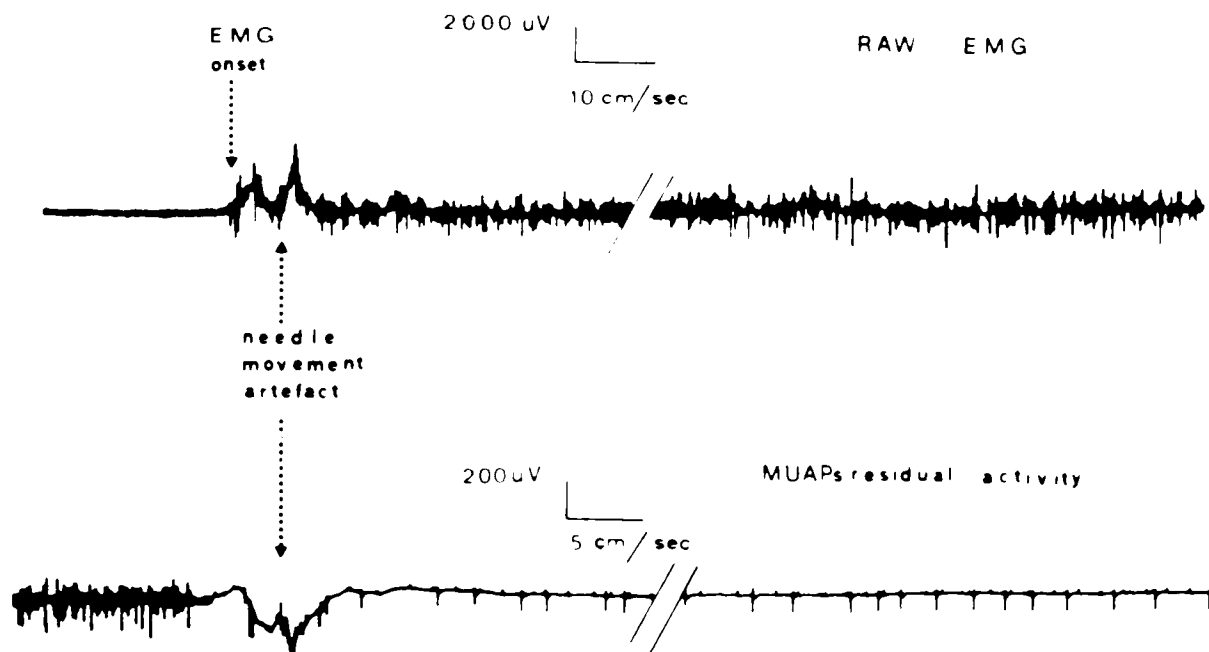
Homogeneity comparison between groups was statistically carried out using Fischer's exact test and Student's *t*-test (Table 1). The analysis of variance (one-way), Fischer's exact test, and Mantel's chi-square were used to compare the effectiveness between treatments. The significance limit was fixed at  $p < 0.05$ .

## RESULTS

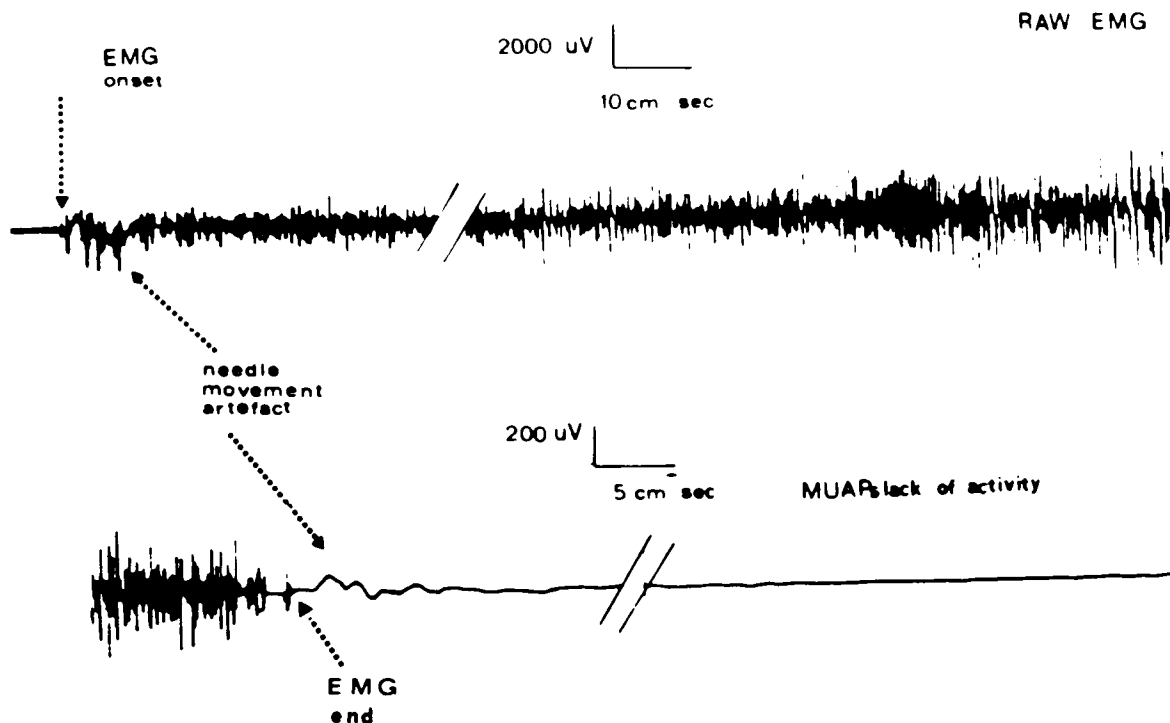
Muscle contracture was evaluated by taking into account the number of cases that improved after treatment. It was seen that the number of patients showing signs of improvement with the drug reached 85% after 3 days and remained the same on day 4. Only 10% of the patients receiving placebo had improved by day 3, rising to 30% on day 4. Statistical comparison reveals a significant superiority ( $p < 0.001$ ) of active treatment over placebo.

Pain behavior (Fig. 3) was also evaluated by considering the number of cases showing improvement after treatment: 90% after 3 days and 100% after 4 days using the active drug, whereas the placebo showed an improvement of only 40%. Here, statistical analysis reveals a significant superiority ( $p < 0.001$ ) of active treatment over placebo.

VAS pain measurements during the maximal voluntary movements showed a decrease in pain rating clearly in favor of dantrolene, with a percentage variation of 50% for the drug and of 8.6% for placebo. Statistical comparison between the two treatments showed dantrolene to have a higher effectiveness ( $p < 0.001$ ).



**FIG. 1.** Maximal voluntary effort registered in the gluteus medius in a patient suffering from acute low back pain. The maximal voluntary activity was of low amplitude and of a reduced interference pattern. Quite a strong MUAP's firing persisted after the voluntary contraction ceased. Registration was performed with a Medelec MS6 electromyograph (band width 8–3,200 Hz and continuous, on-paper Kodak linagraph direct print; paper speed 10–5 cm/s). The figure shows two recording traces. The lower trace is the continuation of the upper one. Traces are interrupted by double bars to allow a better visualization of the voluntary efforts as well as of MUAP's activity persistence.



**FIG. 2.** Maximal voluntary effort and the following period of muscle relaxation registered in the gluteus medius muscle of the same patient 4 days after treatment. The maximal voluntary activity showed an interference pattern of normal amplitude; no MUAP firing was recorded after it had ceased. The sudden arrest of electrical activity at the end of the voluntary contraction can be noted. We used a Medelec MS6 electromyograph (band width 8–3,200 Hz). Registration was continuous on paper (Kodak linagraph direct print; paper speed 10–5 cm/s). Figure shows two recording traces. The lower trace is the continuation of the upper one. Traces are interrupted by double bars to allow a better visualization of the maximal voluntary effort and the electrical silence that followed it.

Electromyographically, the time taken for the patients to completely relax after a voluntary effort against maximum resistance was assessed in seconds (Fig. 4), which showed an improvement of 75.3% in Group A and of only 22.4% in Group B (significant difference  $p < 0.01$ ). No marked differences were found in the EMG activity at maximum voluntary effort before and after treatment, except in 4 cases. Statistical analysis was nonsignificant.

In clinical examination of Group A, 3 of 4 patients who initially showed a reduction in both muscle force and EMG activity recovered after 4 days of treatment to within normal range. Only one patient of 9 in Group B improved after the placebo. The comparison between the two treatments is statistically significant ( $p < 0.05$ ) (Fig. 5).

Kinesiological examination revealed the following: statistical comparison between the two treatments we recorded resulted as significant, as in Group A, the flexion movement of the knee improved by 9.5% after taking dantrolene sodium for 4 days (from 121.7 at the beginning of the study to 133.3 at the end), whereas it remained unchanged in

Group B (124.3) with placebo. As the maximal extension of the knee is commonly defined as 0, and negative values indicate the lack of degrees to reach this complete movement, this extension of the knee showed a remarkable improvement of 77% (from  $-26^\circ$  to  $-6^\circ$ ) in Group A, and a slight improvement of 8% (from  $-17.1^\circ$  to  $-15.7^\circ$ ) in Group B; the statistical comparison was significant ( $p < 0.01$ ).

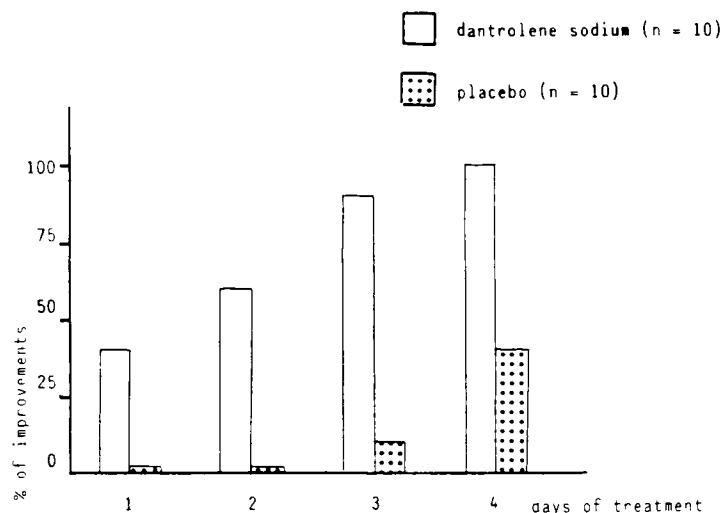
At the hip level, Group A showed a remarkable change for the better as compared with Group B, both for flexion, extension ( $p < 0.5$ ), and also for abduction movements, always observed in Group A. The only variation seen in Group B was an improvement of 11% (from  $60^\circ$  to  $66.7^\circ$ ) related to flexion movements. Hereafter, in the course of passive articular motility of the knee and hip, we observed results almost identical to the former ones.

## DISCUSSION

It is common knowledge that in musculoskeletal pathology, reflex spasm can trigger off a vicious circle of pain–spasm–pain, in which muscle spasm

Antalgic behaviour

Statistical comparison  
 $p < 0.001$   
 (Mantel test)



**FIG. 3.** Antalgic behavior. Frequency of the cases improved after administration of dantrolene sodium, 25 mg daily (n = 10 patients) or placebo (n = 10) for 4 days.

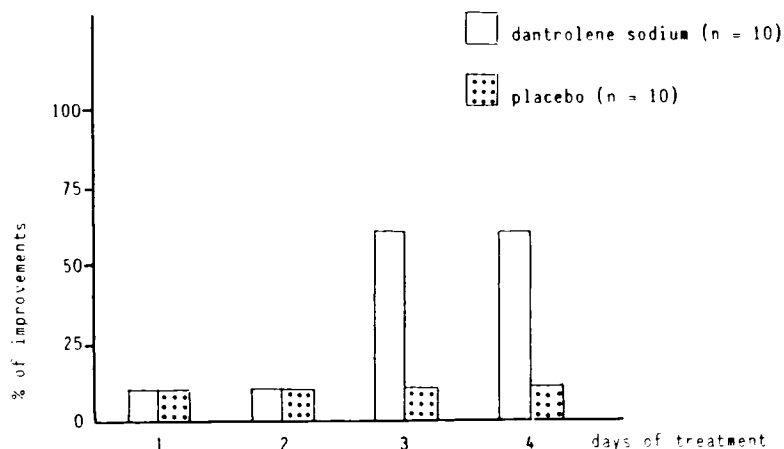
may be the cause of persistent pain (42). The evaluation of the motor unit firing due to antalgic reflex muscle spasm was studied by several authors in different pathologies, such as the headache, and in the osteoarthritis of the knee and shoulder (40,43,44). Masterson and Withe (45) used EMG recordings

from spasmodic paraspinal muscles to validate the pain relief in low back pain treatments.

Objective documentation of muscle spasm in clinical conditions as in low back pain patients was also recently shown by recording electromyographic activity from gluteus medius and lumbar paraspinal

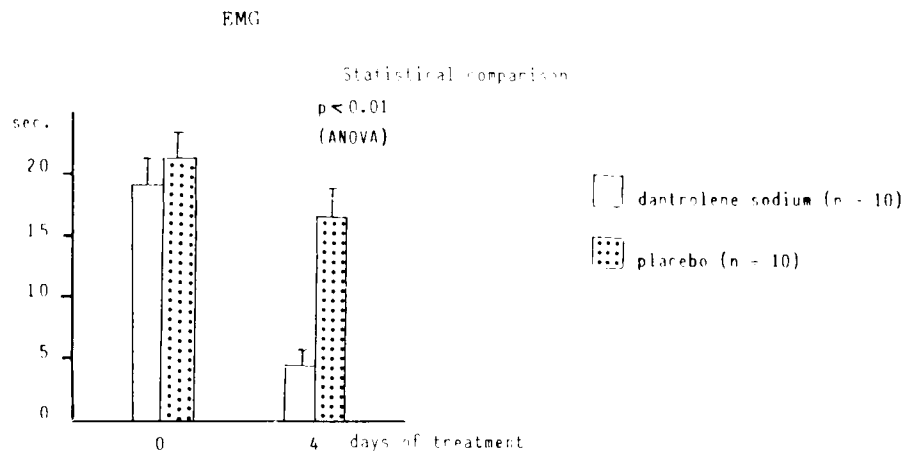
Strength

Statistical comparison  
 $p < 0.05$   
 (Mantel test)



**FIG. 4.** Persistence of involuntary myoelectric activity due to a delayed relaxation (expressed in seconds) after a maximum voluntary effort (mean  $\pm$  SD) before and after 4 days of treatment with dantrolene sodium, 25 mg daily, or placebo.

**FIG. 5.** Muscle strength. Frequency of cases improved after administration of dantrolene sodium, 25 mg daily, or placebo for 4 days.



muscles during a 24-h period (46). In our work, the attention was focused on the persistence of reflex myoelectric activity as an expression of the lack of muscle relaxation after a painful voluntary movement in patients affected by acute low back pain. In this condition, we found a consistent reflex firing in the tested muscle (Table 1) to be a sign of an antalgic reaction to pain (Fig. 1).

After 4 days of treatment, we registered a statistical reduction, and in a few cases, the complete absence, of this postcontraction involuntary myoelectrical activity (Fig. 2) in the dantrolene group. As this motor unit reflex discharge decreased, clinical examination revealed a reduction of the palpable spasm in myotome of patients who demonstrated, in the same muscle, a sustained involuntary electrical activity after a painful voluntary movement.

To evaluate muscle spasm, we used traditional manual semiotics maneuvers even though a new clinical method for objective quantitative documentation of soft tissue consistency has been recently presented (47). The clinical reduction of muscle spasm and the normalization of the considered electromyographic parameters seem to be concomitant, and both may be due to the action of the muscle relaxant. The observation that there was also a reduction in the pain level during the voluntary movement can lead to the conclusion that, taking into account the site of action of dantrolene sodium at the sarcoplasmic reticulum of the muscle, and the lack of hypothetical mechanisms of pain modulation (even secondary) of the molecule, the antalgic effect (50% of pain reduction) could be due to the interruption of the feedback pain-spasm-pain at the level of muscle contracture.

In the pathology being studied—low back pain

without neurological abnormalities—the two main symptoms were then pain and muscle spasm. As demonstrated, a breakdown in the vicious circle of pain-spasm-pain can cause a reduction of both these symptoms and, as in our study, have a consequent improvement in muscle strength and motility. Muscles and joints are functionally linked to produce motion (mimic, gesture, posture, gait); in this respect, to have a “normal motility” two things are needed: full range joint motility and full range muscle activity. Consequently, a change for the better of both these parameters leads to an improvement of the functional ability of the patients. In this respect, the “pain behavior” parameter seems to indicate this general functional improvement.

Notwithstanding these positive results, the placebo effect must not be forgotten. The overall improvement, including both articular and muscle function parameters, also observed in the untreated group, demonstrated, even in its restrictiveness, what is reported in literature (30–48), i.e., that rest may be a factor concurring to obtain improvement. Usually, the placebo effect diminishes following treatment. In this case, for the “muscle contracture” parameter, the placebo effect seems to rise from 10% to 30% due to the therapeutic effect of rest and to the short observation period. We also have a high success rate for the “antalgic behavior” in both groups, even if statistical comparison gave better results in the treated group. This seems to indicate a low reliability of this parameter, depending on the great psychological component of low back pain (13) influencing both groups in the same way.

A secondary but positive observation was the lack of side effects, such as weakness, during the trial. In our neurological practice, we witnessed a

few cases of withdrawal using only high doses of dantrolene (200→400 mg/die) in spasticity due to vascular emiplegia (49,50). In the present study, with a low dosage of dantrolene and short-term treatment, patients did not report any weakness.

### CONCLUSIONS

This work demonstrates the possibility of treating uncomplicated acute low back pain with a pure muscle relaxant drug and obtaining good clinical results without side effects. From a neurophysiological point of view, the observation that a pure muscle relaxant drug without any direct antinociceptive action can produce a reduction in the pain level, secondary to its antispasmodic effect, demonstrates that pain in the uncomplicated low back pain syndrome is maintained by way of the prolonged muscle spasm.

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