Diclofenac/Misoprostol vs Diclofenac/Placebo in Treating Acute Episodes of Tendinitis/Bursitis of the Shoulder

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Summary

This was a double-blind study designed to compare the efficacy and tolerability of diclofenac/misoprostol and diclofenac in patients with acute tendinitis/bursitis of the shoulder. Diclofenac 50mg/misoprostol 200μg (n=185) or diclofenac 50mg (n=187) was administered twice or 3 times daily for 14 days. Various physician's and patient's assessments performed during and at the end of treatment showed similar improvements with both treatments. Abdominal pain, nausea and vomiting occurred somewhat more frequently with diclofenac/misoprostol, but patient withdrawals due to adverse events did not differ markedly between the groups. Thus, in the short term treatment of acute tendinitis/bursitis of the shoulder diclofenac/misoprostol possesses efficacy similar to that with diclofenac alone and provides the gastroprotective benefit of misoprostol. Previous studies in osteoarthritis and rheumatoid arthritis have established diclofenac/misoprostol to be as effective as diclofenac but with significantly less gastrointestinal damage (Verdickt et al. 1992)

1. Methods

1.1 Patients and Study Design

This was a multicentre double-blind parallel-group study. Patients of either sex presenting with an acute episode of tendinitis and/or bursitis of the shoulder were eligible for inclusion. The injury was to have occurred within 72 hours of the start of study medication, and could have included bicipital tendinitis, subacromial bursitis, impingement syndrome stage 1 and tendinitis of any or all of the rotator cuff muscles. A history of painless, unrestricted motion of the affected joint immediately prior to the acute attack was required. Female patients of childbearing potential provided in-
formed, written consent. They were required to be nonlactating, using adequate contraception and provide a negative pregnancy test within the 72 hours before starting study medication.

Patients were excluded from the study if they displayed any signs, symptoms or any other evidence of current fracture of the shoulder bones, joint instability or septic bursitis, and if they had a history of any rheumatoid disease, crystal-induced arthropathy, degenerative joint disease, cervical radiculopathy or the shoulder-hand syndrome. Additional exclusion criteria included active gastrointestinal disease, renal or hepatic disorders, any type of malignancy, known hypersensitivity to NSAIDs or prostaglandins, administration of corticosteroids or any investigational drugs during the previous 30 days, and administration of any NSAIDs or analgesics during the 24 hours prior to the pretreatment assessment.

Patients were randomised to receive either the fixed combination diclofenac 50mg/misoprostol 200µg or diclofenac 50mg. Treatment was administered twice or 3 times daily (according to the investigator's clinical judgement and not changed subsequently) with meals for 14 days or until sufficient improvement had occurred.

During the pretreatment period (up to 72 hours before initiating study medication), a physical examination, shoulder assessment and laboratory tests were performed and repeated on day 14 (or final visit). Shoulder assessments, which were made by physicians and patients, were also carried out on days 4 and 7.

### 1.2 Physician's Assessments

Tenderness was assessed by palpation of 4 sites:
- lateral shoulder and upper arm
- greater tuberosity of the supraspinatus insertion
- anterior edge of the acromion
- front of the shoulder.

The patient's response was scored as 0 = none, 1 = positive response to questioning, 2 = spontaneous response elicited, and 3 = withdrawal by patient on examination.

Pain on resisted motion was assessed by means of 4 manoeuvres:
- application of adducting force by physician with patient's arm fixed in abduction at 60 to 90° from the body
- resisted supination of the forearm (Yergason's supination sign)
- resisted flexion of the elbow (to induce bicipital tendon pain)
- forced forward elevation of the humerus against the acromion (impingement sign).

Pain was scored as 0 = none, 1 = mild, 2 = moderate, and 3 = severe.

Limitation of motion was assessed using the following manoeuvres:
- active abduction scored as 0 = no restriction, 1 = > 120° but < 180°, 2 = > 60° but < 120°, 3 = > 0° but < 60°, and 4 = impossible motion
- internal rotation (highest posterior spinous process that the tip of the thumb can reach; scored as 0 = C1-T6, 1 = T7-T10, 2 = T11-L1, 3 = L2-L4 and 4 = lower than L4)
- external rotation (hand placed behind head on the same shoulder; scored as 0 = no restriction, 1 = > 80° but < 120°, 2 = > 40° but < 80°, 3 = > 0° but < 40°, and 4 = impossible motion).
- acromioclavicular adduction test (forced cross body adduction of the arm; scored as 0 = no restriction, 1 = > 40° but < 60°, 2 = > 20° but < 40°, 3 = > 0° but < 20°, and 4 = impossible motion).

For each of the 3 Physician's Assessments described above the scores for the different procedures were summed to provide an overall score.

Physicians also made a global assessment at each visit. This was based on the patient's disease signs, functional capacity and physical examination, and scored as 0 = normal, 1 = mild, 2 = moderate, and 3 = severe.

### 1.3 Patient's Assessments

Night pain and Patient's Global Assessment were scored as 0 = none/normal, 1 = mild, 2 = moderate, and 3 = severe.