Kalita J, Vajpayee A, Misra UK. Comparison of prednisolone with piroxicam in complex regional pain syndrome following stroke: a randomized controlled trial. Q J Med 2006;99:89-95.

Reviewed, conclusions clarified but not changed, February 2017

Design: Randomized clinical trial

Population/sample size/setting:

- 60 patients (20 women, 40 men, mean age 56) treated for CRPS-I following stroke in a neurology department in India
- All patients had spiral CT within 24 hours of onset of stroke, which were classified as ischemic (n=25) or hemorrhagic (n=35)
- Severity of CRPS was scored on a scale from 0-14 based on pain (5 points_) distal edema (3 points), humeral abduction (3 points), and humeral external rotation (3 points)
- CRPS score of at least 8 was required for entry
- Exclusion criteria were diabetes, uncontrolled hypertension, heart failure, peptic ulcer, history of shoulder dysfunction, brachial plexus injury, GI bleeding, septicemia, and ischemic heart disease

Main outcome measures:

- Stroke was accompanied by severe hemiplegia in 19 patients, and hemisensory loss to pin prick and joint position was present in 8 patients
- Randomized to oral prednisolone (n=30) or piroxicam (n=30)
- All 60 patients received the allocated treatment and completed the trial
- Prednisolone was administered at a dose of 40mg/d for 14 days, then tapered 10mg/week; piroxicam was administered at a dose of 20 mg/d
- Main outcome measure was improvement defined as change in total CRPS score of 2 points or more, and was assessed at the end of 1 month
- Improvement by this definition was seen in 25 of 30 prednisolone patients and by only 5 of 30 piroxicam patients
- Mean CRPS score was reduced from 10.73 at baseline to 4.27 at 1 month in the prednisolone group; the mean CRPS score did not appreciably change in the piroxicam group: 9.83 at baseline and 9.37 at 1 month
- Barthel Index (a measure of activities of daily living such as bathing, feeding, dressing, mobility on a scale from 0-20) improved in both groups: from 1.97 to 9.87 in the prednisolone group and from 2.57 to 7.07 in the piroxicam group
- Mild gastritis occurred in 4 prednisolone patients and in 1 piroxicam patient

Authors' conclusions:

- Oral prednisolone significantly improves the symptoms and signs of CRPS-I following stroke compared to piroxicam
- Both drugs improve activities of daily living, as shown by the Barthel scores

Comments:

- Concealment of allocation is not clear (randomization from a random number table which may have been seen by one of the authors); however, the distribution of important prognostic indicators appears to be balanced, and the risk of selection bias is not likely to be great
- Success of blinding is not described; while one author did the randomization and another did the evaluation, the issue is ambiguously described, and the overall risk of bias is not clear
- Both groups continued physiotherapy, but this is not described
- Complete follow-up and absence of attrition are strengths of the study
- The application of the results to patients who do not have shoulder-hand syndrome is not clear; many patients had hemiplegia and hemisensory loss, which could have been factors in the patterns of symptoms observed
- Presumably, the CRPS score was adopted from a cited article on shoulder-hand syndrome

Assessment: Adequate for evidence that prednisolone can improve CRPS due to stroke (and perhaps from other causes) more effectively than piroxicam