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# Ketanserin in reflex sympathetic dystrophy. A double-blind placebo controlled cross-over trial

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**Summary** Ketanserin, a selective S2 serotonergic antagonist, was assessed against placebo in a double-blind cross-over study of 16 patients with chronic peripheral burning pain. Nine of these had signs of reflex sympathetic dystrophy (RSD). All patients underwent 4 intravenous regional treatments, 2 with ketanserin (10 mg for upper limb pain, 20 mg for lower limb pain) and 2 with placebo. In those patients with RSD ketanserin and not placebo provided significant ($P < 0.05$) sustained pain relief as assessed by linear analogue scales. In patients who did not fulfil the criteria for RSD no significant relief was seen with placebo or ketanserin.

Following tourniquet release, drowsiness, shakiness and faintness were reported at a higher ($P < 0.05$) frequency after ketanserin than after placebo. All side effects were mild and transient, and no changes occurred in heart rate or blood pressure following ketanserin that were significantly different from those seen following placebo.

A role for serotonin in the pathogenesis of RSD is proposed.

**Key words:** Ketanserin; Reflex sympathetic dystrophy

## Introduction

The reflex sympathetic dystrophy syndrome (RSD) characteristically consists of sustained burning pain, vasomotor disturbances, functional disability and trophic changes in the absence of major nerve injury [12]. The syndrome can follow any trauma, particularly at the wrist or ankle, but the initiating event may be mild or unknown [3,12–14]. Sympathectomy has proved an effective therapy, particularly when performed early in the evolution of the condition, but repeated blocks are often needed and may fail if treatment is delayed [12].

Initial reports of the use of the serotonin type 2 receptor antagonist ketanserin by i.v. bolus suggested it to be of considerable benefit in RSD [8], however, this was not confirmed in a controlled investigation [4]. Ketanserin administered using an intravenous regional technique appeared to provide sustained pain relief in patients suffering from RSD in an open unblinded study conducted in this unit (unpublished observation).

A prospective randomised double-blind cross-over trial of ketanserin against placebo was undertaken in order to verify this finding.

## Methods

### *Patient selection*

Sixteen patients with severe peripheral burning pain gave written consent to the study as approved by the hospital ethical committee. Patient details are presented in Table I. Prior to the start of the investigation patients were divided into 2 diagnostic groups on the basis of clinical examina-

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