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# Ameliorating effect of antioxidants and pregabalin combination in pain recurrence after ductal clearance in chronic pancreatitis: Results of a randomized, double blind, placebo-controlled trial

[Rupjyoti Talukdar](#)<sup>1,2</sup>, [Sundeep Lakhtakia](#)<sup>3</sup>, [D Nageshwar Reddy](#)<sup>3</sup>, [G Venkat Rao](#)<sup>4</sup>, [Rebala Pradeep](#)<sup>4</sup>, [Rupa Banerjee](#)<sup>3</sup>, [Rajesh Gupta](#)<sup>3</sup>, [Mohan Ramchandani](#)<sup>3</sup>, [Manu Tandan](#)<sup>3</sup>, [H Vivekananda Murthy](#)<sup>5</sup>

Affiliations

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## Abstract

**Background and aim:** The aim of this study was to evaluate the effect of antioxidant-pregabalin combination on pain recurrence in patients with chronic calcific pancreatitis.

**Methods:** In this randomized, double-blind, placebo-controlled trial, chronic calcific pancreatitis patients with pain recurrence following pancreatic ductal clearance of stones received either antioxidant-pregabalin combination or matching placebo for 2 months followed by open-label antioxidants for the next 4 months in both groups. Compliance, daily pain, and adverse events were recorded weekly and at the end of study by a coordinator blinded to treatment status. Primary outcome was pain improvement (visual analog scale and Izbicki score); secondary outcomes were as follows: complete pain resolution, painful days, and adverse events. Number needed-to-treat was calculated.

**Results:** We randomized 42 and 45 patients (mean age 29.3 years) to treatment and placebo arms, respectively. Baseline characteristics, including pain scores, were similar for both groups. No patients received high-potency narcotic. At 2 months, a significant improvement in the treatment arm was observed in percent reduction of visual analog scale (-50 [-80.0; -32.1] vs -29.5 [-64.5; 0];  $P = 0.01$ ), Izbicki score (14.5 [0; 21.3] vs 30.0 [11.8; 41.3];  $P = 0.001$ ), complete pain resolution (20 [47.6%] vs 12 [26.7%];  $P = 0.04$ ), and number of painful days (10.0 [2.0; 16.0] vs 18.0 [7.0; 34.0];  $P = 0.01$ ). Needed-to-treat was 4.8. Pain reduction persisted at 6 months

in the original treatment group (20.0 [15.0; 28.0] vs 36.0 [20.0; 50.0];  $P = 0.006$ ). A total of 33 patients in the treatment arm experienced mild to moderate self-limiting nausea/vomiting and drowsiness, respectively and did not require any change in study protocol.

**Conclusion:** Antioxidant-pregabalin combination results in significant relief in pain recurrence after ductal clearance in narcotic naïve patients with chronic calcific pancreatitis.

**Keywords:** antioxidants; endotherapy; pain; pregabalin; surgery.

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