

Journal Watch

Efficacy and Safety of Transdermal Buprenorphine: A Randomized, Placebo-Controlled Trial in 289 Patients with Severe Cancer Pain

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Abstract

Strong opioids are recommended for treating severe cancer pain in the advanced stages of the disease. Few data are available concerning the efficacy of buprenorphine in cancer pain. We compared transdermal buprenorphine 70 µg/h (BUP TDS) to placebo in an enriched design study. Opioid-tolerant patients with cancer pain requiring strong opioids in the dose range of 90–150 mg/d oral morphine equivalents entered a two-week run-in phase, during which they were converted to BUP TDS. Patients who could be stabilized on BUP TDS were randomized to BUP TDS or placebo patch for a two-week maintenance phase. Rescue medication (buprenorphine sublingual tablets 0.2 mg) was allowed as required. Response was defined as a mean pain intensity of <5 (0–10 scale) and a mean daily buprenorphine sublingual tablet intake of ≤2 tablets during the maintenance phase. Of 289 patients who entered the run-in phase, 100 discontinued treatment due to lack of efficacy or adverse events; 189 patients continued treatment in the maintenance phase (94 BUP TDS, 95 placebo), of whom 31 discontinued treatment (7 BUP TDS, 24 placebo). A significant difference in the number of treatment responders was observed: 70 BUP TDS (74.5%, 65.7–83.3) vs. 47 placebo (50%, 39.9–60.1) ($P = 0.0003$). This result was supported by a lower daily pain intensity, lower intake of buprenorphine sublingual tablets and fewer dropouts in the BUP TDS group. The incidence of adverse events was slightly higher for BUP TDS. In conclusion, BUP TDS 70 µg/h is an efficacious and safe treatment for patients with severe cancer pain.

Strengths:

- 1- Double blind RTC
- 2- Large number of patients. The authors claimed that this study is the largest placebo controlled study ever performed in pts patients with cancer pain
- 3- A Multicentre study

Weakness:

- 1- Typical pharmaceutical designed and funded study which was done in university based centers
- 2- Run in time “phase” presented as a mandatory part of the study

3-Patients with side effects and lack of efficacy were excluded before the study began

4- Cancer patients with severe pain were included in the placebo group with provision of PRN dosing only which will bring the placebo group a high risk of severe pain and suffering.

5- In this study buprenorphin was compared with placebo rather than with the other available Opioids to determine its comparative efficacy.

Relative to palliative care:

Buprenorphine might be effective in controlling pain in patients with cancer but this study does not provide any evidence regarding the efficacy of buprenorphin compared to other Opioids. This article would alert us all to the need for ethics approval for research projects in this vulnerable population to ensure prevention of patient discomfort and suffering.