

Journal Watch

Randomized Clinical Trial of an Implantable Drug Delivery System Compared With Comprehensive Medical Management for Refractory Cancer Pain: Impact on Pain, Drug-Related Toxicity, and Survival.

Smith TJ, Staats PS, Deer T, et al. *J of Clinical Oncology* 2002; 29(19):4040-4049.

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Received during: Journal Rounds on the Tertiary Palliative Care Unit, Grey Nuns Hospital

Abstract:

Purpose: Implantable intrathecal drug delivery systems (IDDSs) have been used to manage refractory cancer pain, but there are no randomized clinical trial (RCT) data comparing them with comprehensive medical management (CMM).

Patients and Methods: We enrolled 202 patients on a RCT of CMM versus IDDS plus CMM. Entry criteria included unrelieved pain (visual analog scale [VAS] pain scores ≥ 5 on a 0 to 10 scale). Clinical success was defined as $\geq 20\%$ reduction in VAS scores, or equal scores with $\geq 20\%$ reduction in toxicity. The main outcome measure was pain control combined with change of toxicity, as measured by the National Cancer Institute Common Toxicity Criteria, 4 weeks after randomization.

Results: Sixty of 71 IDDS patients (84.5%) achieved clinical success compared with 51 of 72 CMM patients (70.8%, $P = .05$). IDDS patients more often achieved $\geq 20\%$ reduction in both pain VAS and toxicity (57.7% [41 of 71] vs 37.5% [27 of 72], $P = .02$). The mean CMM VAS score fell from 7.81 to 4.76 (39% reduction); for the IDDS group, the scores fell from 7.57 to 3.67 (52% reduction, $P = .055$). The mean CMM toxicity scores fell from 6.36 to 5.27 (17% reduction); for the IDDS group, the toxicity scores fell from 7.22 to 3.59 (50% reduction, $P = .004$). The IDDS group had significant reductions in fatigue and depressed level of consciousness ($P < .05$). IDDS patients had improved survival, with 53.9% alive at 6 months compared with 37.2% of the CMM group ($P = .06$).

Conclusion: IDDSs improved clinical success in pain control, reduced pain, significantly relieved common drug toxicities, and improved survival in patients with refractory cancer pain.

Comments:

Strengths/uniqueness:

This is an original study with an interesting and well-described design that compares spinal opioids to best medical management.

Weaknesses:

The unblinded study design is a weakness, but it would be very difficult to blind patients given the nature of IDDS.

Relevance to Palliative Care:

This data does suggest that IDDS delivery may offer benefit for some cancer patients, however more research is required to determine which patient subset would be mostly likely to benefit.