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Diclofenac Versus Tramadol for Mucositis Related Pain in Head and Neck Cancer Patients Undergoing Concurrent Chemoradiation - A Phase 3 Study

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Abstract

Background

Oral mucositis related pain during CTRT in head and neck cancers is a common problem. Unfortunately, in spite of it being common, there is limited evidence for selection of systemic analgesic in this situation. Hence, this study was designed to compare the analgesic effect of an NSAID (diclofenac) versus a weak opioid (tramadol).

Methods

This was an open-label, parallel design, superiority randomized controlled study. In this study head and neck cancer patients undergoing radical or adjuvant chemoradiation, who had grade 1 or above mucositis (in accordance with CTCAE version 4.03) and had pain related to it were randomly assigned to either diclofenac or tramadol for mucositis related pain control. The primary endpoint was analgesia after the 1st dose. The secondary endpoints were the rate of change

in analgesic within 1 week, adverse events, and quality of life.

Results

128 patients were randomized, 66 in diclofenac and 62 in tramadol arm. The median AUC for the diclofenac arm and the tramadol arm were 348.936 units (Range 113.64-1969.23) & 420.87 (101.97-1465.96) respectively ($p=0.05619$). Five patients (8.1%) in the tramadol arm and 11 patients (16.7%) in the diclofenac arm required a change in analgesic within 1 week of starting the analgesic ($p=0.184$). There was no statistically significant difference in any adverse events between the 2 arms. However, the rate of any grade of renal dysfunction was numerically higher in diclofenac arm (10.6% versus 4.8%, $p=0.326$).

Conclusion

In this phase 3 study, evaluating diclofenac and tramadol for CRIM pain, the analgesic efficacy of both analgesics was found to similar but diclofenac was associated with a higher rate of renal dysfunction.

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