Efficacy and Tolerability of 20mg Controlled-release Oxycodone Tablets in Opioid-naïve Cancer Pain Patients with NRS higher than 6

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BACKGROUND: According to the guideline of NCCN cancer pain management, titration of cancer pain therapy needs to start with 5-15mg fast release morphine. However, titration with fast release morphine may take more time and efforts to achieve stable analgesic effect. Therefore, controlled-release Oxycodone might serve as an appropriate alternative for morphine in titration.

HYPOTHESIS: Controlled-release Oxycodone is a semi-synthetic opioid analgesic drug that has been widely used for cancer pain management. It should also be considered to use a higher starting dose for cancer patients with NRS higher than 6, because it might save time to titration and attained better and sustained analgesic efficacy.

There are the reasons why the 20 mg CR oxycodone tablets were chose to manage the moderate pain patients with NRS higher than 6. First, it will achieve quick and sustained analgesic effect compared to fast-release morphine. Secondly, CR oxycodone might have less side effect compared to morphine. Therefore, we conducted an open-label, 3 day dose titration study in cancer pain patients with NRS higher than 6 who had not been taking opioid analgesics over the previous 2 weeks. We assessed the efficacy and tolerability of controlled-release oxycodone in the therapy of cancer pain management, starting with 20 mg tablet every 12 h. The aim of this study was to compare the the length of time and the dose needed for attaining stable and adequate pain control, and to evaluate the efficacy and safety of CR oxycodone tablets, with a starting dose of 20 mg every 12 h.

METHODS: Sixty-four cancer pain patients with NRS higher than 6 who had not been taking opioid analgesics over the previous 2 weeks were enrolled into two groups. Patients in group 1 received 20mg controlled-release oxycodone tablet from the beginning. Patients in group 2 received 15 mg hydrochloride morphine. The length of time and the dose needed to attain stable and adequate pain control were evaluated in addition to the assessment of analgesic efficacy and safety during the study period.

RESULTS: 30 patients in group 1 (30 out of 32, 93.75%) attained stable, adequate pain control in 24 h. 26 patients in group 1 (26out of 32, 81.25%) attained stable, adequate pain control without any dose titration. In these patients, the pain was significantly reduced in intensity, even at 1 h after the initial dose intake. 28 patients in group 2 (28 out of 32, 87.5%) attained stable, adequate pain control in 24 h. However, all patients needs to undergo at least 2 cycles of titration to attaine adequate, stable pain control. The results suggest that 20mg controlled-release oxycodone tablets offered stable and adequate pain control within a short period of time in most cancer pain patients with NRS higher than 6 who have not been taking opioid analgesics. The most common side effect was constipation and nausea. However, no significant side effects were observed. This indicates that 20mg controlled-release oxycodone formulation may make it possible to start and titrate the dose more appropriately and carefully in patients who are sensitive to opioid analgesics.