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Prevalence of Opioid-related Adverse Events in Cancer Pain: Analysis of Discrepancy between Investigator- and Patient-reported Prevalence

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**Introduction:** Although opioid therapy has been the mainstay of treatment for cancer pain, the prevalence of opioid-related adverse events (AEs) has not been reported in Korea. **Objectives:** The study aimed to investigate the prevalence of opioid-related AEs amongst cancer pain patients and compare the difference in AEs reported by investigators and patients.

**Methods:** A cross-sectional analysis of patients' charts and questionnaires from 30 teaching hospitals was performed. Clinical characteristics and prevalence for AEs were assessed.

Results: Of the 2,395 patients recruited, the most common opioid-related AEs as reported by investigators were constipation (29.7%),dry mouth (17.2%), and somnolence (14.7%). Patients, however, reported common AEs as dry mouth (61.1%), asthenia (52.2%), somnolence (49.4%) and constipation (49.2%). In addition to the difference in prevalence rates, results indicated a wide discrepancy in reporting of AEs between patients and investigators. Rates of patient-reported AEs which were not reported at all by investigators were as follows: dry mouth1,054(44%), asthenia1,040(43%), somnolence831(35%), and constipation489(20.4%).On the contrary, the differences in rates of AEs reported by investigators and not reported by patients were extremely small.

**Conclusions:** The study demonstrates the magnitude of discrepancy in reporting opioid-related adverse events between physicians and patients which highlights the importance of patient-reported outcomes. There is a need for improved assessment of patients' AEs,not only to actively manage AEs, but also to improve patients' pain and quality of life pertinent to cancer pain.

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## Efficacy and Safety of Methadone as a Second-line Opiod for Cancer Pain

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Institut Català d'Oncologia, IDIBELL, Palliative Care Service, L'Hospitalet de Llobregat, Spain **Aims:** To evaluate the efficacy & safety of methadone (MTD) as a second-line opioid in advanced cancer patients (pts) 14 and 28 days after rotation.

Material and methods: Prospective efficacy & safety study at days 3,7,9,14,21 & 28 after MTD rotation. The Brief Pain Inventory (BPI) was used to assess pain & CTCAE v3.0 for toxicity. Categorical data were compared using Pearson's  $\chi^2$  & Fisher's exact test. Means of continuous variables were compared using Student's t-test (normal distributions), and Mann-Whitney and Kruskal-Wallis test (non-normal distributions).

**Results:** A total of 145 pts (67% men) were included after informed consent was obtained. Mean age was 59. M1 was 79%, mean PPS 70%, and PaP score "A" 75%. ECS-CP pain poor prognosis criteria was 87%. Pre-rotation opioids were: Fentanyl(56%); morphine(19%); oxycodone(15%); Buprenorphine(8%), and other(2%). Rotation opioid ratio was DDEMO(mg) 194.4: MTD, 24.2 (8:1). Pts in follow up, by day: day 3(94%); 7(79%); 9(68%); 14(59%); 21(45%); and 28(38%).

**Mean differences from day 0 to 14** (86 pts) were: average pain (5.6 vs 3.0;P < 0.0001); worst pain (8.3 vs 5.0 (P< 0.0001); no. of rescue doses (4.3 vs 1.7;P< 0.0001); side effects (0.29 vs 0.30;P= 0.91). MTD PO mg/d (24.2 vs 27.1;P=0.01).

Mean differences from day 0 to 28 (55 pts) were: average pain(5.6 vs 2.3; P < 0.0001); worst pain(8.2 vs 4.0; P < 0.0001); no. rescue doses(3.8 vs 1.2; P < 0.0001); pain interference (6.6 vs 2.5; P < 0.0001); side effects(0.28 vs 0.28; P = 0.86). MTD PO mg/d(24.5 vs 26.4; P = 0.206). Missing pts were due to clinical deterioration/death(49%), analgesic procedures(25%), lost follow up(13%), voluntary withdrawal(9%), and other(3%).

**Conclusions:** In a sample of advanced cancer pts with poor pain prognosis, the use of MTD as a  $2^{\rm nd}$  line opiod resulted in a rapid, safe, and sustained analgesia. The high rate of missing pts is attributable to the expected disease course, with < 10% due to voluntary abandonment.

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## Barriers to Accessing Opioid Medicines: An Analysis of Legislation of 11 Eastern European Countries

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