RESEARCH COMMUNICATION

Clinical Observations on Safety and Efficacy of OxyContin® Administered by Rectal Route in Treating Cancer Related Pain

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Abstract

Objective: To determine the efficacy and adverse reactions of OxyContin® administered by rectal route in advanced cancer patients. Methods: Patients were enrolled into this study in which OxyContin was administered by the rectal route. The visual analogue scale (VAS) was applied to score pain intensity, separated into five degrees. National Cancer Institute-Common Toxicity Criteria (NCI-CTC) were adopted to record the side effects. Results: VAS scores were 10 before treatment, and decreased to 5-6 after OxyContin application by the rectal route.The main side effects were constipation, flatulence and fatigue,with no elevation of transaminases and creatinine. Conclusion: OxyContin admistered by rectal route is safe for advanced cancer patients with satisfactory pain control effects, thus deserving further clinical observation.

Keywords: Cancer pain - safety - efficacy - OxyContin® - rectal route

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Introduction

OxyContin®(Oxycodone Hydrochloride Prolonged-release Tablets) is an opioid analgesic effective for the relief of moderate to severe (visual analog scale VAS) score of postoperative (Morrison et al.,1971; Takki et al.,1973; Korttila et al.,1980; Nuutinen et al.,1986; Kalso et al.,1991) and cancer pain (Beaver et al., 1978; Kalso et al., 1990; Leow et al., 1992; Glare et al., 1993). Although oral route of administration is preferred for the management of cancer pain, alternative routes are considered where this is impossible, for example, when patients have disease of the upper gastrointestinal tract, dysphagia, nausea, or vomiting.Apart from parenteral drug administration, opioid through rectal route is a commonly used alternative method for drug delivery for a local or systemic effect.

Clinical impression and anecdotal reports suggest at a 30mg oxycodone suppository available as oxycodone pectinate in a fatty-base provides pain relief for up to 8h (Twycross,1989;Dunlop,1992).The use of oxycodone suppositories (30mg) at 4h intervals has also been reported to provide adequate pain relief with minimal side effects (Stathers et al.,1963). Compared with intravenous administration, rectal oxycodone provided analgesia of much longer duration, without increase in incidence and severity of side effects (Leow et al.,1985).

The aim of this study was to determine the efficacy of pain control and adverse reactions of OxyContin®(Oxycodone Hydrochloride Prolonged-release Tablets) administered by the rectal route in advanced cancer patients.

Materials and Methods

Patients who were enrolled in this study should have pathologically diagnosed with advanced or metastatic cancer and with cancer pain.The causes of pain were bone pain, visceral pain and soft tissue invasion. Previous treatment could include non-opioid drugs or weak opioids. The rectal administration of OxyContin®(Oxycodone Hydrochloride Prolonged-release Tablets,Mundipharma (China) Pharmaceutical Co.,Ltd.) started at 10mg every 12 hours, if pain control was not satisfactory,dose escalation of OxyContin was 10mg every time.

Evaluation Criteria

Pain intensity*:* Using crossed Records Act (Visual Analogue Scale VAS),to score pain intensity, ahorizontal line marked score 0 to 10 from left to right of equal segments:score 0 definrs no pain; l-3, mild pain,;4-6 moderate pain, 7-10 severe pain.

Side effects: Nausea,vomiting, dizziness, constipation and other treatment related side effects were evaluated according to National Cancer Institute-Common Toxicity Criteria(NCI-CTC) (Kaba et al., 2004).

Results

Two patients were enrolled into this study, one (registration number of Affiliated Jiangsu Cancer Hospital of Nanjing Medical University was 217201) was pathologically diagnosed with metastatic gastric cancer bone and lymph nodes metastases, the other (registration

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number of Affiliated Jiangsu Cancer Hospital of Nanjing Medical University was 216787) was advanced lung cancer with liver,bone and lymph nodes metastases.VAS scores both were 10 before OxyContin application by rectal route, and decreased at 5-6 after application. The main side effects were constipation flatulence, and fatigue, with no elevation of transaminases and creatinine.

Discussion

Pain is one of the most common symptoms associated with cancer. Pain is defined as "a sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Classification of chronic pain). A recent survey reported that 82% of patients with cancer experience pain and that at least 61% experience "very distressing" pain(Costantini et al.,2009). In patients with cancer, pain results directly from the tumor in about 80% of cases, primarily from anticancer treatments in 17%, and from causes unrelated to cancer or its treatments in 3% (Foley KM.,2004).In addition,this is one of the symptoms patients fear most. Unrelieved pain denies them comfort and greatly affects their activities,m otivation,interactions with family and friends,and overall quality of life.

The WHO suggests that patients with be started on acetaminophen or other nonsteroidal anti-inflammatory drug (NSAID).If this is not sufficient,the patients should be escalated to a "week opioid,"such as codeine,and subsequently to a "strong opioid,"such as morphine. OxyContin is an opioid analgesic effective for the relief of moderate to severe cancer pain (Beaver et al.,1978; Kalso et al.,1990; Leow et al., 1992; Glare et al.,1993). Although oral route of administration is preferred for the management of cancer pain, alternative routes are considered when patients have disease of the upper gastrointestinal tract, dysphagia, nausea, vomiting,etc. Apart from parenteral drug administration, the rectal route is a commonly used alternative method for drug delivery for a local or systemic effect.In this study, pain relief effect in advanced cancer patients was significant when OxyContin was admistered by a rectal route. The main side effects were constipation flatulence, and fatigue. There were found no other side effects of morphine-like drugs such as sweating, anxiety, euphoria, confusion, hallucinations, delirium, respiratory depression.

In conclusion, OxyContin admistered by rectal in advanced cancer patients was safe , effective and simple, deserves further clinical observation.

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