

Study on the Clinical Effect and Safety of Oxycodone Hydrochloride Sustained-release Tablets in the Treatment of Advanced Malignant Tumor Pain

Liu Surong, Wei Yuanyuan, Xu Yanli, Li Xinhong, Liu Juan, Qin Yan

521 Hospital of Ordnance industry, Xi'an Shaanxi, 710065, China

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ABSTRACT

Objective: To investigate the clinical effect and safety of oxycodone hydrochloride sustained-release tablets in the treatment of advanced malignant tumor pain. **Methods:** From January 2016 to November 2016, 128 patients with advanced malignancy, 42 patients with gastric cancer, 18 patients with hepatocellular carcinoma, 35 patients with esophageal cancer and 33 patients with breast cancer were selected. All patients were randomly divided into study group and control group, 64 cases in each group, the study group of 42 male patients, 22 females, aged 32-68 years, mean 52.1 ± 1.8 years; control group of 38 male patients, female the patients in the study group received endoscopic therapy and antibiotics to prevent infection. The control group received only endoscopic therapy. **Results:** The pain relief rate of the study group was significantly lower than that of the control group and the quality of life was higher than that of the control group. The incidence of adverse reactions was less in the study group than in the control group ($P < 0.05$). **Conclusion:** The oxycodone hydrochloride sustained-release tablets has a significant clinical effect and a small side-effect in the treatment of advanced malignant tumor pain. It is of high clinical value.

0 Introduction

Corresponding author:

Liu Surong, 521 Hospital of Ordnance industry, Xi'an Shaanxi, Email: xiaolongxia2008@163.com

The pain brought by advanced malignancy to patients is often not the high death rate of the disease but the pain perception in the process of disease development [1], and the investigation of patients shows those patients' quality of life and state of mind could be greatly affected due to the fierce pain they suffer. If the pain of the patients has not been relieved for a long period of time, it will make patients emotionally unstable, easily have anxiety and depression that also will affect their positivity in cooperation in treatment, even possibly question the correctness of treatment and refuse to accept further treatment [2]. Oxycodone hydrochloride sustained - release tablets are a newly developed analgesic, which mainly acts on the opioid receptor in patients to achieve analgesic effects. Due to its characteristics of better effect and small side effect, this drug is widely recognized in clinical treatment of advanced malignancy [3]. 128 patients with advanced malignancy were selected in our hospital and administered with oxycodone hydrochloride sustained - release tablets to easy pain, which results in remarkable effects. Now it is reported as follows.

1 Materials and methods

1.1 General materials

128 patients with advanced malignancy admitted to our hospital from January 2016 to November 2016 were selected, and among them, there are 42 patients with gastric cancer, 18 patients with hepatocellular carcinoma, 35 patients with esophageal cancer and 33 patients with breast cancer. The enrollment standard for those patients is that the pain score is 4-6, no opioids have been administered to relieve pain one month before the experimental study, patients express they are in normal mental condition and can clearly describe their own pain perception and patients with renal and other organ dysfunctions and respiratory system disorders should be excluded through diagnosis. All the patients were randomly divided into study group, which includes 42 male patients and 22 female patients, aged 32-68, with the mean age of 52.1 ± 1.8 ,

and control group, which includes 38 male patients and 26 female patients, aged 33-69, with the mean age of 52.3 ± 1 , 46 cases each group. The general materials of both groups are not statistically significant ($P > 0.05$).

1.2 Methods

Morphine is administered to the patients in the study group in an oral dose of 30 mg, twice a day to relieve pain, and oxycodone hydrochloride sustained - release tablets are administered to the patients in the control group in a dose of 30 mg, twice a day to relieve pain. After the trial, the pain of the patients is scored once every two days, dosage is appropriately adjusted according to the size of scores and can be duly increased under the arrangement of the physician in charge if needed when the pain of patients has not been relieved timely, but the dose at each time should not be increased by more than 50% compared with a previous dose to prevent patient tolerance from being exceeded, at the same time, the interval of taking the medicine should be strictly controlled in 12 hours. If unbearable intensive pain occurs in patients during the treatment, oxycodone and acetaminophen tablets are administered to relieve pain, and the previous medication is restored after the pain of patients is under control. The oxycodone hydrochloride sustained - release tablet and morphine taken by the patients in both groups should be administered as a whole tablet, breaking off or grinding tablets is prohibited in order to prevent the medicine from being absorbed in a very short period of time, making patients have an adverse reaction.

1.3 Outcome measures

In the trial, the degree of pain relief is divided into five gradients from 0 to 4, 0 degree means the pain of patients has not been relieved at all and even with a trend of aggravation; 1 degree means the pain perception of patients is approximately one-fourth of the pre-treatment pain perception and the pain of patients is slightly relieved; 2 degrees mean the pain perception of patients is reduced to half the original pain perception and the pain is relieved to some extent;

3 degrees mean the pain is remarkably relieved, and the times and degree of pain of patients are obviously improved; 4 degrees mean the pain perception of patients have completely disappeared. The proportion of patients with 2 degrees and above serves as the relief rate of treatment in the trial.

The patients' quality of life mainly includes appetite, sleepiness and mental state etc., with the score ranging from 1 to 10, and higher scores mean patients have higher quality of life in this regard. At the same time, the number of cases of categories of adverse reactions that the patients in both groups had during the treatment is uniformly recorded

1.4 Statistical methods

Detection data is analyzed using SPSS18.0 and represented as ($\bar{x} \pm s$), T-tests are employed for the degree of pain relief and the proportion of adverse reaction and χ^2 tests are applied for blood calcium and parathyroid hormone. $P < 0.05$ means there is a statistical significance.

2 Results

The degree of pain relief for patients in the two groups in the treatment were compared, Patients in the study group with the degree of relief of 2 degrees and above took a larger proportion, and their rate of relief is transparently higher than that of the control group ($P < 0.05$). For specific results, see Table 1.

Table 1 Comparison of degree of pain relief of patients in two groups (example)

Category of group	Number of example	Degree of pain relief					Rate of relief (%)
		0	1	2	3	4	
Control group	68	8	9	13	24	14	75.00
Study group	68	1	2	5	33	27	95.59
X ²	/	7.44	6.88	5.256	6.783	6.012	6.967
P	/	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05

Table 2 shows records of quality of life of patients in both groups after receiving treatment. From the data in the table, it can be seen the quality of life for the study group is obviously higher than that of the control group ($P < 0.05$).

Adverse reaction conditions of patients in two groups during the treatment were compared, and the number of incidence cases of various items of adverse reactions is obviously lower than that of the control group ($P < 0.05$). See Table 3.

Table 2 Comparison of quality of life of patients in two groups (example, &)

Category of group	Time	Appetite	Sleep	Daily life	Mental state	Dealing with people
Control group	Pre-treatment	3.95±0.51	4.64±0.56	4.78±0.53	5.69±0.61	4.01±0.45
	Post-treatment	6.08±0.45 ^{ab}	6.48±0.67 ^{ab}	7.12±0.61 ^{ab}	8.18±0.64 ^{ab}	7.15±0.71 ^{ab}
Study group	Pre-treatment	3.92±0.67	4.58±0.47	4.81±0.59	5.68±0.72	4.04±0.53
	Post-treatment	8.18±0.66 ^{ab}	8.03±0.35 ^{ab}	8.34±0.64 ^{ab}	9.38±0.83 ^{ab}	8.22±0.27 ^{ab}

Note: Compared with preoperative ones, ^aP<0.05; comparison of the study group and the control group, ^bP<0.05

Table 3 Comparison of patients in two group with adverse reactions in the treatment (example, %)

Category of group	Number of case	Constipation	Vomit	Mental disorder	Dry mouth	Urinary retention	Rash
Control group	68	18 (28.6)	11 (16.2)	7 (10.3)	13 (28.6)	3 (4.4)	8 (11.8)
Study group	68	5 (7.4)	7 (10.3)	1 (1.5)	6 (8.8)	0	2 (3.2)
X ²	/	7.448	6.885	7.256	6.783	4.967	6.992
P	/	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05

3 Conclusion

Pain is a subject and physiological feeling and will have a certain influence on a person's physiological emotion [4]. The reason pain occurs typically is the tissues in the body are damaged or nerves are compressed. One of factors that ordinary patients are most afraid of during the development of disease is pain. If chronic pain is not relieved, the quality of life and mental state of patients are seriously reduced [6]. Like blood pressure and heart rate, pain was considered as a vital sign in the United States medical community in as early as 1995 [6]. According to clinical data, the incidence rate of pain in patients with

advanced malignancy can reach about 70%, of which pain with moderate and above degree take up 50%, and pain in the treatment of advanced malignancy is viewed as a center of attention[7].

There are many causes of pain in patients with tumors, and the infiltration of pain-sensitive structures like internal organs, nervous tissues and vessels is the most common cause. The pain caused by tumors is divided into two categories of neuropathic pain and nociceptive pain in the medical community. Neuropathic pain means cancerous lumps compress peripheral nervous systems, causing pain perception of patients; nociceptive pain normally means pain in internal

organs or limbs of patients [8]. In the treatment of patients with advanced malignancy, opioids are the most commonly used analgesic, morphine is used in the initial analgesic treatment, later with the development of medicine, oxycodone is found to have significant advantage in terms of analgesic effects and relatively small side effect on patients, and thus considered as an ideal alternative to morphine [9]. Oxycodone will trigger the activity of the opioid receptor in the body of patients after entering the body and is combined with the receptor. This drug has better analgesic effects in different types of pain, generally, about 2 times that of the same dose of morphine [10]. In this test, the rate of pain relief for the study group is 95.59%, obviously higher than that of the control group at 75% ($P < 0.05$), which shows the high efficiency of oxycodone hydrochloride sustained - release tablets in analgesic treatment. Before administration, the pain status of patients is diagnosed by the physician in charge, the dosage of patients is arranged according to the results of diagnosis, and the dosage shall be appropriately adjusted based on the pain condition of patients; if needed, the dosage will be duly increased on the condition that the times of administration remain unchanged. The cases of patients in different degrees of pain relief are: 13 cases for 2 degrees, 24 cases for 3 degrees, and 14 cases for 4 degrees, with significant analgesic effects.

The pain cause by advanced malignancy could greatly affect the quality of life of patients. With the content of oxycodone of 38%, the oxycodone hydrochloride sustained - release tablet functions within 1 hour after administration, and continuously plays a role in 12 hours, therefore, taking the medicine once every 12 hours can maintain better analgesic effects and be critically helpful in ensuring the quality of life of patients [11]. In addition to remarkable analgesic effects, oxycodone hydrochloride sustained - release tablets have an analgesic role in patient emotion, and after the treatment, all the patients' appetite, sleep, daily life, mental state, aspect of dealing with people have been

improved, but the quality of life of the patients in the study group was improve more obviously compared with those in the control group ($P < 0.05$).

During the use of opioids to relieve pain, some side effects occur in patients with advanced malignancy, mainly including constipation, vomit, mental disorder, dry mouth, urinary retention, rash etc., and these adverse reactions will have a certain influence on the daily life of patients [12]. But studies show that, with the increases in the administration time of patients, drug resistance will gradually be strengthened and adverse reactions caused by the medicine will be relieved. In this test, through observation and recoding of adverse reactions in patients, we found that the adverse symptoms like nausea and vomit occur mainly in the first week after administration, and after one week, these symptoms would be significantly improved [13]. To reduce the impact of adverse reactions, adequate nutrition should be provided to all patients, provision of dietary fibers in food should be ensured, and the incidence rate of adverse symptoms should be controlled as much as possible [14]. To better study the oxycodone hydrochloride sustained - release tablet, statistical analysis were carried out on the cases of incidence of adverse reactions in the patients in the two groups in the process of treatment in this test. The results showed that, the incidence rate of adverse reactions like vomit and mental disorder in patients in the study group was notably lower than the control group ($P < 0.05$). This is mainly because the main metabolic products of oxycodone hydrochloride sustained - release tablets inside the body are noroxycodone and hydromorphone. These products can completely pass out of the body through renal metabolism, without any toxic side effects, at the same time, the incidence rate of adverse reactions caused by this drug is not correlated with dosage, thus exhibit better safety in patients with advanced malignancy with large dosage [15].

In short, in the treatment of advanced malignancy, oxycodone hydrochloride sustained - release tablets

have better analgesic effects with small incidence rate of adverse reactions, are greatly helpful in improving the quality of life of patients and can be clinically promoted and used.

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