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ORIGINAL ARTICLE

Therapeutic effects of 5-fluorouracil sustained-release particles in 81 malignant pericardial effusion patients

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Abstract This study aimed to investigate the clinical application value of the 5-fluorouracil (5-FU) sustained-release particles implanted along the cardiac tangent direction into malignant pericardial effusion (MPCE). A total of 81 MPCE patients underwent pericardiocentesis, and were implanted with 5-FU sustained-release particles into the pericardial cavity under ultrasound guidance. The puncturing path was along the cardiac tangent direction. Ultrasound examinations were performed every week, and the efficacy was evaluated 4 weeks after treatment. The 45 patients who were treated with pericardial catheter drainage and simultaneous intracavitary chemotherapy were used as the control group. The success rate of pericardiocentesis was 100%. Ultrasound reviews performed 4 weeks after treatment showed that 71 cases achieved complete remission and eight cases achieved partial remission, while treatment was completely ineffective in two cases. The total remission rate was 97.53%, which was significantly higher than that of the control group (77.78%, $p < 0.01$). The implantation of 5-FU sustained-release particles along the cardiac tangent direction was safe, and demonstrated good efficacy and fewer adverse reactions. Thus, this method could be ideal for the treatment of MPCE.

Conflicts of interest: All authors declare no conflicts of interests.

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Introduction

Malignant pericardial effusion (MPCE) is a common clinical manifestation in patients with advanced malignant cancers that seriously affect the prognosis. The effective control of pericardial effusion is significant at alleviating the suffering of patients and prolonging their lives. Pericardiocentesis, accompanied with catheter drainage (CD) and intracavitary chemotherapy, is the main treatment method for MPCE. In recent years, China has independently developed implantable sustained-release fluorouracil, which has been applied for the treatment of various malignant tumors or prevention of metastasis and recurrence, and achieved certain positive effects [1,2]. Many scholars have applied this method during surgery for various gastrointestinal cancers [3]. Some scholars have also made useful attempts in the treatment of liver cancer [4], pancreatic cancer, breast cancer, and ovarian cancer [5]. Numerous studies have shown that 5-fluorouracil (5-FU) sustained-release implantation dose has good safety and efficacy in the treatment of malignant pleural effusions and malignant ascites, especially in palliative treatment [6]. As for its treatment, the currently widely-accepted strategy during the emergency was rapid pericardial puncture, fluid-drainage-decompression and saving lives, and the regeneration of the effusion should be controlled or suppressed, which is the current clinical research hotspot. In this study, 5-FU particles instead of other chemotherapeutic drugs were imported into pericardial cavity by ultrasonic intervention technology to treat MPCE. This method is a novel exploration in the ultrasonic intervention field. In this study, a particle implantation (PI) needle was used to pierce through the skin and into the pericardial cavity, completing the processes of pumping fluid and implanting medicine. The pericardium was decompressed, and etiological treatment was simultaneously performed, which achieved good results. A preliminary summary regarding the treatment of 81 cases of MPCE patients is reported in this paper.

Patients and methods

Case selection

A total of 81 hospitalized patients (PI group: comprised 33 males and 48 females, mean age, 61 years), suffering from pericardial metastasis of late malignant tumors and different levels of pericardial effusion, were selected from the Shengli Oil Field Center Hospital from October 2006 to October 2011. The KPS scores of the PI group ranged from 20 points to 50 points, with an expected survival duration $>$ 2 months. The primary tumors were pathologically confirmed, included 44 cases of lung cancer, 11 cases of breast cancer, 11 cases of gastrointestinal cancer, six cases of ovarian and cervical cancer, and nine cases of other malignancies. The selected cases suffered from a large or very large surrounding pericardial effusion, in which the width of the nonecho region was 2.0—6.0 cm, and accompanied with a *swinging heart*. Eight cases exhibited pericardial metastases or irregular thickening of the parietal pericardium (Fig. 1), and 73 cases exhibited pleural effusion (90%).

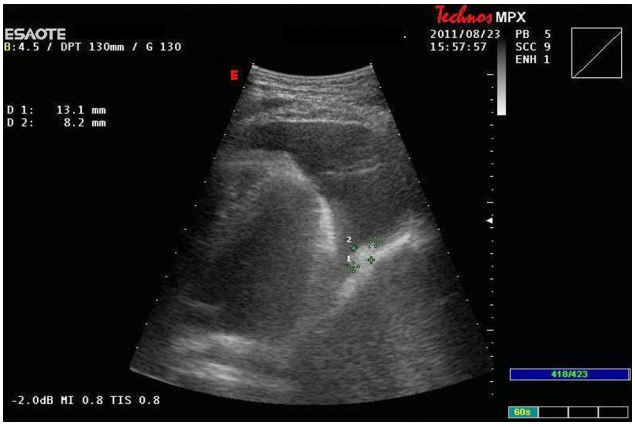

Figure 1. The metastatic lesion can be seen in the pericardium.

A total of 45 patients (25 males and 20 females with an average age of 59 years old) underwent pericardial CD and intracavitary chemotherapy during the same period, and they were established as the controls (CD group). Among these 45 cases, 23 were of lung cancer, nine were of breast cancer, six were of gastrointestinal cancer, one was of ovarian cancer, and six were of other malignancies. All the CD patients had large or extremely large surrounding pericardial effusion.

Equipment

A DU8 and DU6 color Doppler ultrasonic diagnostic apparatus (Esaote Group Co., Genoa, Italy), with a convex array probe (2.5—7.0 MHz) and/or linear array probe (5.0—10 MHz), was used as the intervention monitoring and guiding device. An angle-fixed side-type titanium guiding device, which was provided by the ultrasound machine manufacturer (angles of 20°, 25°, 30°, 35°, and 45°), was used as the puncturing guide. An 18-gauge particle-implantation (PI) dedicated needle (outer diameter 1.2 mm, internal diameter 1.0 mm) was used in the apparatus.

Drugs

The drugs used were sustained-release 5-FU (Wuhu Zhongren Pharmaceutical Co., Ltd., Wuhu, China), which has the trade name of Sinofuan (Approval No: H20030345). This drug is a long-term antitumor formulation, and appear as a milk-white cylinder-like particle. The diameter of each particle is 0.8 mm, length 4 mm. Each particle contains approximately 2 mg of 5-FU, and 100 mg for each unit. The releasing period ranges from 15 days to 20 days [7].

Puncturing path

To improve the safety of paracentesis, the cardiac tangent or approximately tangent direction was established as the puncturing path (denoted as the cardiac tangent direction) under real-time ultrasonic guidance, which would avoid the possibility of heart damage.

The puncturing point was preoperatively located at the place where the pericardial effusion volume was relatively