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Adoption of nanoparticle micro-infusion valve in venous port access for tumor patients and self-care analysis

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ABSTRACT

It aimed to discuss the adoption of nanoparticle micro-infusion valves in the totally implantable venous access port (TIVAP) of tumor patients and analyze the self-care of patients after surgery. A total of 189 tumor patients who received TIVAP chemotherapy were selected from the day chemotherapy outpatient department of the Second People's Hospital of Lianyungang City from June to October 2021. The questionnaire survey was conducted to collect and analyze the general information about the patients and the patient's self-care ability. All the surveys and analyses were performed using a general information questionnaire, self-care competence scale, self-management efficacy scale, social support scale, and self-rating anxiety scale. Moreover, the nanoparticle micro-infusion valve was prepared, and its characterization, in vitro drug release, and cytotoxicity were studied. The self-management ability of patients was concentrated in the middle and high levels. Marital status, education level, and economic status all had a great impact on the patient's self-care ability. The infusion of dithiothreitol (DTT) increased the drug release of the nanoparticle micro-infusion valve. When pH=5.0, the drug-loaded nanoparticle micro-infusion valve release amount was greater than when pH=7.4. When pH=5.0 and pH=7.4, the cell survival rates under the drug-loaded nanoparticle micro-infusion valve were both lower than that without drug loading. Nanoparticle micro-infusion valves can specifically identify tumor cells, and have good adoption prospects in TIVAP implantation in tumor patients. Gender, marital status, education level, etc. all affected the self-care ability of patients.

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Introduction

The global incidence of malignant tumors is increasing with time, and epidemiological statistics show that there are approximately 14.09 million new cancer patients worldwide each year. There are about 380.4 new patients with malignant tumors every year in China (1). This number is very large, and the incidence of tumors is getting higher and higher, which seriously affects human life, health, and quality of life. At present, the treatment of malignant tumors is generally combined with surgery, chemotherapy, radiation, immunity, and other treatment methods. The most frequently used treatment method is chemotherapy (2). Chemotherapy relies on drugs to kill cancer cells and is generally administered by oral, intraperitoneal, or intravenous methods. The most important method of administration is intravenous drip, which leads to a large number of patients needing to inject drugs through intravenous injection for a long time. However, long-term adoption of traditional methods for intravenous administration often causes problems such as phlebitis, local redness, drug extravasation, difficulty in puncture, and exposure of the distal end of the catheter. Moreover, the traditional intravenous injection method also has great limitations on the patient's activities (3). In addition, the traditional way of infusion is through superficial vein injection, which is simple and easy to implement at a low cost. It is suitable for patients with short-term injections, for general chemotherapeutic drugs stimulate the superficial veins greatly (4). However, patients can't tolerate it for a long time, so traditional intravenous injection can't be used in patients who require long-term intravenous injection (5). The above problems reduce the quality of life of patients and also lead to poor treatment results. Therefore, venous port access TIVPA came into being.

Implanted TIVAP is a new type of intravenous infusion device that can be placed under the skin for a long time. Compared with other intravenous infusion methods, it has various advantages such as portability, beautiful appearance, long retention time, and simple daily care. Moreover, it can also effectively reduce the workload of nursing staff and indirectly improve the relationship between doctors and nurses (6). Based on the above-mentioned advantages, it has been widely utilized in clinical chemotherapy for cancer patients. Although TIVAP brings various benefits, it also brings many complications. Patients in the indwelling period of infusion port often need to cultivate at home for a short period, during which there is no help and support from professional nursing staff. The incidence of various related complications has increased significantly. Some scholars conducted studies on breast cancer patients receiving TIVAP and found that since the patients have been mopping the floor at home for a long time, some discounts on the infusion port have been caused. At the same time, long-term constipation led to increased pressure in the chest cavity, which further caused blockage of the

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catheter. Some patients had infections in the skin tissues around the harbor because they didn't pay attention to personal hygiene (7). Clinical investigation data showed that there were many complications caused by improper personal care, similar to the above-mentioned complications. In summary, scientific self-care directly determined the incidence of TIVAP complications and the treatment effect.

The concept of self-care was first proposed by Orem in 1971. The concept is an activity that people carry out to maintain their health or avoid diseases. In general, it is the ability to self-care (8). It mainly includes three parts: basic competence, the ability to ensure self-care ability implementation, and self-care implementation ability. At present, relevant domestic research is gradually deepening, and the current research content is mainly concentrated in the field of chronic diseases such as asthma, cardiovascular, and stroke. Research related to malignant tumors was also increased. However, there were very few studies on the self-care of cancer patients during the indwelling period of TIVAP (9). In this work, research was conducted on related issues to provide a basis for the study of self-care of TIVAP indwelling period of cancer patients.

In the clinical treatment of malignant tumors, in addition to the problems caused by long-term intravenous injection, another major factor affecting the therapeutic effect is the inability of drugs to specifically identify tumor tissues. While killing cancer cells, it also causes great damage to normal tissues. Moreover, the effect of the drug itself is also compromised because of the non-targeting effect, which increases the side effects during the treatment process and reduces the treatment effect. In view of the above problems, many scholars made a lot of explorations on the treatment of high-specific response drug carriers. Studies found that peptides had strong biocompatibility and degradability, and were good drug carriers (10). In this work, a nanoparticle micro-infusion valve was designed based on peptide molecules, and the cytotoxicity, in vitro drug release path, and targeting of tumor tissues was studied. It was hoped that this technology can be combined with TIVAP technology to achieve a better therapeutic effect.

Materials and Methods

Research subjects

A total of 189 tumor patients who received TIVAP chemotherapy were selected from the day chemotherapy outpatient department of the Second People's Hospital of Lianyungang City from June to October 2021. All patients were with malignant tumors, and all subjects received intravenous chemotherapy through TIVAP. The subjects were all older than 18 years old, and they were all conscious and able to communicate normally. Exclusion criteria: those who can't undergo TIVAP chemotherapy, and those who had cognitive impairment or can't communicate normally. All subjects in the experiment signed informed consent and met medical ethics requirements.

Preparation of nanoparticle micro-infusion valve

810mg Mesoporous silica nanoparticle (MSN) was tri-dispersed into 64mL methanol by ultrasound, and then 3mL 3-thio-propyltrimethoxy silane was added and stirred at room temperature for 24h. After centrifugation at 8000r/min for 10 minutes, it was washed with methanol several times and vacuum dried. Then, it was dispersed into 84mL methanol again, and the ultrasonic operation was carried out to make it evenly dispersed. After that, 5.2mL of concentrated hydrochloric acid was added and refluxed at 60℃ for 48 hours. The nanoparticle micro-infusion valve was centrifuged again at 8,000 r/min for 10 minutes and then dried several times after being washed with methanol.

In vitro drug release behavior study

Two portions of 2.0mg MSN-S-S-Peptide-MPEG/DOX were dispersed in 2mL phosphate buffer at 37℃. After 24h, one of them was centrifuged, and the supernatants of the two were taken as required and placed under the excitation wavelength of 488nm to observe the fluorescence intensity at 560nm. Two portions of 2.0mg MSN-S-S-Peptide-MPEG/DOX were dispersed in 2mL phosphate buffer at 37℃ Without any treatment, the supernatant was taken according to the rules and placed under the excitation wavelength of 488nm to observe the fluorescence intensity at 560nm. Three portions of 2.0mg MSN-S-S-Peptide-MPEG/DOX were dispersed in three concentrations of dithiothreitol (DTT) at 37℃. Then, the supernatants of the three groups were taken according to the regulations and placed under the excitation wavelength of 488nm to observe the fluorescence intensity at 560nm.

In vitro cytotoxicity study

U-87MG cells were separated into 96-well plates at a density of 5.0×10^4 cells/well and then added with 100μL fetal bovine serum (FBS) at 37℃ and cultured in 5% CO_2 for 24h. Then, MSN-S-S-Peptide-MPEG/DOX cultured under pH 7.4 and pH 5.0 was added to each well. The medium was absorbed, and 200μL fresh medium was added. 20μL of thiazolyl blue (MTT) solution was added, and the medium was cultured at 37℃ for 4 hours. Then, the medium was absorbed and 150μL dimethylsulfoxide (DMSO) was added. The absorption values at 570nm of each well were determined by an enzyme-plate analyzer. The relative survival rate of cells was calculated and the control cell survival rate was considered to be the control.

Treatment methods

TIVPA implantation was done by experienced doctors. Before the drug injection, the doctor's permission and double-check were required. The condition was explained to the patient to let the patient cooperate. Whether the skin around the infusion port had swelling, hematoma, infection, etc. should be checked. In addition, the patient was guided to urinate and defecate. Nurses needed to use the seven-step handwashing method to wash their hands. The medicine packs, non-damaged needles, alcohol, saline, etc. were prepared in advance. After disinfection, the heparin was injected, and then the non-damaged needle was fixed. The blood was withdrawn, and 10mL of normal saline was injected in pulse mode. Then, the infusion system was connected to complete the injection of the drug-loaded nanoparticle micro-infusion valve. Finally, conventional pulse flushing and positive pressure sealing of the tube were done. It should be noted that the tube needed to be flushed every four weeks, and the non-damaged needle needed to be replaced every seven days.

Self-care ability scale

The evaluation scale was first designed and proposed by American scholars Kearney and Fleischer. Later, it was

translated into Chinese by Taiwanese scholars. At present, China scholars are applying this score scale to evaluate the self-care ability of patients with chronic diseases. Studies showed that the accuracy, reliability, and evaluation efficiency of the scale were high. The scale contains four aspects of self-concept (8), self-care responsibility (6), health knowledge (11), and self-care skills (12), with a total of 43 questions. From "very much like me" to "very unlike me", 0-4 points are assigned, respectively. Among them, 11 items need to be assigned a score of 0 to 4 points from "very unlike me" to "very much like me". The minimum score is 0 points and the full score is 175 points. The sum of the scores is the evaluation index of the patient's self-care ability. The higher the score, the stronger the nursing ability. The specific grading standard of self-care ability based on the score is as follows. <56: poor; 56-113: good; > 113: excellent.

Self-management efficacy scale

This evaluation scale was first designed and proposed by American scholars Lev and Owen, and it was used to evaluate the self-efficacy of patients with chronic diseases in the early stage. After being introduced in China, it has been modified and adjusted into a self-management effect scale suitable for cancer patients in China based on the actual situation. The assessment form mainly includes three parts: self-decision (3), positive attitude (13), and self-decompression (10). There are 28 questions in total, and the specific scoring criteria for each question are: no confidence: 1 point; a little confidence: 2 points; confident: 3 points; very confident: 4 points; and highly confident: 5 points. The minimum total score of all items is 28 points, and the full score is 140 points. The higher the score, the higher the self-management efficiency. According to the total score, self-management efficacy is graded into three levels. 28-55: poor; 56-112: good; 113-140: excellent.

Self-rating anxiety scale

This scale can quickly and accurately reflect the patient's anxiety. The test has a total of 20 assessment questions, and the 5th, 9th, 13th, 17th, and 19th questions need to be scored in reverse, that is no or very little: 4 points; occasionally: 3 points; most of the time: 2 points; and nearly all the time: 1 point. The total score of all items is multiplied by 1.25 to get the final score. According to the total score, the specific anxiety level is graded into: no anxiety: < 50 points; mild anxiety: 50-59 points; severe anxiety: 60-69 points; and severe anxiety: ≥ 70 points.

Social support rating scale

The evaluation scale was independently proposed and designed by Chinese scholars. There are 10 questions in total, covering three aspects: objective support, subjective support, and support utilization. Among them, questions 1 to 4 and questions 8 to 10 are single multiple-choice questions. The four options are scored 1 to 4 points in turn. The 5th question is cumulatively scored, and none, very few, general, and full support are scored 1, 2, 3, and 4 points in turn. Questions 6 and 7 are indefinite multiple-choice questions that have several sources and scores. The sum of all project scores is the final score, of which the lowest score is 12 points and the full score is 66 points. The specific social support grades are as follows: poor: 12-22 points; good: 23-44 points; and excellent: 45-66 points.

Results

Subject's general information

All subjects included were tumor patients who received intravenous chemotherapy through implantable TIVAP. The age was 31-77 years old. Female patients accounted for 86%, and male patients accounted for 14%. High school education and above accounted for 19%, junior high school and below 81%; and married 92%. 54% lived in suburbs or urban areas, while 46% in towns or rural areas. 78 cases of farmers, and 55 cases of individuals or service personnel. The average monthly household income per capita was 20% above 3,000 yuan, and 80% below 3,000 yuan. The main caregivers were 58% of spouses and 34% of children. 98% of those who live with family or friends. There were 45% of provincial and municipal medical insurance and public expenses and 53% of new rural cooperative medical care. Table 1 illustrated the specific details.

Results of in vitro drug release studies

The results of in vitro drug release studies of the nanoparticle micro-infusion valve were shown in Figure 1, Figure 2, and Figure 3. Figure 1 showed that the amount of drug released after DTT was added was dramatically lower than that without DTT. Figure 2 showed that the

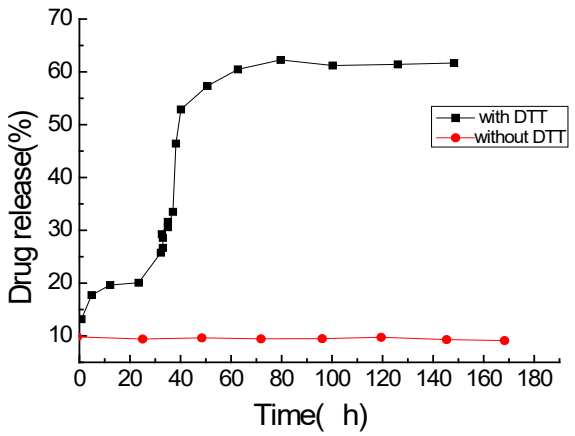

Figure 1. Comparison of drug release of nanoparticles micro-infusion valve with and without DTT.

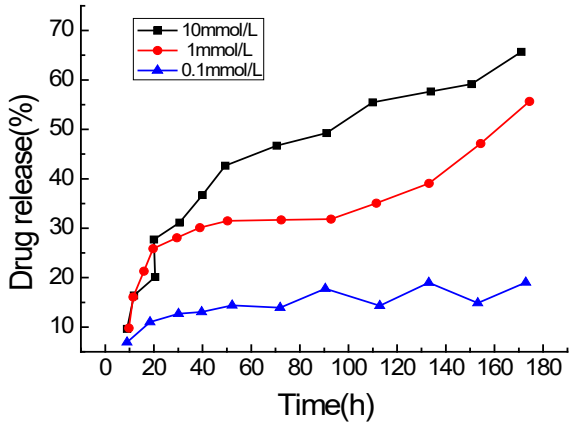

Figure 2. Nanoparticle micro-infusion valve drug release under different concentrations of DTT.

Table 1. General information of subjects.

Item	Group	The proportion (%)
Age (years old)	18~44	13
	45~59	58
	≥ 60	29
Gender	Female	86
	Male	14
Educational level	Elementary school and below	30
	Junior high school	51
	High school	27
	University	2
Marital status	Married	92
	Unmarried	1
	Widowed	1
	Divorced	6
Residence	Suburbs	35
	Urban area	19
	Township or rural area	46
Living alone or not	Live alone	2
	Live with family or friends	98
Average monthly household income	≤ 1000	34
	1001~3000	46
	3001~5000	18
	>5000	2
Primary caregiver	Mate	58
	Child	34
	Parents	3
	Brothers and sisters	5
Payment methods	Public expense	1
	Own expense	1
	Provincial and municipal medical insurance	45
	Rural cooperative medical system	53

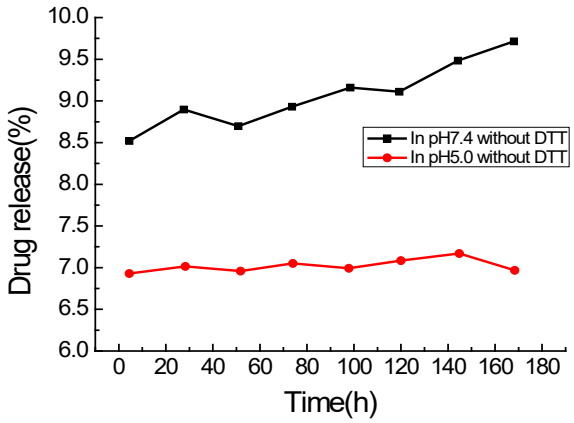

Figure 3. Comparison of drug release of nanoparticle micro-infusion valve at different pH without DTT.

amount of drug released increased as the concentration of DTT increased. Figure 3 showed that the drug release amount under pH 5.0 was higher than that of pH 7.4.

Cytotoxicity test results

The cell survival status of unloaded and drug-loaded nanoparticle micro-infusion valve U87 cells at different pH after 48 hours of co-cultivation was shown in Figure 4 and Figure 5. Figure 6 showed the cell survival rate of the nanoparticle-free micro-infusion valve without drug-loaded culture. From Figure 4, in the case of drug-loaded nanoparticles micro-infusion valve, as the concentration of DTT continued to increase, the cell survival rate continued to decrease. The cell survival rate at pH 7.4 was significantly higher than that of pH 5.0. From Figure 5, cell survival rates at different pHs under the micro-infusion valve of unloaded nanoparticles were high. From Figure 6, the cell survival rate was high under different pH with no nanoparticle micro-infusion valve without the drug.

Patient self-management efficacy, social support, and anxiety survey results

The survey results of patients' self-management efficacy, social support, and anxiety were shown in Table 2, Table 3, and Table 4, respectively. From Table 2, the pro-

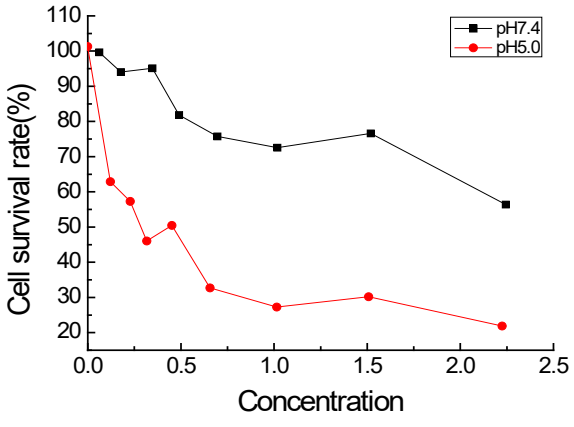

Figure 4. U87 cell survival rate of drug-loaded nanoparticles micro-infusion valve at different pH.

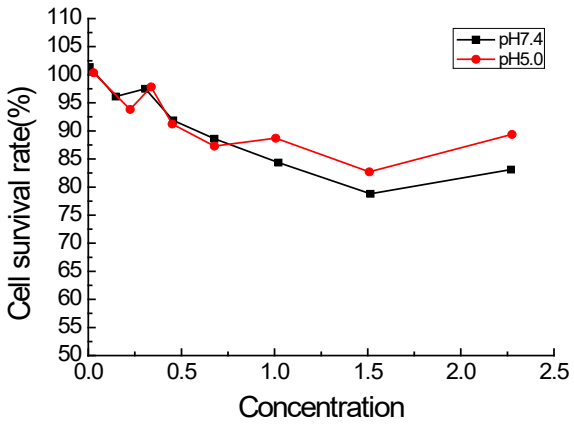

Figure 5. U87 cell survival rate of unloaded nanoparticles micro-infusion valve at different pH.

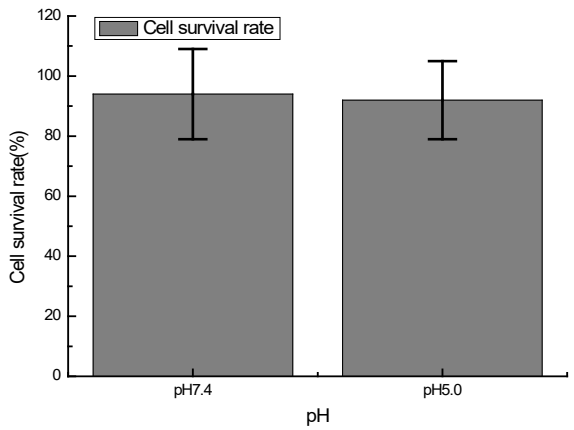

Figure 6. U87 cell survival rate at different pH.

portion of patients with poor self-management levels was 0%, the proportion of good ones was 66%, and the proportion of excellent ones was 34%. From Table 3, the proportion of low-level social support was 0%, the proportion of medium-level was 62%, and the level of high-level was 38%. From Table 4, patients with no anxiety accounted for 43%, patients with mild anxiety accounted for 48%, patients with moderate anxiety accounted for 7%, and patients with severe anxiety accounted for 0%.

Discussion

Malignant tumors are currently one of the important causes of human deaths, and their incidence is increasing day by day. At present, the main clinical treatment methods for malignant tumors are surgery, chemotherapy, radiation, and immunization. Under normal circumstances, these methods are used together and generally not used alone. Among them, chemotherapy is the most frequently used and common treatment method (14). The most important ways of administration of chemotherapy are oral, intraperitoneal, and intravenous. Because of the high efficiency of intravenous injection, it is often used clinically to treat patients with chemotherapy (12). The traditional method of intravenous injection is injecting drugs through a superficial vein. Although this injection method is simple, easy, and economical, it is only suitable for short-term use. If utilized for a long time, it is easy cause phlebitis, local redness, and puncture difficulties (15). The chemotherapy treatment of tumors generally requires long-term injections. If the traditional intravenous injection method is used, various complications may seriously affect the treatment effect (16). From the above conditions, the traditional mirror injection method is not suitable for the treatment of tumors. In recent years, TIVAP has developed rapidly and has been widely used in clinical chemotherapy for cancer patients. TIVAP is a new type of closed intravenous infusion device that can be placed under the skin for a long time. Many research data showed that IVPA can be repeatedly pierced 2,000 times without repeated replacement of the infusion device, which is suitable for long-term use. In addition, many clinical data showed that TIVAP was very safe. In addition, TIVAP has many advantages such as portability, beauty, and simple care (15). The tumor patients included in this research received TIVAP,

Table 2. Evaluation results of patients' self-management efficacy.

Score groups	Grade	Cases	Proportion (%)
28~55	Poor	0	0
56~112	Good	125	66
113~140	Excellent	64	34

Table 3. Evaluation results of patients' social support level.

Score groups	Grade	Cases	Proportion (%)
≤ 22	Poor	0	0
23~44	Good	117	62
45~66	Excellent	72	38

Table 4. Evaluation results of patients' anxiety level.

Score groups	Grade	Cases	Proportion (%)
< 50	No	83	44
50~59	Mild	89	47
60~69	Moderate	12	9
≥ 70	Severe	0	0

the treatment effect was good, and there were no problems that often occurred in traditional injection methods, which was consistent with the above research. Although TIVAP has many advantages, patients in the indwelling period in the infusion port often need to rest at home for a period of time. During this period, without the professional guidance of medical staff, the self-care ability of patients is very high. Clinical data showed that many complications related to TIVAP occurred during the patient's home resting period. For example, studies suggested that breast cancer patients undergoing TIVAP had been mopping the floor for a long time at home, resulting in partial discounts at the infusion port, and long-term constipation had caused increased pressure in the chest cavity, which further caused catheter blockage. Some patients had infected the skin tissues around the harbor because they didn't pay attention to personal hygiene. All patients in this study didn't have TIVAP-related complications, which may be related to the fact that most of the patients in this study were women and had high self-care awareness and ability.

The so-called self-care is the activity of self-care people to maintain their health or avoid diseases. It includes the basic ability and quality, the ability to ensure the implementation of self-care ability, and the ability to implement self-care. In recent years, related research in China has gradually increased, and the research content is mainly concentrated in the field of chronic diseases such as asthma, cardiovascular, and stroke (17,11). At present, research on malignant tumors has also increased. However, there are very few researches on the self-care of cancer patients during the TIVAP indwelling period (18). Therefore, questionnaire was utilized in this research to study the self-care of cancer patients undergoing IVPA during the indwelling period. It was found that gender, marital status, education level, etc. all had an impact on patients' self-care ability. It provided a basis for better self-care for patients receiving TIVAP during the indwelling period.

The long-standing problem in the treatment of malignant tumors in the clinic is that chemotherapeutic drugs can't specifically identify tumor tissues, killing cancer cells while also damaging normal tissues (19). Therefore, highly specific response drug carriers have become a hot spot in current research. Studies found that the nanoparticle micro-infusion valve had strong biocompatibility and degradability, and was a good drug carrier (20). Therefore, a nanoparticle micro-infusion valve was designed based on peptide molecules, and its cytotoxicity, in vitro drug release path, and targeting to tumor tissues were analyzed. It was found that the nanoparticle micro-infusion valve had a strong specificity for tumor cell recognition, and it had a good adoption prospect in the treatment of tumors.

Conclusion

In this research, the adoption effect of nanoparticle micro-infusion valves in TIVAP of cancer patients and patients' self-care ability were analyzed. It was found that nanoparticle micro-infusion valves can specifically recognize tumor cells, which had a good adoption prospect in TIVAP implantation in tumor patients. In addition, gender, marital status, education level, etc. all had a great impact on the patient's self-care ability after TIVAP implantation. However, due to limited space and samples, this work isn't comprehensive and in-depth enough. To combine the nanoparticle micro-infusion valve with TIVAP for direct clinical adoption, further research is needed. In addition, the exploration of self-care for cancer patients receiving TIVAP is not comprehensive enough, and further research is needed.

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