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Original Article

The effects of endocrine treatment assisted elective surgery on the survival and life quality in patients with stage 2 endometrial carcinoma

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Abstract: Objective: We investigated the data of the survival and life quality in patients with stage 2 endometrial carcinoma who underwent endocrine treatment assisted elective surgery in order to confirm the clinical value and provide data support for its promotion. Methods: 183 selected endometrial cancer patients of stage 2 who were treated with surgery in our hospital from March 2009 to March 2010 were enrolled. They were divided into two groups by random number table method, and scheduled for elective surgery and endocrine treatment assisted elective surgery therapy, respectively. The clinical efficacy, complications, survival and life quality of the patients during follow-up were compared and analyzed. Result: Effective rate of the observation group and the control group was 94.6% and 86.8%, respectively, and the observation group was significantly superior to the latter ($P < 0.05$). The incidence of complications was separately 10.9% and 17.6%, and the observation group had a significant advantage as well ($P < 0.05$). 2 years, 3 years, 4 years as well as 5 years after operation, the number of survival cases in the observation group was remarkably higher than that in the control group ($P < 0.05$). The average scores of life quality after treatments were (3.5+70.6) and (63.4+4.1) respectively, and the observation group was also superior to the control group ($P < 0.05$). Conclusion: Endocrine treatment assisted elective surgery for endometrial carcinoma of stage 2 can improve the curative effect, reduce complications, prolong survival, and improve the recurrence rate and life quality. As a result, it is valuable for popularization.

Keywords: Endocrine treatment assisted, elective surgery, endometrial cancer of stage 2, survival, life quality

Introduction

Endometrial carcinoma is one of the common clinical gynecologic malignancies, and its incidence and mortality rank the top levels of gynecologic tumors. The research on the treatment and efficacy has been the hot topic of clinical research. Although the efficacy along with the control of mortality is significantly improved with the improvement of surgical technique, it is still unable to meet the clinical demands [1]. It has been shown that endocrine therapy, used as an adjuvant in the perioperative period, can improve the clinical efficacy, prolong the postoperative survival rate and improve the life quality. Nevertheless, the side effects caused by drug administration are relatively high, and further improvement and research are still required. At present, there are more researches using patients with stage 1 endometrial cancer as the subjects compared to those with stage 2 endometrial cancer. What's more, there is no study about endocrine treatment assisted elective surgery, and it is urgent to confirm the efficacy through the data [2]. In this research, the patients with stage 2 endometrial cancer were studied. In order to confirm the clinical value of endocrine treatment assisted surgery and provide guidance for clinical treatment, the clinical data of surgical treatment and endocrine treatment assisted surgery were compared. The research process and conclusion are introduced as follows.

Materials and methods

Inclusion and exclusion criteria

In order to improve the guidance value and safety, cases in the study was selected strictly

Table 1. The comparison of surgical efficacy between the two groups

Groups (n)	CR	PR	SD	PD	Effective rate (%)
Observation Group (92)	56	31	5	0	94.6
Control Group (91)	45	34	10	2	86.8
X^2					4.684
P					0.038 < 0.05

according to the inclusion and exclusion criteria.

Inclusion criteria: 1) the cases were diagnosed as endometrial cancer of stage 2 according to both imaging and pathologic examination [3]; 2) the predicted survival was more than 3 years; 3) the cases were indicated for surgery and voluntary for surgical treatment; 4) the cases were voluntary for the research and signed "informed consent"; 5) the related requirements developed by Medical Ethics Association were met [4].

Exclusion criteria: 1) malignant tumors metastasized to other organs or sites; 2) the cases were treated with radiation therapy or hormone therapy; 3) history of drug allergy; 4) incomplete data due to drop out of the research or failed follow-up.

General information

One hundred and eighty three cases in the study were randomly divided into two groups by using the random number table method. The basic clinical data were as follows.

The observation group had 92 cases: 1) age: 45-68 years, (56.3+12.2) years on average; 2) course: 1-3 years, (1.8+0.5) years on average; 3) pathological types: there were 89 cases of adenocarcinoma and 3 cases of other types; 4) differentiation: there were 53 cases of high differentiation, 32 cases of moderate differentiation and 7 cases of low differentiation.

The control group involved 91 cases: 1) age: 44-66 years, (55.8+12.6) years on average; 2) course: 1-3.5 years, (1.9+0.6) years on average; 3) pathological types: there were 87 cases of adenocarcinoma and 4 cases of other types; 4) differentiation: there were 49 cases of high differentiation, 36 cases of moderate differentiation and 6 cases of low differentiation. Intergroup comparison in the data above showed that there was comparability without significant difference (P > 0.05).

Treatment methods

Treatment of the control group: The control group was treated with endocrine treatment assisted elective operation. After laparoscopic exploration, laparoscope assisted vaginal hysterectomy combined with pelvic lymph node dissection under general anesthesia was conducted. If the resection was not ideal or there was severe abdominal adhesion, open surgical treatment was used. All the procedures, such as detailed inspection, anesthesia, the establishment of pneumoperitoneum, surgery, intraoperative nursing, treatment of complications, drainage tube indwelling, wound suture, postoperative nursing, etc., were operated according to clinical routine.

Treatment of the observation group: The observation group was treated with endocrine treatment assisted elective surgery, and the surgical procedures were similar to those of the control group. The endocrine therapy was as follows: (1) Drugs: 1) Medroxyprogesterone acetate (MPA): Dispersible tablets were produced by Nanjing Xianhe Pharmaceutical Co., Ltd., with the National Drug Approval No. of H2001012 and specification of 250 mg/tablet; 2) Megestrol acetate (MA): Dispersible tablets were produced by Xi'an Detian Pharmaceutical Corp., with the National Drug Approval No. of H20040001 and specification of 40 mg/tablet; 3) Hydroxyprogesterone caproate: Injection was produced by Shanghai General Pharmaceutical Corp., with the National Drug Approval No. of H31021267 and specification of 0.125 g/piece; (2) Dosage and administration: 1) MPA: 1 tablet/time, 2 times/day, oral administration after meals; 2) MA: 2 tablets/time, 2 times/day, oral administration after meals; 3) Hydroxyprogesterone caproate: 4 pieces/time, 2 times/week, deep intramuscular injection. Dose adjustment should be performed according to the patient's condition changes; (3) Administration time and course of treatment: Endocrine therapy, continuous treatment for 1 month as a course, was given 1 month preoperatively and 1 week postoperatively, a total of 1 course preoperatively and 6-10 courses postoperatively.

Evaluation items and standards

Surgical efficacy: The evaluation criteria are listed as follows, which were drafted according to "the evaluation criteria of solid tumor efficacy". 1) Complete remission (CR): The lesions

Table 2. The comparison of complications between the two groups

Groups (n)	Hemorrhage	Uroschesis	Venous Thrombosis	Ureteral Injury	Lymphocyst	Complication Rate (%)
Observation Group (92)	2	3	2	1	2	10.9
Control Group (91)	3	2	4	4	3	17.6
X^2						3.966
P						0.048 < 0.05

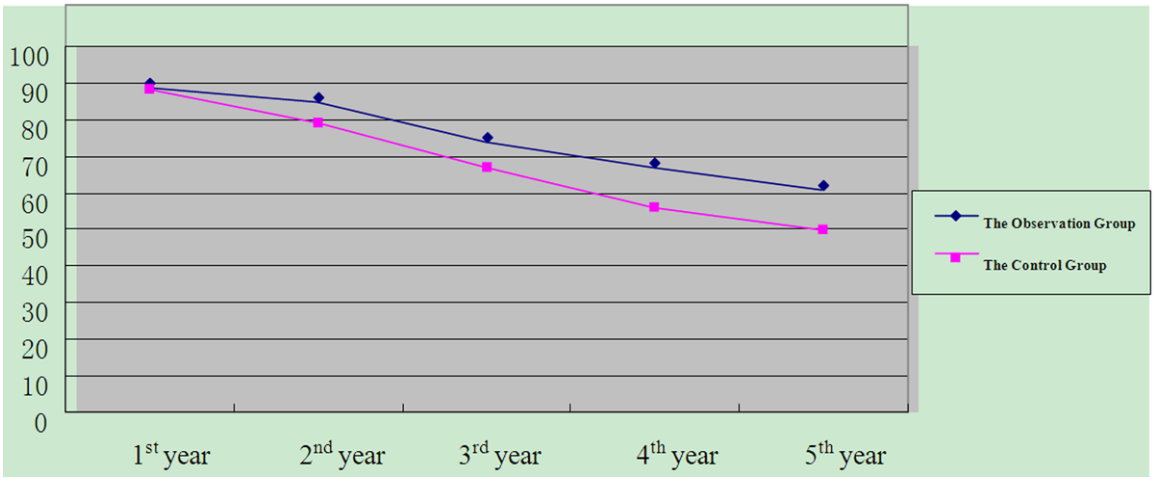

Figure 1. The distribution of postoperative survived cases.

completely disappeared, with the short diameter of the pathologic lymph nodes < 10 mm; 2) Partial response (PR): The sum of the lesion diameter decreased by more than 30% compared with the level of the baseline; 3) Disease stabilization (SD): The extent of the target lesion did not decrease to PR level, while the extent of the increase did not reach PD level; 4) Disease progression (PD): The diameter of the lesions increased by more than 20%, and the absolute value increased by over 5 mm. Effective percentage = (CR+PR) case load/case load of the whole research *100% [7].

Complications: the number of cases suffering complications during the surgery together with the incidence rate was calculated [8].

Survival: The number of cases who survived at year 1, year 2, year 3, year 4 and year 5 after surgery was calculated, respectively, which was used as the evaluation content of survival, and it was implied that the number of survived cases was positively correlated with survival [9]; (4) Recurrence rate: The number of cases with recurrence at year 1, year 2, year 3, year 4 and year 5 after surgery and the recurrence rate at each time point were calculated, respectively; (5) Life Quality: QLQ-C30 questionnaire developed by WTO was used to score life quality. The higher the total scores, the higher the life quality [10].

Statistical methods

All the research data were processed by SPSS19.0 software. Measurement data were expressed as "median ± standard deviation", and t-test was employed; Count data were expressed as percentage (%), and X^2-test was employed. $P < 0.05$ indicated significant difference for intergroup comparison.

Results

Surgical efficacy

Laparoscopic operations were performed successfully on all cases except 3 cases of the observation group and 5 of the control group on which open abdominal operations were performed. Efficacy was assessed according to the evaluation criteria of efficacy. It indicated that the effective rate of the observation group and the control group was 94.6% and 86.8%, respectively, and the former was superior to the latter (**Table 1**, $P < 0.05$).

Table 3. The comparison of the recurrence rate between the two groups (%)

Groups (n)	1st year	2nd year	3rd year	4th year	5th year
Observation Group (92)	8.7 (8)	13.0 (12)	19.6 (18)	22.8 (21)	27.2 (25)
Control Group (91)	14.3 (13)	20.9 (19)	25.3 (23)	29.7 (27)	35.2 (32)
X^2	3.962	3.864	4.138	4.326	4.569
P	0.046	0.048	0.042	0.038	0.036

Table 4. The comparison of the life quality scores between the two groups (scores)

	Physiology	Psychology	Environment	Social Relations	Average Life Quality Scores
Observation Group	65.6±4.2	68.2±3.8	72.8±4.6	71.5±4.3	70.6±3.5
Control Group	59.5±3.9	59.8±4.2	64.7±5.3	62.2±4.6	63.4±4.1
t					28.659
P					0.036

Complications

Minor complications occurred in only partial cases during the operation process, which were improved after treatment. The process of study and treatment was thus not affected. The complication rate was 10.9% and 17.6%, respectively. The observation group had a significant advantage ($P < 0.05$). The detailed data are listed in **Table 2**.

Survival time

There was no marked difference in the number of survived cases between the two groups at year 1 after surgery. However, the number of survived cases in the observation group was significantly larger compared to the control group ($P < 0.05$). That's, the survival of the former was far longer compared to the latter. The distribution of survived cases is shown in the following **Figure 1**.

Recurrence rate

According to the imaging and pathological examination, the number of recurrent cases during the 5-year follow-up was recorded. Regarding comparison of the recurrence rate at each time point, the observation group was remarkably superior to the control group. The detailed data are listed in **Table 3**.

Life quality

The average life quality scores of the two groups before treatment were (55.3+3.6) and (54.8+3.9), respectively, showing no significant difference ($P > 0.05$), while the scores after treatment were (70.6+3.5) and (63.4+4.1), respectively, both showing significant improvement ($P < 0.05$). In addition, the average life quality scores in the observation group after operation were obviously higher compared to the contr ol group ($P < 0.05$). The detailed data are listed in **Table 4**.

Discussion

Endometrial carcinoma in stage 2 is a common malignancy in gynecology, which brings great harm to health and life of the patients. Besides, the state of the disease is complex. As a result, the clinical efficacy is poor. Although the operation treatment has obvious efficacy, the compliance remains low due to its higher complication rate. Endocrine therapy has a certain effect, but a long-term and large-dose administration is required. Meanwhile, the drug resistance increases as time. Thus the efficacy may be further decreased [11]. Yet there is no consistent conclusion concerning the administration time, although studies have confirmed that the endocrine treatment assisted elective surgery for endometrial cancer in stage 2 has remarkable efficacy. Therefore, study on the value of endocrine treatment assisted elective surgery performed as a treatment for endometrial cancer in stage 2 has a great guidance value in selecting proper treatment modality for the disease.

Endocrine treatment assisted elective surgery was used for endometrial cancer in stage 2, and the tumor and the lesion were removed by radical operation and lymph node dissection, improving the clinical symptoms and the patients' life quality rapidly [13]. Furthermore, endocrine drugs were used postoperatively to maintain and regulate hormones in vivo. Consequently, it can reduce recurrence of the disease, then improve long-term efficacy of the treatment, extend survival of the patients and improve their life quality [14]. The therapy is significant for the treatment of endometrial carcinoma in stage 2. However, endocrine therapy

remains to be further investigated and massive data are still required to provide support for popularization of the treatment.

Based on the data of this study, the endocrine treatment assisted elective surgery group was significantly superior to the simple operation group in terms of efficacy, complications, survival, recurrence rate and life quality ($P < 0.05$), indicating endocrine treatment assisted selective surgery for endometrial cancer in stage 2 had remarkable efficacy. The surgeons, anesthesiologists and nurses involved in the surgery were randomly assigned and the modes of operations and nursing methods were performed routinely, thereby eliminating the influence of medical level, experience, and surgical approach on the efficacy of surgery. The study was based on the endocrine therapy in patients with conventional surgery. As a result, endocrine therapy can be provided to the patients 1 month before elective surgery so that the development of tumor can be controlled to a certain extent, laying foundation for the improvement of surgical performance, surgical efficacy and complications. Furthermore, efficacy of the combined treatment, survival and life quality of the patients can also be improved. Thus its surgical efficacy, complications, survival, recurrence rate and life quality are superior to the relevant studies [15]. The treatment method is worthy popularization Though there were drawbacks in the study, such as the limited case number, the further refinement of administration, the improvement of the evaluation content, etc., the intergroup comparison of these factors were not influenced. Thus, the data and conclusion of our study are scientific and valid, which have significant clinical value.

In summary, endocrine treatment assisted elective surgery for the patients with endometrial cancer in stage 2 can improve the efficacy, reduce the complications, prolong the survival, and improve the recurrence rate and life quality, thereby worthy popularization.

Disclosure of conflict of interest

None.

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