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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

APPLICATION OF MINIMALLY INVASIVE SURGERY BASED ON PATHOHOSTOLOGICAL CRITERIA IN UTERINE CANCER

Speciality: 3224.01 – Oncology

Branch of science: Medicine

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RELEVANCE OF THE TOPIC

Relevance of the theme: Uterine cancer (UC) or endometrial cancer (EC) is one of the most common types of gynecological cancer in the world[1]. UC is a disease that occurs mainly in postmenopausal women, and the prognosis worsens with age. One in every 40 women gets uterine cancer.

Total hysterectomy (TH), bilateral salpingo-oophorectomy (BSO), and lymph node dissection (LND) are important procedures for staging. The lower incidence of surgical complications and shorter postoperative rehabilitation compared to laparotomy have increased the indications for the use of minimally invasive surgical (MIS) methods in the treatment of early-stage UC[2,3]. Laparoscopic surgery has been successfully applied to patients with early-stage UC at the Oncology Clinic of AMU since 2017[4,5]. The clinical results of minimally invasive TH+BSO+BPLND operations in early-stage UC have been proven in two randomized controlled trials[6]. After the results of studies known as LAP2 and LACE in oncogynecology became known, the application of laparoscopic surgery in the early stages of

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[2] Ibrahimov A.M. Oncological Outcomes of Stage II Endometrial Cancer: A Retrospective Analysis of 250 Cases / A. Ibrahimov, N. Ozgul, G. Boyraz, [et al.] // International Journal of Gynecological Cancer, – 2018. V.28 № 1. – p.161-170.

[3] Ibrahimov, A.M. Application and clinical results of minimally invasive surgery based on pathohistological criteria in uterine cancer: A Single Center Study in a Low-income Country //Aktualni Gynekologie A Porodnictvi, – 2024, V.16,p.70-74.

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[5] Ibrahimov, A.M. Clinicopathological and Survival Outcomes Between Minimally Invasive and Open Surgery in Endometrial Carcinoma: A Population-Based Study in a Low-Income Country / A. Ibrahimov, A. Gaziyev // Journal of Reproductive Health Eastern Europe, – 2025, V. 15, № 1, – p. 32-40.

[6] Janda M. Effect of Total Laparoscopic Hysterectomy vs Total Abdominal Hysterectomy on Disease-Free Survival Among Women With Stage I Endometrial Cancer: A Randomized Clinical Trial / M. Janda, V. Gebski, LC. Davies, [et al.] // Jama, – 2017,V.317 № 12, – p.1224-1233.

UC became even more widespread. On the other hand, the use of uterine manipulator (UM) in minimally invasive surgical operations has been a matter of controversy, especially due to its potential theoretical oncological risks; this issue remains a focus of oncologists.

In practice, the relationship between laparoscopic surgery and recurrence and overall survival rates has been documented in numerous studies[7]. The effect of UM application on lymphovascular invasion, myometrial invasion, recurrence, and cure rates in patients treated with MIS for UC has been a priority issue in recent years. UM was not used in all cases in the LACE study and occasionally in the LAP2 group. The above has made the issue of the appropriateness of UM application in patients treated with MIS for UC a topic of discussion among experts. In the early stages of uterine cancer, the myometrium acts as a protective barrier between the tumor tissue and neighboring organs. Therefore, intact removal of tumors confined to the uterine cavity is of oncological clinical importance. During maneuvers in laparoscopic surgeries, UM can iatrogenically damage this barrier. Studies by Machida et al. indicate that the risk of uterine perforation associated with UM is 0.4-1%[8]. In recent years, various theoretical considerations have been put forward regarding the increased iatrogenic risks and worsening oncological prognosis due to direct contact of UM with tumor tissue in the uterine cavity. In other words, the question of how the application of UM affects the prognosis of oncology patients has also been the focus of attention of experts and remains an unresolved issue.

On the other hand, the possibilities of applying minimally invasive surgery, taking into account the pathohistological criteria of the tumor, including histological type, depth of myometrial invasion, invasion of the lymphovascular area, and presence of cervical canal

[7] Meng, Y. The effects of uterine manipulators in minimally invasive hysterectomy for endometrial cancer: A systematic review and meta-analysis / Y. Meng, [et al.]// Eur J Surg Oncol, – 2020, V. 46 №7, p. 1225-1232.

[8] Machida H. Timing of Intrauterine Manipulator Insertion During Minimally Invasive Surgical Staging and Results of Pelvic Cytology in Endometrial Cancer / H. Machida, JP. Casey, J. Garcia-Sayre, [et al.] // J Minim Invasive Gynecol, – 2016, V.23 №2, p.234-241.

and adnexal invasion, have not been fully evaluated. Based on the above, studying the possibilities of applying MIS and assess the prognostic impact of UM application based on pathohistological criteria (histological type of tumor, depth of myometrial invasion, presence or absence of invasion of the lymphovascular area and cervical canal) was considered relevant by us and provided the basis for conducting the current research study.

Object and subject of study. The study involved 117 patients with UC, focusing on the analysis of clinical, morphological examinations, and treatment results in groups with and without UM.

Aim and objectives of the study. The study aimed to study the feasibility of minimally invasive surgery during UC based on pathohistological criteria (histological type of tumor, depth of myometrial invasion, presence or absence of invasion of the lymphovascular area, and cervical canal) and to assess the impact of UM application on prognosis.

To achieve the stated goal, the following tasks were considered necessary:

1. Characterization of the pathohistological criteria of the tumor and the treatment methods used in patients who underwent MIS surgery for uterine cancer;

2. Clinical-morphological characterization of patient groups with and without UM during UC and comparative analysis of treatment outcomes;

3. Characterization and comparative evaluation of pathohistological criteria (depth of myometrial invasion, evaluation of lymphovascular invasion, cervical and adnexal invasion) in groups of patients who were and were not administered UM during UC;

4. Evaluation of the effect of UM use on recurrence and overall survival rates.

Research methods. The research study analyzed outpatient observation cards, medical histories, clinical and morphological examinations, and surgical treatment methods. All calculations were evaluated in the EXCEL-2021 spreadsheet and SPSS-20 package program.

Main provisions to be defended:

The surgical treatment of choice for endometrioid-type UC

without cervical invasion is minimally invasive surgery. Before inserting the UM, both fallopian tubes should be coagulated proximal to the uterus in all patients with a bipolar coagulator to prevent transtubal dissemination. The UM should be placed under laparoscopic visualization in all patients.

The use of UM in the application of MIS during UC does not worsen the prognosis; this result necessitates the widespread use of UM as a tool used in minimally invasive surgical procedures during UC, providing cranial traction to the uterus, facilitating the surgical technique and improving perioperative clinical parameters, including shortening the operative time.

Scientific novelty of the study: In the study, the possibilities of applying MIS based on pathohistological criteria during UC were studied and the impact of UM application on prognosis was evaluated. According to the results of the study, the use of UM does not negatively affect lymphovascular invasion, myometrial invasion, recurrence, and cure rates in patients with endometrioid histological type. Thus, it is scientifically justified to recommend MIS as the standard choice for endometrioid endometrial cancer in clinical practice.

Theoretical and practical significance of the study. A comparative analysis of the results of laparotomy and MIS in patients with different histological types and stages of UC allowed us to determine the indications for the use of MIS. The conducted research study justified the use of MIS as the method of choice in the surgical treatment of tumors without cervical invasion in endometrioid-type UC. In the study, no statistically significant difference was observed between the groups that underwent and did not undergo UM in terms of relevant pathohistological criteria during UC, as well as recurrence and survival indicators, which necessitates the widespread use of UM in MIS during UC.

Application of the study. The results of the study are successfully applied in the practical activities of the Oncology Clinic of the Azerbaijan Medical University, Ministry of Health of the Republic of Azerbaijan, and are used in the preparation of relevant teaching and methodological materials and the teaching process at the Department of Oncology of the Azerbaijan Medical University.

Approbation of dissertation. The primary materials and results of the dissertation work were presented and discussed at international congresses and conferences held in a number of European countries, the United Arab Emirates, the Republic of Turkey, and our republic, the names of which are listed below: MIJOD – Minimally İnvasive Gynecologic Oncology Congress (Istanbul, 2020, 2022, 2024), International Congress of Gynaecology and Obstetrics (Istanbul, 2021), TAJEV – Turkish German Gynecologic Congress (Antalya, 2022), ESGO – The European Society of Gynaecological Oncology (Barcelona, 2024), GYNITALY24 – International Society for Gynecologic Endoscopy (Salerno, 2024), ESGE – European Society for Gynaecological Endoscopy (Marseille, 2024), ENDODUBAI-9 (Dubai, 2024), I International Marmara Scientific Research and Innovation Congress (Istanbul, 2021), International Breast Cancer Congress (Baku, 2023, 2024), Actual Problems of Medicine International Scientific and Practical Congress (Baku, 2021, 2023, 2024).

Findings of the research study, once finalized, was initially discussed at an interdepartmental meeting held jointly by the staff of the Departments of Oncology, Cytology, Embryology, and Histology, III Surgical Diseases, and the Oncology Clinic of Azerbaijan Medical University on December 24, 2024.

A report was presented and discussed at the meeting of the scientific seminar on the specialty 3224.01–"Oncology" of the FD 1.02 Dissertation Council operating under the National Oncology Center, held on June 20 (Protocol №2).

Application of the study. The dissertation work was carried out at the Department of Oncology of the Azerbaijan Medical University, Ministry of Health of the Republic of Azerbaijan.

Published research articles. Totally, 45 scientific works have been published on the topic of dissertation. Of these, 16 articles and 27 theses have been published. The main results of the research work were also commented on in the relevant chapters of 1 monograph and one textbook. Articles related to the subject of the study have been published in international abstract and indexing systems (Web of Science, SCOPUS, Ulakbim).

Volume and structure of the dissertation.

The dissertation consists of an introduction (12678 characters), a chapter on current views on the treatment of uterine cancer (66091 characters), a chapter on materials and methods of the study (11433 characters), 2 chapters covering personal research (6565182 characters), a chapter on discussion of the results obtained (46207 characters), sections on conclusions, practical recommendations (2071+1055 characters) and a list of used literature (29870 characters). The dissertation is illustrated with 15 tables, 2 pictures, 6 diagrammas and 1 graph. The list of references consists of 165 sources. The volume of the dissertation consists of 142 pages and 204717 characters in computer printout.

MATERIALS AND METHODS OF RESEARCH

The clinical material of the study consisted of 117 patients who underwent minimally invasive surgery for UC at the Oncology Clinic of AMU in 2018-2024. In accordance with the goals and objectives of the study, endometrioid and non-endometrioid histological types were examined. Since the histological type of carcinosarcoma of uterine corpus malignant tumors contains mesenchymal components, this type was not taken into account and comparative analyses on other parameters were conducted on 116 patients.

General characteristics of patients. Clinical, radiological, laboratory and morphological examinations were performed in the study. Anamnesis was collected from all patients through clinical examination, patients' complaints were listened to through questionnaires, and attention was paid to the cardinal symptoms of the disease. Also, transvaginal ultrasound (in 2 patients) and pelvic MRI (in 96 patients) examinations were performed on patients as indicated, as well as thoracoabdominal CT examinations (in 19 patients) in patients included in the high-risk group, endometrial biopsy was performed in all patients and the diagnosis was confirmed by morphological examination of the biopsy materials. The functional status of the cardiorespiratory systems was also analyzed in the patients, and laboratory tests were performed to analyze the indicators of hepatorenal functional tests, general blood tests, biochemical tests, and relevant

oncomarkers. The FIGO stage of the process was determined based on histological examination of the surgically removed specimen. Laparoscopy was performed as primary surgical treatment in patients diagnosed with endometrial cancer included in our study. TLH+BSO+BPPALND was performed for primary surgical treatment in patients included in the study cohort.

The study included patients with endometrioid and non-endometrioid histological types, histological differentiation grades I-III, and who underwent total hysterectomy, pelvic, and periaortic lymphadenectomy procedures. In 95 of the patients included in the study, the uterus manipulator was used, and in 21 it was not. A HOHL brand UM was used in all patients included in the study. The UM is inserted by the surgeon under laparoscopic visualization and maneuvered by an assistant doctor during the operation.

The study analyzed the patients' age, body mass index, menopausal status, CA 125 discrimination level, duration of surgery and hospitalization, whether or not a UM was used during surgery, FIGO stage of the process, tumor size, histological type and degree of differentiation, depth of myometrial invasion, LVSI, presence or absence of cervical and adnexal invasion, lymph node status, perioperative complications, adjuvant treatment, recurrence status, and whether or not the patients are currently alive.

Mathematical statistical analysis methods. All calculations were performed in the Excel 2021 spreadsheet and the SPSS 20 statistical program, and the results obtained were placed in tables. The numerical indicators have been statistically analyzed in the text.

The Kolmogorov-Smirnov test was used to assess the accuracy of the calculated diagrammas. The indicators in the groups were arranged in order of variation by percentage. Comparison of indicators in categories was performed using the Fisher Exact test. The effect of parameters on recurrence and cure rates was calculated using Logistic Regression analysis. The difference between the statistical indicators of the groups was considered statistically significant if $p<0.05$. The difference between the qualitative indicators was determined by calculating Pearson's χ^2 test.

THE RESULTS OF THE RESEARCH AND THEIR DISCUSSION

The majority of patients included in our study were postmenopausal women. In our study groups, 102 (87.2%) patients were postmenopausal and 15 (12.8%) patients were premenopausal. When distributing patients by age, the number of patients over 50 years of age was 105 (89.7%), and the number of patients under 50 years of age was 12 (10.3%) (table 1).

Table 1

Comparative analysis of clinical characteristics of patients by groups

Characteristics of signs	UM used	UM not used	χ^2; p
Age			
≤50	9 (9.5%)	3 (14.3%)	χ^2:0.429
>50	86 (90.5%)	18 (85.7%)	p= 0.512
Menopausal status			
Premenopause	11 (11.6%)	4 (19.0%)	χ^2:0.852
Postmenopause	84 (88.4%)	17 (81.0%)	p=0.356
BMI			
≤30	26 (27.4%)	12 (57.1%)	χ^2**:6.922**
>30	69 (72.6%)	9 (42.9%)	**p=0.009**
Preoperative diagnostic examination			
CT	8 (8.6%)	10 (47.6%)	χ^2=**19.614**
MRI	85 (91.4%)	11 (52.4%)	**p< 0.001**
CA-125 (n:88)			
≤35 V/ml	56 (81.2%)	11 (61.1%)	χ^2=3.241
>35 V/ml	13 (18.8%)	7(38.9%)	p= 0.072
Histological diagnosis			
EIN	11 (11.7%)	0 (0.0%)	χ^2=2.590
EC	83 (88.3%)	20 (100.0%)	p= 0.108

Body mass index of patients included in the study was assessed for all patients: 79 (67.5%) patients had a BMI >30, and 38 (32.5%) patients had a BMI ≤30. The fact that 67.5% of patients had a BMI >30 indicates a strong association between endometrial cancer and obesity.

In the study cohort, pelvic MRI was performed to assess local spread of the process in the preoperative period, and thoracoabdominal CT scans were performed to detect lymphogenous and hematogenous spread. Thus, magnetic resonance imaging was performed in 96 (82.1%) patients, computed tomography in 19 (16.2%) patients, and transvaginal ultrasound in 2 (1.7%) patients.

In 88 of the patients included in the study, the discrimination level of CA 125 was examined preoperatively, 67 of them (76.1%) had a discrimination level of CA 125 ≤35 U/ml, and 21 (23.9%) had a CA 125 >35 U/ml. In our study, the high level of discrimination of CA 125 in 23.9% of cases once again demonstrates the importance of this test in preoperative risk assessment.

A standard surgical approach was applied to 88 (75.2%) patients included in the study, and total hysterectomy, bilateral salpingo-oophorectomy, and bilateral pelvic lymphadenectomy were performed.

Considering that 13 (11.1%) patients were clinically in a high-risk group, total hysterectomy, bilateral salpingo-oophorectomy, bilateral pelvic lymphadenectomy, and omentectomy were performed. Total hysterectomy, bilateral salpingo-oophorectomy, bilateral pelvic lymphadenectomy, and frozen section were performed in 8 (6.8%) patients who needed intraoperative confirmation of the preoperative histological diagnosis. Also, 4 (3.4%) patients with non-endometrioid type (type 2) uterine cancer included in the study underwent total hysterectomy, bilateral salpingo-oophorectomy, omentectomy, and bilateral pelvic and periaortic lymphadenectomy. In 2 (1.7%) patients, only total hysterectomy and bilateral salpingo-oophorectomy were performed, and in 1 (0.9%) patient, total hysterectomy, bilateral salpingo-oophorectomy, and frozen section were performed. In the study group, 1 (0.9%) patient with suspected lymphogenous metastasis in the right groin underwent total hysterectomy, bilateral salpingo-oophorectomy, bilateral pelvic lymphadenectomy, and right inguinofemoral lymphadenectomy. In the study group, a total of 115 (98.3%) patients underwent regional lymphadenectomy, while 2 (1.7%) patients did not undergo this procedure.

109 (93.2%) patients included in the study had endometrioid (type 1) and 7 (6.8%) patients had non-endometrioid (type 2) uterine

cancer. Thus, serous type of uterine cancer was observed in only 5 (4.3%) patients included in the study. Only 2 (1.7%) patients included in the study had clear cell uterine cancer. 1 (0.8%) patient included in the study had carcinosarcoma histological type of uterine corpus cancer (diagramma 1).

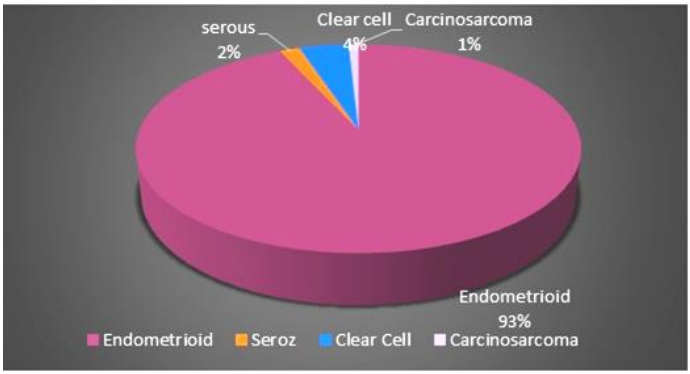


Diagramma 1. Distribution of patients with uterine corpus cancer studied depending on the histological type of tumor

The distribution of tumor histological differentiation grade was varied in the patients included in the study. Thus, Grade 1 tumors were found in 29 (25%) patients, Grade 2 tumors in 44 (38%) patients, and Grade 3 tumors in 40 (34.4%) patients. Histological differentiation of the tumor was not determined in 3 (2.6%) patients included in the study (diagramma 2).

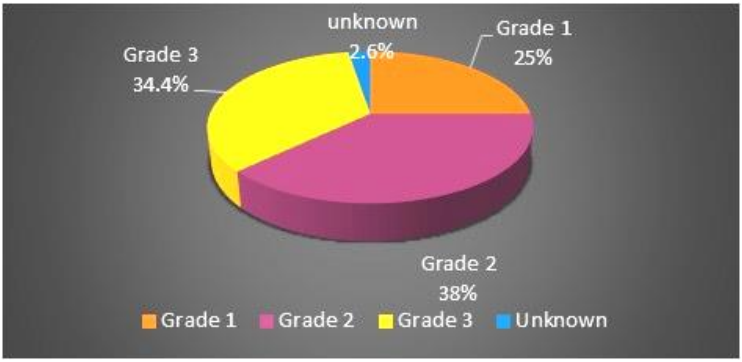


Diagramma 2. Distribution of the studied patients with uterine cancer depending on the degree of histological differentiation of the tumor

One of the factors that affects the risk of lymph node metastasis and patient survival in uterine cancer is the size of the tumor. In clinical studies, a 2 cm margin has generally been adopted. Larger tumor size (>2 cm) correlates with aggressive tumor biology. Tumor size >2 cm was recorded in 70 (59.8%) patients included in the study, and ≤2 cm in 47 (40.2%) patients (diagramma 3).

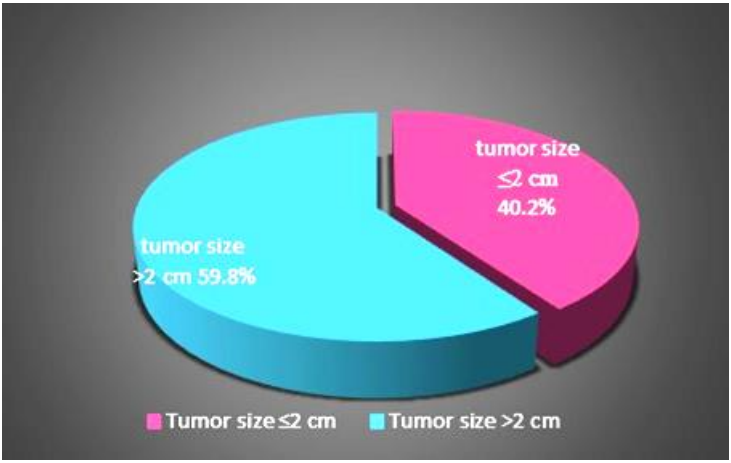


Diagramma 3. Distribution of studied uterine cancer patients according to tumor size

105 (89.7%) patients included in the study had FIGO stage I, with the tumor confined to the uterine corpus and ovary. Of these, in 50 patients (42.7%), the tumor, which was confined to the endometrium, invaded up to half (<1/2) of the myometrium thickness, while in 55 (47.0%) patients, myometrial invasion was ≥1/2, and lymphovascular invasion was negative. Only 1 (0.9%) patient had an aggressive histological type (FIGO stage II) with invasion of the cervical stroma, but limited to the uterine border, or with diffuse lymphovascular or myometrial invasion. In other stages, 2 (1.7%) patients were registered in stage IIIA, 7 (6.0%) in stage IIIC1, 1 (0.9%) in stage IIIC2, and 1 (0.9%) in stage IVB. As can be seen from the study results, symptom-based early diagnosis (stage I, 89.7%) was effectively provided. Late (stages II-IVB 10.3%) stage reflects an aggressive or asymptomatic course of the tumor. The detection of lymphogenous metastases

(IIIC1/IIIC2 stages 6.9%) once again proves the importance of surgical staging.

It should be noted that the depth of myometrial invasion is highly correlated with lymphogenous and hematogenous metastases. Myometrial invasion (MI) was >50% in 58 (49.6%) patients included in the study, MI was <50% in 46 (39.2%) patients, and myometrial invasion was not observed in 3 (11.1%) patients. Approximately half (49.6%) of the study group had MI ≥50%, requiring adjuvant therapy.

Lymphovascular invasion (LVSI) was present in 77 (65.8%) patients included in the study. Lymphovascular invasion was not observed in 40 (34.2%) patients. In all histological types of uterine cancer, invasion of the lymphovascular space is considered a significant risk factor for lymphogenous spread and recurrence, significantly affecting recurrence and mortality rates.

Adnexal invasion was observed in 3 (2.6%) patients included in the study. Adnexal invasion was not observed in 114 (97.4%) patients. Looking at the presented data, it is clear that adnexal invasion was recorded in a small number of cases (2.6%) since the pathologies in the study group were mostly detected at an early stage.

Cervical invasion was observed in 4 (3.4) patients included in the study, while cervical invasion was not observed in 113 (96.6%) patients. Endometrial carcinoma most commonly spreads to the cervix and uterus through direct contact. When the tumor invades the isthmus segment and cervix of the uterus, the chances of the process spreading beyond the uterus, metastasis to the lymph nodes, and recurrence increase.

Lymph node metastasis was detected in 9 patients (7.7%) included in the study. No lymph node metastasis was observed in 108 (92.3%) patients. The low incidence of lymphogenous metastases in our study (7.7%) is associated with the large number of patients in the study cohort, mainly with early stage and endometrioid histological type.

In the presented data, 84 (71.8%) patients had a surgical duration of >120 minutes and 33 (28.2%) patients had a duration of ≤120 minutes. In the presented data, the high number of operations lasting >120 minutes (71.8%) was due to the high prevalence of obesity in this cohort (67.5%).

The duration of hospitalization was less than 4 days in 88 (75.2%) patients included in the study, and the duration of hospitalization was more than 4 days in 29 (24.8%) patients. In our study, 75.2% of patients were discharged home for ≤4 days and this was due to the use of the MIS method.

No complications were observed in the perioperative period in 114 (97.4%) patients included in the study, while complications were recorded in 3 (2.6%) patients. Urethral fistula was noted in 1 patient included in the study, postoperative bleeding in 1 patient, and abscess in 1 patient. According to literature data, the risk of complications in UC patients receiving MIS is <5%. It should be noted that the absence of complications in 97.4% of patients included in the study cohort once again proves the superiority of modern MIS techniques and is consistent with the results of contemporary meta-analysis. However, the observation of complications in 3 patients requires a more careful and individual approach.

Of the 34 (29.1%) patients included in the study cohort, only surgery was performed, while 82 (70.1%) patients additionally received adjuvant treatment. Surgery and radiation therapy were applied in 60 (51.3%) patients. Brachytherapy alone was performed in 32 (39.8%) patients, distansion radiotherapy and brachytherapy were performed together in 29 (34.9%) patients.

During the 6-year follow-up, a total of 15 (12.8%) patients included in the study experienced recurrence and death. The risk of recurrence in patients with endometrial carcinoma is 10-15% in the early stage and 50-70% in the late stage. Looking at the data presented, the reported risk of recurrence (12.8%) is consistent with the results of a modern meta-analysis.

The study analyzed the treatment outcomes of a total of 116 patients **in both groups** who underwent surgery using the MIS method with a diagnosis of UC. Of the patients included in the study, 95 (81.9%) used a UM, while 21 (18.1%) did not.

In the group where the UM was used, TH-BSO was performed in 2 (2.1%) patients, TH-BSO + Frozen in 1 (1.1%) patient, TH-BSO + BPLND in 83 (87.4%) patients, TH-BSO + BPLND +Frozen in 8 (8.4%) patients, and TH-BSO + BPLND + right inguinofemoral LND

in 1 (1.1%) patient (table 2).

Table 2

Comparative analysis of operations performed on patients included in the study contingent by study groups

Characteristics of operations	UM used	UM not used	χ^2; p
Operation name			
TH-BSO	2 (2.1%)	0 (0.0%)	χ^2=90.261 p<0.001
TH-BSO + Frozen	1 (1.1%)	0 (0.0%)	
TH-BSO + BPLND	83 (87.4%)	4 (19.0%)	
TH-BSO + BPLND +Frozen	8 (8.4%)	0 (0.0%)	
TH-BSO+BPPALND + Omentectomy	0 (0.0%)	4 (19.0%)	
TH-BSO + BPLND + Omentectomy	0 (0.0%)	13 (61.9%)	
TH-BSO + BPLND + right inguinofemoral LND	1 (1.1%)	0 (0.0%)	
Regional lymphadenectomy			
Implemented	93 (97.9%)	21 (100.0%)	χ^2=0.450 p= 0.502
Not implemented	2 (2.1%)	0 (0.0%)	

In the group where the UM was not used, TH-BSO + BPLND was performed in 4 (19.0%) patients, TH-BSO + BPPALND + Omentectomy in 4 (19.0%) patients, and TH-BSO + BPLND + Omentectomy in 13 (61.9%) patients (χ^2=90.261; p<0.001). The results from our study show that there is a statistically significant relationship between the use of a UM and the types of surgery performed. A p-value of less than 0.001 proves that the results are not random.

In the study, analysis of tumor size in the groups with and without the use of the UM showed that in the group with the use of the UM, 41 (43.2%) patients had tumor size ≤2 cm, and 57 (56.8%) patients had tumor size >2 cm. In the group without the use of a UM, 5 (23.8%) patients had a tumor size ≤2 cm, and 16 (76.2%) patients had a tumor size >2 cm (χ^2=2.691; p=0.101). p >0.05 indicates that the difference in tumor size between the groups with and without UM was not statistically significant.

In the group using the UM, 45 (47.4%) patients were found to be in stage IA, 43 (45.3%) patients in stage IB, 2 (2.1%) patients in stage IIIA, 4 (5.7%) patients in stage IIIC1, and 1 (1.1%) patient in stage IVB (table 3).

Table 3

Distribution of the disease according to FIGO classification in the groups with and without the use of UM **in the patients included in the study contingent**

Stage of the disease	UM used	UM not used	χ^2; p
According to the FIGO classification			
IA	45 (47.4%)	5 (23.8%)	χ^2=15.006 p= 0.020
IB	43 (45.3%)	11 (52.4%)	
IIA	0 (0.0%)	1 (4.8%)	
IIIA	2 (2.1%)	0 (0.0%)	
IIIC1	4 (5.7%)	3 (14.3%)	
IIIC2	0 (0.0%)	1 (4.8%)	
IVB	1 (1.1%)	0 (0.0%)	

No tumors were detected in stages IIA and IIIC2 in this group. In the group where the UM was not used, 5 (23.8%) patients were found to be in stage IA, 11 (52.4%) patients in stage IB, 1 (4.8%) patient in stage IIA, and 3 (14.3%) patients in stage IIIC1. No tumors were detected in stages IIIA and IV in this group (χ^2=15.006; p=0.020).

In the group using the UM, 25 (26.3%) patients had grade 1 tumors, 38 (40.0%) patients had grade 2 tumors, and 30 (31.6%) patients had grade 3 tumors. In the group where the UM was not used, 4 (19.0%) patients had grade 1 tumors, 6 (28.6%) patients had grade 2 tumors, and 10 (47.6%) patients had grade 3 tumors (χ^2=2.708; p=0.439) (Table 4).

The higher incidence of grade 3 tumors (47.6%) in the group without the use of a UM is due to the low use of the manipulator in patients with high-risk histological types.

Table 4

Comparative analysis of the degree and type of histological differentiation of tumors in patients included in the study cohort across study groups

Histological characteristics of the tumor	UM used	UM not used	χ^2; p
Histological differentiation degree of the tumor			
Grade 1	25 (26.3%)	4 (19.0%)	χ^2=2.708 p= 0.439
Grade 2	38 (40.0%)	6 (28.6%)	
Grade 3	30 (31.6%)	10 (47.6%)	
Histological type of tumor			
Endometrioid	91 (94.7%)	18 (85.6%)	χ^2=6.059 p= 0.109
Clear cell	1 (1.1%)	1 (4.8%)	
Serous	4 (4.2%)	1 (4.8%)	
Carcinosarcoma	0	1 (4.8%)	

In the group where the UM was used, 91 (94.7%) patients had endometrioid-type tumors, 1 (1.1%) patient had clear-cell-type tumors, and 4 (4.2%) patients had serous-type tumors. In the group where the UM was not used, endometrioid type tumors were identified in 18 (85.6%) patients, clear cell type in 1 (4.8%) patient, serous type in 1 (4.8%) patient, and carcinosarcoma type in 1 (4.8%) patient (p=0.109). No statistically significant relationship was found between the use of the UM and the distribution of histological types (χ^2=6.059; p>0.05).

In the UM group, 12 (12.6%) patients had negative myometrial invasion, 40 (42.1%) patients had myometrial invasion ≤50%, and 43 (45.3%) patients had myometrial invasion >50%. In the group without UM use, 1 (4.8%) patient had negative myometrial invasion, 6 (28.6%) patients had myometrial invasion ≤50%, and 14 (66.7%) patients had myometrial invasion >50% (χ^2=3.348; p=0.187) (table 5).

In the group using the UM, lymphovascular invasion was negative in 36 (37.9%) patients, and lymphovascular invasion was positive in 59 (62.1%) patients. In the group without the use of the UM, lymphovascular invasion was negative in 4 (19.0%) patients, and lymphovascular invasion was positive in 17 (81.0%) patients (χ^2=2.704; p=0.100). The difference between groups was not statistically

significant. LVSI significantly affected recurrence and mortality rates in all histological types of UC.

Table 5

Comparative analysis of pathohistological criteria between groups in patients included in the study contingent

Pathohistological criteria	UM used	UM not used	χ^2; p
Tumor size			
≤2 cm	41 (43.2%)	5 (23.8%)	χ^2=2.691
>2 cm	57 (56.8%)	16 (76.2%)	p= 0.101
Myometrial Invasion (MI)			
None	12 (12.6%)	1 (4.8%)	χ^2=3.348 p= 0.187
≤50%	40 (42.1%)	6 (28.6%)	
>50%	43 (45.3%)	14 (66.7%)	
Lymphovascular invasion (LVSI)			
None	36 (37.9%)	4 (19.0%)	χ^2=2.704
Yes	59 (62.1%)	17 (81.0%)	p= 0.100
Adnexal invasion			
None	92 (96.8%)	21 (100.0%)	χ^2=0.681
Yes	3 (3.2%)	0 (0.0%)	p= 0.409
Cervical invasion			
None	94 (98.9%)	18 (85.7%)	χ^2=9.046
Yes	1 (1.1%)	3 (14.3%)	p= 0.003
Lymph node metastasis			
None	89 (93.7%)	18 (85.7%)	χ^2=1.526
Yes	6 (6.3%)	3 (14.3%)	p= 0.217

In the group using the UM, 89 (93.7%) patients did not have lymph node metastases, and 6 (6.3%) patients had metastases. In the group where the UM was not used, 18 (85.7%) patients did not have lymph node metastases, and 3 (14.3%) patients had metastases (χ^2=1.526; p=0.217). The difference between the groups was not statistically significant.

In the group using the UM, 94 (98.9%) patients did not have cervical invasion, and cervical invasion was observed in 1 (1.1%) patient. In the group where the UM was not used, 18 (85.7%) patients did not have cervical invasion, and only 3 (14.3%) patients had cervical invasion (χ^2=9.046; p=0.003). In the presented material, it was noted that cervical stromal invasion was observed very rarely

(1.1%) in the group using the UM ($p<0.05$).

In the group using the UM, 92 (96.8%) patients did not have adnexal invasion, and 3 (3.2%) patients had adnexal invasion. In the group without UM use, 21 (100.0%) patients did not have adnexal invasion ($\chi^2=0.681$; $p=0.409$).

Statistical analysis of the operations performed on patients included in the study group showed that in the UM group, the operation time was ≤120 minutes in 30 (31.6%) patients and >120 minutes in 65 (68.4%) patients (table 6).

In the group without UM, the operative time was ≤120 minutes in 2 (9.5%) patients and >120 minutes in 19 (90.5%) patients ($\chi^2=4.188$; $p=0.041$).

In the group using the UM, 74 (77.9%) patients had a hospitalization period of ≤4 days, and 21 (22.1%) patients had a hospitalization period of >4 days. In the group where the UM was not used, 13 (61.9%) patients had a hospitalization period of ≤4 days, and 13 8 (38.1%) patients had a hospitalization period of >4 days ($\chi^2=2.345$; $p=0.126$).

Table 6

Comparative analysis of perioperative clinical parameters in groups with and without the use of a uterine manipulator

Clinical parameters	UM used	UM not used	χ^2; p
Duration of the operation			
≤120 min.	30 (31.6%)	2 (9.5%)	$\chi^2=4.188$
>120 min.	65 (68.4%)	19 (90.5%)	p= 0.041
Duration of hospitalization			
≤4 day	74 (77.9%)	13 (61.9%)	$\chi^2=2.345$
>4 day	21 (22.1%)	8 (38.1%)	p= 0.126
Perioperative complication			
None	93 (97.9%)	20 (95.2%)	$\chi^2=0.482$
Yes	2 (2.1%)	1 (4.8%)	p= 0.488

In the group using the UM, 93 (97.9%) patients had no perioperative complications, while 2 (2.1%) patients had perioperative complications. In the group where the UM was not used, 20 (95.2%) patients did not have perioperative complications, and 1 (4.8%)

patient had a perioperative complication (χ^2=0.482; p=0.488). The incidence of complications showed no statistically significant difference between the groups. These statistical results suggest the perioperative safety of the UM. At the same time, the lack of significant differences between the groups indicates technically correct use of the manipulator.

In our study, in the group using the UM, 29 (30.5%) patients did not receive adjuvant treatment, and 66 (69.5%) patients received adjuvant treatment (table 7). In the group without the use of a UM, 6 (28.6%) patients did not receive adjuvant treatment, and 15 (71.4%) patients received adjuvant treatment (χ^2=0.031; p=0.860). According to this statistic, there is no significant association between the use of a UM and adjuvant treatment.

Table 7

Comparative characteristics of the applied treatment methods across study groups

Characteristics of treatment methods	UM used	UM not used	χ^2; p
Treatment methods used			
Surgery	29 (30.5%)	5 (23.8%)	χ^2=3.191 p= 0.363
Surgery + Radiotherapy	50 (52.6%)	9 (42.9%)	
Surgery + Chemotherapy	6 (6.3%)	2 (9.5%)	
Surgery + Radiotherapy + Chemotherapy	10 (10.5%)	5 (23.8%)	
Adjuvant Therapy			
not implemented	29 (30.5%)	6 (28.6%)	χ^2=0.031 p= 0.860
implemented	66 (69.5%)	15 (71.4%)	
Adjuvant treatment methods (n:82)			
Distansion radiotherapy	1 (1.5%)	1 (6.2%)	χ^2=10.435 p= 0.064
Distansion radiotherapy + Brachytherapy	21 (31.8%)	7 (43.8%)	
Distansion radiotherapy + Brachytherapy + Chemotherapy	8 (12.1%)	3 (18.8%)	
Brachytherapy	31 (47.0%)	2 (12.5%)	
Distansion radiotherapy + Chemotherapy	0 (0.0%)	1 (6.2%)	
Chemotherapy	5 (7.6%)	2 (12.5%)	

In the group using the UM, 1 (1.5%) patient received distansion radiotherapy, 21 (31.8%) patients received distansion radiotherapy and brachytherapy, 8 (12.1%) patients received distansion radiotherapy, brachytherapy and chemotherapy, 31 (47.0%) patients received brachytherapy, and 5 (7.6%) patients received chemotherapy. In the group without the use of a UM, 1 (6.2%) patient received distansion radiotherapy, 7 (43.8%) patients received distansion radiotherapy and brachytherapy, 3 (18.8%) patients received distansion radiotherapy, brachytherapy and chemotherapy, 2 (12.5%) patients received brachytherapy, 1 (6.2%) patient received distansion radiotherapy and chemotherapy, and 2 (12.5%) patients received chemotherapy (χ^2=10.435; p=0.064). In the UM group, brachytherapy alone was performed in 47% of cases due to the preference for UM in low-risk patients.

In the group using the UM, 83 (87.4%) patients did not have recurrence, while 12 (12.6%) patients did. In the group where the UM was not used, 18 (85.7%) patients did not have recurrence, while 3 (14.3%) patients did (χ^2=0.042; p=0.838). The incidence of recurrence was similar in both groups (12.6% and 14.3%), and, based on the p value, UM had no statistically significant effect on the risk of recurrence. In the group using the UM, 83 (87.4%) patients are currently alive, while 12 (12.6%) patients died from various causes within 6 years after surgery (table 8).

Table 8

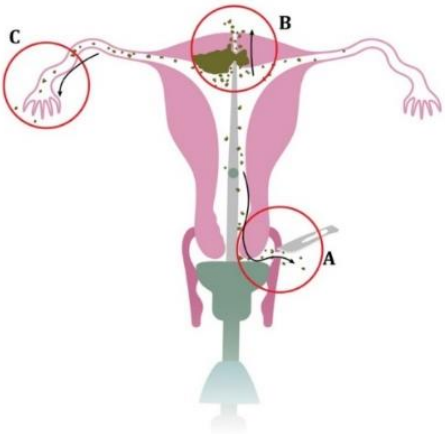
Statistical analysis of recurrence and survival rates between study groups

Characteristics of symptoms	UM used	UM not used	χ^2; p
Recurrence			
None	83 (87.4%)	18 (85.7%)	χ^2=0.042 p= 0.838
Yes	12 (12.6%)	3 (14.3%)	
Survival rate			
Lives	83 (87.4%)	18 (85.7%)	χ^2=0.042 p= 0.838
Dead	12 (12.6%)	3 (14.3%)	

In the group where the UM was not used, 18 (85.7%) patients survived, while 3 (14.3%) patients died from various causes (χ^2=0.042;

p=0.838). Among the causes of death, stroke, chronic heart failure, mitral valve prolapse, and pulmonary artery thromboembolism have attracted our attention. Overall survival rates were similar across groups (87.4% and 85.7%). This difference indicates the oncological and clinical safety of UM use during MIS. The statistical results from our study also prove this. According to the results of our study, the application of UM does not worsen the prognosis. Thus, in our study results, since no statistically significant difference was observed between the groups using UM and those not using UM in terms of pathohistological criteria (lymphovascular invasion, myometrial invasion) during UC, as well as recurrence and survival rates, the use of UM is recommended as a standard option in patients with UC without cervical invasion.

The relationship between the use of UM s and LVSI, recurrence, and recovery rates in oncology patients is still not fully clarified. The macroscopic and microscopic hypotheses put forward to date are schematically depicted in the picture (Picture 1).



Picture 1: Potential mechanisms of tumor cell dissemination during minimally invasive surgical procedures.

According to the *macroscopic hypothesis,* when placing a uterine manipulator, especially in an atrophic uterus, the tip of the instrument may pierce the myometrium, causing iatrogenic perforation and

dissemination of tumor cells into the peritoneal cavity[9]. In our practice, no cases of uterine perforation or rectal penetration were recorded, as the Hohl manipulator was placed under laparoscopic visualization control in all patients.

According to the *microscopic hypothesis,* UM increases the pressure in the endometrial cavity, causing diffuse tension according to Pascal's law. As a result, the risk of invasion of the lymphovascular space and transtubal spread of tumor cells into the peritoneal cavity increases. In articles with this hypothesis, iatrogenic lymphovascular invasion, retrograde spread of tumor cells, and positive peritoneal cytology risks were considered important parameters[10,11]. In our practice, both fallopian tubes were coagulated proximal to the uterus with a bipolar coagulator in all patients to prevent transtubal dissemination before the insertion of the Hohl-type uterine manipulator. According to our results, the use of a UM during surgery did not significantly affect LVSI, recurrence, and recovery rates, but the discussion and controversial opinions about the use of a UM during minimally invasive surgical procedures in oncogynecology are still ongoing[12]. We note that our research opens up new opportunities for expanding research on the application of UM during UC. Therefore, we consider it appropriate to conduct similar prospective and multicenter studies on more patients in the future. Therefore, we consider it appropriate to conduct similar prospective and multicenter studies

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on more patients in the future. Also, the exact determination of the type of UM used, duration of application, and adjuvant treatment methods may be included in the tasks of further studies.

CONCLUSIONS

1. The surgical treatment of choice for endometrioid histological type UC without cervical invasion is total hysterectomy, bilateral salpingo-oophorectomy, and bilateral pelvic lymphadenectomy performed using the MIS method [14, 17, 18].
2. The perioperative clinical parameters in the groups of patients with and without UM who underwent MI surgery were as follows: operative time ≤120 minutes - 31.6% and 9.5% (χ^2=4.188, p=0.041), hospitalization time ≤4 days - 77.9% and 61.9% (χ^2=2.345, p=0.126), and complications were observed in 2.1% and 4.8% of patients (χ^2=0.482, p=0.488). The rates of operative time ≤120 minutes were statistically significantly higher in the UM group compared to the non-UM group [10, 11].
3. In patients undergoing MI surgery for UC, no statistically significant difference was found between the groups of patients with and without UM in terms of parameters characterizing lympho-vascular invasion (χ^2=2.704, p=0.100) and myometrial invasion (χ^2=3.348, p=0.187) [9, 10].
4. Evaluation of recurrence in patients who underwent surgery using the MIS method for UC showed that recurrence was observed in 87.4% of patients in the UM group and in only 12.6% of patients; in the non-UM group, recurrence was observed in 85.7% of patients and in 14.3% of patients. The incidence of recurrence was similar in both groups (χ^2=0.042, p=0.838). The statistical results from our study showed that the use of UM does not increase the risk of recurrence [9, 10].
5. A comparative analysis of survival rates in the groups with and without UM using the MIS method according to UC showed that overall survival rates were consistent between the groups and were 87.4% and 85.7%, respectively (p>0.05). According to the results of our study, the application of UM does not worsen the prognosis [9, 10].

PRACTICAL RECOMMENDATIONS

1. Since no statistically significant difference was observed between the groups using UM and those not using UM in terms of pathohistological criteria (lymphovascular invasion, myometrial invasion) during UC, as well as recurrence and survival rates, the use of UM is recommended as the standard option in patients with UC without cervical invasion.
2. It is advisable to prefer classical laparotomy in the surgical treatment of uterine cancer of non-endometrioid histological type.
3. Considering the risks of complications of pelvic and periaortic lymphadenectomy in uterine cancer, it is recommended that the decision on these operations be made based on the results of sentinel lymphadenectomy performed using the MIS method.
4. Before inserting the UM, it is advisable to coagulate both fallopian tubes proximal to the uterus with a bipolar coagulator to prevent transtubal dissemination.
5. The use of an atraumatic tip HOHL uterine manipulator in all patients reduces iatrogenic risks. Furthermore, placement of the uterine manipulator under laparoscopic visualization is recommended in all patients.

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LIST OF ABBREVIATIONS

BMI – Body Mass Index
BPLND – Bilateral pelvic lymphnode dissection
LND – Lymphnode dissection
BPPALND – Bilateral pelvic and paraaortic lymphnode dissection
BSO – Bilateral salpingo-oophorectomy
EH – Endometrial Hyperplasia
EC – Endometrial Cancer
EIN – Endometrial Intraepithelial Neoplasia
FIGO – International Federation of Gynecology and Obstetrics
CT – Computed tomography
LVSI – Lymphovascular invasion
MI – Myometrial invasion
MIS – Minimally invasive surgery
MRI – Magnetic resonance imaging
p –Value, Probability, Statistical integrity value
TAH – Total Abdominal Hysterectomy
TH – Total Hysterectomy
TLH – Total Laparoscopic Hysterectomy
UC – Uterine cancer
UM – Uterine manipulator

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