

Study protocol.

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Title of the study: "Modern surgical tactics in the treatment of infertility in combination with uterine myoma"

Study dates: 11/01/2021 - 01/01/2024

1. Aims/tasks/research questions/hypotheses.

Purpose of the study

to improve the results of infertility treatment in women with uterine myoma, which deforms its cavity, by laparoscopic myomectomy with temporary occlusion of the uterine arteries.

Research objectives

1. Determine the indications and choice of surgical approach and method in the surgical treatment of uterine fibroids of types 0 according to FIGO larger than 4 cm in women of reproductive age with infertility

An alternative hypothesis is that the choice of treatment method depends on the type of fibroid, its size and localization.

Null hypothesis - the choice of treatment method does not depend on the type of fibroids, its size and localization.

2. To develop an examination algorithm and stages of treatment of patients with uterine myoma types 0 larger than 4 cm in combination with infertility

An alternative hypothesis is that a clear algorithm and staged treatment of patients with type 0 uterine fibroids larger than 4 cm reduces the prevalence of infertility among women of reproductive age.

Null hypothesis - a clear algorithm and stages of treatment of patients with uterine fibroids of types 0 larger than 4 cm does not reduce the prevalence of infertility among women of reproductive age

3. Evaluate the effectiveness of temporary occlusion of the uterine arteries during laparoscopic removal of fibroids with opening of the uterine cavity and modification of restoration of its integrity

An alternative hypothesis is that temporary occlusion of the uterine arteries during laparoscopic myomectomy with opening of the uterine cavity reduces the amount of blood loss, the duration of the operation, the recovery time after the operation and the reproductive function

Null hypothesis - temporary occlusion of the uterine arteries during laparoscopic myomectomy with opening of the uterine cavity does not reduce the volume of blood loss, the duration of the operation, the recovery time after the operation and the reproductive function

4. Assess the condition of the scar on the uterus and endometrium after laparoscopic myomectomy with temporary clamping of the uterine arteries during hysteroscopy

An alternative hypothesis is that there is a significant relationship between the choice of the method of removal of uterine fibroids types 0 with the opening of its cavity and the quality of the scar and the state of the endometrium.

Null hypothesis - there is no significant relationship between the choice of the method of removal of uterine fibroids types 0 with the opening of its cavity and the quality of the scar and the state of the endometrium.

5. To evaluate the long-term results of treatment of women with uterine fibroids of types 0 larger than 4 cm after myomectomy for the implementation of reproductive function

An alternative hypothesis is that there is a significant relationship between the choice of the method of removal of uterine fibroids of types 0 larger than 4 cm and the implementation of a woman's reproductive function.

Null hypothesis - there is no significant relationship between the choice of method for removing uterine fibroids of types 0 larger than 4 cm and the implementation of a woman's reproductive function

2. General information and rationale:

The prevalence, steady increase in the frequency and "rejuvenation" of uterine fibroids, which entail a decrease in the reproductive function of women, dissatisfaction with the results of treatment, determine the relevance and prospects of research on this issue [1,3,5,7,9,13].

In the population, the frequency of uterine fibroids in women with infertility varies from 44 to 70%. At present, the introduction of new technologies has made it possible to expand the indications for organ-preserving surgical benefits aimed at preserving the reproductive function of women, leaving behind them the right and opportunity to become a mother [1,2,6,8,10,11]. At the same time, laparoscopic surgery remains the main option for surgical treatment of patients with uterine myoma, and the use of techniques that provide transient uterine ischemia reduces the risk of intraoperative blood loss and provides optimal conditions for performing the operation [2,5,7,12,13].

In the treatment of gynecological pathologies such as uterine fibroids, surgical intervention remains a priority method [3,4,5]. Given the achievements of modern medicine, the range of possible combinations is expanding when choosing the optimal strategy and tactics of therapy, and the integration of innovative endoscopic treatment becomes natural [10,11].

It should be noted that surgery remains the main treatment for uterine fibroids [12,15]. Quite often, a hysterectomy is performed, which is a demonstration of the impotence of modern medicine in the treatment of these diseases, since it leads to the loss of reproductive function, excluding the possibility of having children, and reduces the quality of life of a woman [1,8]. Therefore, hysterectomy has become limited to situations where there is no need to preserve fertility, when it is impossible to perform an organ-preserving operation. Accordingly, against the background of the introduction of new technologies, organ-preserving tactics have become a priority in the surgical treatment of this pathological condition [11,12]. To reduce the volume of intraoperative blood loss during laparoscopic myomectomy of large nodes, technologies for performing the operation against the background of transient uterine ischemia began to be used, and hysteroresectoscopy is used to remove submucosal nodes. To do this, clamps are applied to the internal iliac or uterine arteries, which ensures that myomectomy is performed on a “dry organ” [4,6].

Methods of surgical treatment of the disease are the subject of controversy and discussion. Hysterectomy cannot be performed in patients who wish to achieve reproductive function or preserve the uterus in the presence of large interstitial-submucosal nodes. Conducting organ-preserving operations with such an arrangement of nodes is everywhere accompanied by profuse bleeding, difficulty in performing operations, hysterectomy and failure of the scar on the uterus.

3. Study Design and Statistical Procedures (Participants: Population, Selection Criteria, Identifiers, Description of the Questionnaire, Statistical Procedures)

The design of the study is a retrospective cohort study.

For the study, 160 case histories of patients admitted to the hospital of the Institute of Reproductive Medicine LLP with a diagnosis of infertility in combination with uterine myoma larger than 4 cm, type 0 according to FIGO were studied. The operations were carried out between 2015 and 2022. All patients are divided into 4 groups:

Group 1 - patients who underwent laparotomy myomectomy,

Group 2 - patients who underwent laparoscopic myomectomy,

group 3 - patients who underwent laparoscopic myomectomy using the method of temporary occlusion of the uterine arteries,

Group 4 - patients who underwent myomectomy by hysteroresectoscopy.

Selection criteria for inclusion in the research program: reproductive age and the presence of uterine fibroids types 0 larger than 4 cm in combination with infertility or multiple. The study did not include patients with extragenital diseases in the stage of subcompensation and decompensation, exacerbation of chronic extragenital and gynecological diseases with uterine myoma in combination with adenomyosis, endometrial hyperplastic processes.

By age, duration of the disease, size and number of myomatous nodes, obstetric and gynecological anamnesis and extragenital diseases, duration of infertility considered in clinical trials, the groups should correspond to each other and be statistically comparable.

To control the quality of the operation, the number of reoperations, complications and the implementation of the reproductive function, all patients were invited to a follow-up examination to collect and record data from September 2021 to January 2022.

Statistical analysis was carried out using the SPSS Statistics 26 software.

Statistical characteristics of quantitative variables will be presented as arithmetic means, standard deviations, medians, minimum and maximum values in the form of numbers and percentages. The normal distribution of continuous variables will be tested with the Shapiro-Wilk test. The statistical significance of differences between groups will be tested using the t-test and Pearson's chi-square with the case of a normal distribution, in the case of non-normal using the U-test and Spearman's correlation coefficient, analysis of variance will be performed to compare groups.

4. Data security and privacy protection of subject information: privacy breach mitigation plan, data retention plans.

When processing patient data, all passport data are coded by groups, all data on operations and postoperative treatment are anonymous.

5. Recruiting process: recruiting materials, privacy issues in recruiting.

Patients who received surgical care for uterine fibroids are entered into the database with phone numbers, the database does not contain passport data about the patient, only the group code and personal serial number, which is the patient's personal code, the examination in dynamics was carried out using the patient's personal code, thus, the risk of violation of anonymity is eliminated. All patients are warned that if they do not wish to continue observation, they undertake to report this, also using their personal code.

Consent process and documentation.

All participants provided voluntary informed consent to participate. After filling it out, the data of the questionnaires and examination can be used for analysis.

6. Risks: risks associated with the study and its procedures, risk minimization steps, burden on participants during the course of the study, protection of privacy during data collection.

Due to the fact that at the beginning of the study all data is encoded with the name of the study group, there is no risk of data privacy violation.

There is no risk to the health or condition of the patient, since no invasive and laboratory diagnostic procedures are included in the scope of the study, the outcomes of the surgical intervention will be assessed retrospectively.

Benefit: direct benefit from participation in the study, potential social benefit from the study.

Social benefit:

Based on the data obtained, a new method of surgical treatment of uterine fibroids with a deformation of its cavity larger than 4 cm will be proposed to gynecologists-surgeons of gynecological hospitals.

Direct benefit.

For study participants, the benefit lies in close, free monitoring of their condition after surgery for 5 years, preventive examination, assessment of the risks of recurrence and receiving recommendations on prevention.

7. Payment/payments. Not provided

8. Security monitoring. Provided by the management and staff of the clinic.

Chief physician for the medical part: Ph.D. Dzhakupov Daniyar Valikhanovich

Responsible for the study, doctoral student, obstetrician-gynecologist - Barmanasheva Z.E.

Scientific consultants - d.m.s. Kudaibergenov T.K., MD Kotlobovsky V.I.

9. Reporting plan for unforeseen problems/adverse events.

The report on the work performed and negative phenomena will be controlled by the chief physician for the medical part Dzhakupov D.V. and scientific consultants d.m.s. Kudaibergenov T.K., MD Kotlobovsky V.I.

10. External cooperation. Not provided

Control plan. Control of the work performed and negative phenomena will be carried out by the chief physician for the medical part Dzhakupov D.V. and scientific consultants d.m.s. Kudaibergenov T.K., MD Kotlobovsky V.I.