RESOLUTION OF ADVISORY BOARD

MODERN APPROACHES TO SURGICAL AND POSTSURGICAL MEDICAL MANAGEMENT OF PATIENTS WITH ENDOMETRIOSIS

December 8, 2016 in Kyiv Advisory board was held related to modern approaches to surgical and postsurgical medical management of patients with endometriosis. The meeting was chaired by **V.V. Kaminskiy**, MD, Professor, corresponding member of the NAMS of Ukraine, **T.F. Tatarchuk**, MD, Professor, corresponding member of the NAMS of Ukraine, **I.Z. Gladchuk**, MD, Professor, by the personal participation of leading Ukrainian experts in obstetrics, gynecology and surgery and with involvement of foreign expert, MD, Professor **M. Mueller**.

Endometriosis is a chronic estrogen-dependent gynecological disease which requires a life-long management plan with the goal of maximizing the use of medical treatment and avoiding repeated surgical procedures. There are three types of endometriosis: peritoneal endometriosis, ovarian endometriosis (endometrioma) and deep infiltrating endometriosis (DIE). Separately adenomyosis is considered as a manifestation of endometrioid lesion of uterus. The symptoms manifestation depends on localization of endometriosis lesions, their form and extension of the process. The most common clinical symptoms of endometriosis are pain and infertility. In the absence of treatment, endometriosis may cause the dysfunction of the affected organs and may have a negative effect on the woman's quality of life.

The disease management tactics in patients with endometriosis are determined by the clinical symptoms and includes observation, medical treatment, surgical treatment (conservative, radical), using of the assisted reproductive technologies (ART).

The main goals of endometriosis management are treatment of symptoms (pain relief if available), fertility restoration, prevention of recurrence and repeated surgeries in future.

To prevent endometriosis recurrence it is reasonable to use a combined approach – surgical methods and hormonal therapy.

SURGICAL TREATMENT

According to the unified clinical protocol "Management of patients with genital endometriosis" approved by Order of the Ministry of Health of Ukraine No. 319 dated April 06, 2016, the surgical treatment of endometriosis should be performed when the clinical symptoms are present:

- availability of contraindications and failure of the medical treatment;
- availability of external endometriosis forms;
- availability of DIE with involvement of bowel, bladder, ureter or pelvic nerves in case of severe complications (severe rectal bleedings, obstruction, stenosis, deep involvement of the bowel wall, bowel obstruction, the presence of large or multiple lesions, hematuria, dysuria in cases of obstruction)
- acute adnexal conditions (cyst distortion or ruptured ovarian cyst);
- progression of pelvic pain syndrome despite of an adequate medical treatment;
- in case of ovarian endometrioma with use of techniques targeted to preserve the ovarian reserve;
- failure of conservative treatment of infertility.

Surgical methods allow to clarify and to finally confirm the diagnosis, remove endometriosis lesions and adhesions as completely as possible and restore the anatomy. In case of surgical tactics selection, it is necessary to take into account the patient age, her reproductive plans, surgeon experience (or availability of multidisciplinary team in case of DIE), localization, number and size of the endometriosis lesions.

Peritoneal endometriosis. The surgical treatment of peritoneal endometriosis may include both laparoscopic ablation and resection to relieve the endometriosis associated pain. Its resionable to remove lesions by cryo- or laser destruction. To reduce pain in some cases intersection sacro-uterine ligaments is possible.

Endometriomas. Surgical treatment is conducting in case of endometriomas bigger than 3 cm in size. Using of laparoscopy in endometrioma surgery allows to decrease the risk of recurrence and improve fertility. However, it should be taking into account, that ablation of ectopic lesions and electrosurgical coagulation, which are used to remove the cysts, may impair the stoma and ovarian vascular network, and a part of a normal ovarian tissue may be removed which results in the decreased ovarian reserve.

In patients with endometriomas more than 3 cm in diameter, the laparoscopic excision compared with drainage or fulguration ensures more evident relief of the pain syndrome and prevents disease recurrence. During primary treatment of endometrioma, the cyst capsule should be removed completely, fenestration is not sufficient.

Deep infiltrating endometriosis. DIE is usually presented with the infiltration of sacro-uterine

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ligaments, posterior vaginal wall, anterior rectum wall and in the most severe cases with infiltration of parametrial tissue with the involvement of major vessels and distal areas of ureters. For DIE treatment complete resection of lesions should be performed. However, compromises are possible in case when fertility is the main goal. The extent of resection should be discussed with a patient in details considering the benign nature of condition and possible complications. DIE treatment requires the multidisciplinary approach with involvement of the different specialists (urologist, proctologist). If conservative management of DIE is required in pre- and postsurgical period, ultrasound examination of kidneys is mandatory in order to avoid silent hydronephrosis. DIE-associated hydronephrosis is an absolute indication for the appropriate treatment.

The surgical treatment of rectocervical endometriosis includes the prudent dissection, resection of the posterior uterine wall and posterior vaginal vault, removal of endometrioid infiltrate of rectovaginal tissue with the mandatory control of ureter path, major vessels and rectum wall. Deep excision of the nodes during the treatment of uterine ligament endometriosis improves the long-term effects: facilitates complete disappearance or partial reduction of symptoms. The surgical treatment of endometriosis lesions of urinary tract is performed by using "shaving" technique, partial resection of bladder wall, partial cystectomy. After removal of endometriomas, bilateral ovarian fixation, ureter visualization and dissection within peritonectomyregimen, which may be partial or total (in case of advanced endometriosis) should be performed. The mantadory condition of the surgical intervention is the ureter visualization, as risk of its damage is preserved during the excision of the complicated forms of endometrioid heterotopies. In case of lateral expansion of endometriosis process, the lesion excision is performed bilaterally or centrally. The whole tissue complex with the endometrioid nodes are subject to removal. If a method of discoid resection with the circular stapler is used in the surgical treatment of endometrioid node in the bowel wall, it is possible to perform the resection of lesions up to 3 cm in diameter. The bowel resection is performed in case of obstruction, stenosis, presence of large or multiple lesions, severe rectal bleeding and deep involvement of bowel wall.

Adenomyosis. Hysterectomy is recommended for a patient with the achieved reproductive plans who has adenomyosis and pelvic pain. If a patient wishes to preserve the uterus, drug-induced amenorrhea is recommended or LNG-IUD with the purpose of dysmenorrhea and/or abnormal uterine bleedings treatment. Hysterectomy is performed in women with the severe endometriosis (multiple lesions, severe pain, which does not respond to therapy), who do not plan pregnancy.

POSTSURGICAL MEDICAL TREATMENT

Postsurgical prevention of endometriosis recurrence is an important stage of management of patients with endometriosis, as regardless of the proven efficacy of the surgical treatment, a risk of endometriosis lesions and pain recurrence is exist. Currently no clear criteria for endometriosis recurrence evaluation are available. The following criteria have been used in the clinical studies to evaluate the endometriosis recurrence: pain > 5 scores by VAS (visual analogue scale) (dysmenorrhea, dyspareunia, chronic pelvic pain); lesions 20 mm in diameter detected by ultrasound examination; endometriomas more than 2 cm in size. If no postsurgical medical therapy is used, pain returns in 21.5 % within 2 years after surgery and increase to 40–50% within 5 years post-surgery. Compared to women who had ovariectomy related to endometriosis, the risk of pain recurrence is 6.1-fold higher and risk of repeated surgery is 8.1-fold higher in the patients who had hysterectomy with preserved ovaries. Rate of lesions recurrence varies based on the endometriosis type (endometrioma – 24.6 %, peritoneal – 17.8 %, DIE – 30.6 % within 4-year follow up after surgery).

In case of treatment of recurrent symptoms after the primary surgery due to the endometriosis-associated pain, the level of radicality of used approaches varies from minimal (conservative medical treatment, minimally invasive surgical treatment of recurrences) to maximal (hysterectomy +/- ovariectomy).

The hormonal therapy may maintain the positive effect of the surgical treatment for a long time and may minimize the risk of pain and endometrioid lesions recurrence. **For secondary prevention of endometriosis recurrence and associated pain long-term hormonal therapy is recommended (> 6 months).**

A surgeon plays a key role in prescription of postsurgical medical treatment: he/she determines its strategy for the first 6 months after the surgery in alignment with the outpatient physician.

According to the unified clinical protocol "Management of patients with genital endometriosis" approved by Order of Ministry of Health of Ukraine No. 319 dated April 06, 2016, progestins are the first line therapy of endometriosis, and the treatment should be continued till the age of menopause or till the desired pregnancy. According to the results of some clinical studies, the disease recurrence rate in the postsurgical period after discontinuation of hormonal therapy with the

use of different progestins significantly varies: lynestrenol – 12–34%, norethisterone acetate – 22–27%, medroxyprogesterone acetate – 9%, dydrogesterone – 53% of recurrences. According to the results of clinical study which evaluated the efficacy of dienogest within 5 years for the postsurgical prevention of endometrioma recurrence, the cumulative 5-year recurrence rate was 4% in dienogest group (compared to 69% in patients who did not receive treatment). Dienogest usage in endometriosis treatment is pathogenetically justified, as it has antiproliferative and anti-inflammatory effect on the endometrial and endometrioid stromal cells and exerts antiangiogenic effect. Dienogest effectively reduces endometriosis induced pain (dysmenorrhea, dyspareunia, chronic pelvic pain) and has good tolerability, which is an important for long-term therapy. For patients with pain syndrome (including dysmenorrhea), who do not plan pregnancy and are unable to use dienogest for a long time (more than 6 months after the surgery), LNG-IUD may be a treatment of choice since it has high clinical efficacy, is easy to use (single insertion for 5 years) and has an acceptable safety profile.

Today it is proved that endometriosis is estrogen-dependent disease. Estrogen is a key hormone which simulates the growth and persistency of endometrioid tissue and causes the inflammation and associated pain. Most COCs contain ethinylestradiol, its activity is significantly higher compared to endogenous estrogen. Taking into consideration the above mentioned, it is not possible to exclude the potential stimulation of development, progression and recurrence of endometriosis during COCs use. Current data of the clinical studies demonstrate that previous use of COCs due to the primary severe dysmenorrhea is associated with increased risk of DIE in future. In addition, not all types of pain have the equal response to the postsurgical treatment with COC use. There is no consensus today regarding the efficacy of the postsurgical COCs in the chronic pelvic pain and dyspareunia treatment. There is also a lack of data to confirm the long-term safety of endometriosis treatment with COCs.

ENDOMETRIOSIS AND INFERTILITY

Mechanisms which cause infertility in this disease are comprehensive and has not been completely studied yet. They include the adhesive process, involvement of Fallopian tubes, decreased ovarian reserve, impaired embryo implantation, inflammatory reaction of tissues surrounding the endometriosis lesions.

To treat the women with endometriosis and infertility, the surgeon should have the appropriate skills and experience. Cooperation with the centers of reproductive medicine is also mandatory. In the patients with endometriomas less than 3 cm in diameter and without pain symptoms the surgical intervention should not be conducted, they are recommended to naturally conceive with further ART use if needed.

In persistent infertility (failure of long-term therapy) of non-defined origin and suspected endometriosis (presence of pain syndrome), it is reasonable to perform the laparoscopy to rule out the endometriosis as a cause of infertility and its surgical treatment.

After surgery, the patients with the reproductive plans are recommended to prescribe dienogest for 3 months and in case of infiltrating endometriosis forms – at least for 6 months to minimize the inflammatory process.

In case of recurrent endometriosis, ART is preferred compared to the repeated surgery considering the incidence of pregnancy. In case of repeated surgeries due to ovarian endometrioma, decreased ovarian reserve related with the procedure should be taken into consideration. In case of making the decision on the laparoscopy conducting, patient opinion should be taking into account. In some cases hormonal therapy with the further follow up is possible.

Medical and surgical methods of endometriosis treatment should not be considered as competitive but as compatible, which increase the treatment efficacy and improve the disease prognosis.

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СУЧАСНІ ПІДХОДИ ДО ХІРУРГІЧНОГО ТА ПОСТХІРУРГІЧНОГО МЕДИКАМЕНТОЗНОГО ВЕДЕННЯ ПАЦІЄНТОК ІЗ ЕНДОМЕТРІОЗОМ
Резолюція експертної ради

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та інші члени експертної ради

В Києві 8 грудня 2016 року пройшло засідання експертної ради з питань сучасних підходів до хірургічного та постхірургічного медикаментозного ведення пацієнток із ендометріозом. Ендометріоз – хронічне естрогенозалежне гінекологічне захворювання, яке потребує розробки плану довгострокового ведення пацієнтки з метою максимального використання медикаментозного лікування й уникнення повторних хірургічних втручань. Лікувальна тактика при ендометріозі визначається клінічними симптомами захворювання і включає спостереження, медикаментозне лікування, хірургічне лікування (консервативне, радикальне), застосування допоміжних репродуктивних технологій. З метою запобігання рецидивам ендометріозу доцільно застосовувати комбінований підхід – хірургічні методи та гормональну терапію.

В резолюції детально описана хірургічна тактика ведення хворих із ендометріозом в залежності від клінічних симптомів та умов доцільності даного втручання, згідно з уніфікованим клінічним протоколом «Тактика ведення пацієнток із генітальним ендометріозом», затвердженим наказом МОЗ України № 319 від 06.04.2016.

Післяопераційна профілактика рецидивів – важливий етап менеджменту пацієнток із ендометріозом, оскільки, попри доведену ефективність хірургічного лікування, існує ризик виникнення рецидивів ендометріоїдних вогнищ і болю. В резолюції зазначено, що на сьогодні відсутні чіткі критерії оцінки рецидиву ендометріозу. Наголошено, що гормональна терапія може зберегти позитивний ефект хірургічного лікування протягом тривалого часу та мінімізувати ризик виникнення рецидивів болю й ендометріоїдних вогнищ. Для вторинної профілактики повторного виникнення ендометріозу і асоційованого з ним болю рекомендовано проводити тривалу гормональну терапію (> 6 місяців). Ключову роль у призначенні післяопераційного медикаментозного лікування відіграє хірург: саме він визначає його стратегію на перші 6 місяців після операції при узгодженні з лікарем амбулаторної ланки.

Для лікування жінок із ендометріозом і безпліддям обов'язковими є наявність у хірурга відповідних навичок і досвіду в хірургії безпліддя, а також співпраця з центрами репродуктивної медицини. При стійкому безплідді (неефективності проведеної тривалої терапії) невстановленого ґенезу і підозрі на ендометріоз (наявність больового синдрому) доцільним є проведення лапароскопії з метою виключення ендометріозу як причини безпліддя і його хірургічне лікування. Після проведення операції пацієнткам із репродуктивними планами рекомендується призначити дієногест на 3 місяці, а при інфільтративних формах ендометріозу – щонайменше на 6 місяців, з метою мінімізації запального процесу.

Загалом зазначено, що медикаментозні та хірургічні методи лікування ендометріозу слід розглядати не як конкуруючі, а як поєднувані, що підвищують ефективність лікування та покращують прогноз захворювання.

Ключові слова: ендометріоз, безпліддя, хірургічні методи, гормональна терапія, вторинна профілактика.

MODERN APPROACHES TO SURGICAL AND POSTSURGICAL MEDICAL MANAGEMENT OF PATIENTS WITH ENDOMETRIOSIS
Resolution of Advisory Board

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December 8, 2016 in Kyiv Advisory Board was held related to modern approaches to surgical and postsurgical medical management of patients with endometriosis. Endometriosis is a chronic estrogen-dependent gynecological disease which requires a life-long management plan with the goal of maximizing the use of medical treatment and avoiding repeated surgical procedures. The disease management tactics in patients with endometriosis are determined by the clinical symptoms and includes observation, medical treatment, surgical treatment (conservative, radical), using of the assisted reproductive technologies. To prevent endometriosis recurrence it is reasonable to use a combined approach – surgical methods and hormonal therapy.

In resolution surgical tactics of management of patients with endometriosis is described in detail based on clinical symptoms and appropriate conditions for this intervention, according to the unified clinical protocol "Management of patients with genital endometriosis" approved by Order of Ministry of Health of Ukraine No. 319 dated April 06, 2016.

Postsurgical prevention of endometriosis recurrence is an important stage of management of patients with endometriosis, as regardless of the proven efficacy of the surgical treatment, a risk of endometriosis lesions and pain recurrence is exist. As noted in the resolution, currently no clear criteria for endometriosis recurrence evaluation are available. The hormonal therapy may maintain the positive effect of the surgical treatment for a long time and may minimize the risk of pain and endometrioid lesions recurrence. For secondary prevention of endometriosis recurrence and associated pain long-term hormonal therapy is recommended (> 6 months). A surgeon plays a key role in prescription of postsurgical medical treatment: he/she determines its strategy for the first 6 months after the surgery in alignment with the outpatient physician.

To treat the women with endometriosis and infertility, the surgeon should have the appropriate skills and experience. Cooperation with the centers of reproductive medicine is also mandatory. In persistent infertility (failure of long-term therapy) of non-defined origin and suspected endometriosis (presence of pain syndrome), it is reasonable to perform the laparoscopy to rule out the endometriosis as a cause of infertility and its surgical treatment. After surgery, the patients with the reproductive plans are recommended to prescribe dienogest for 3 months and in case of infiltrating endometriosis forms – at least for 6 months to minimize the inflammatory process. As its noted in resolution medical and surgical methods of endometriosis treatment should not be considered as competitive but as compatible, which increase the treatment efficacy and improve the disease prognosis.

Keywords: endometriosis, infertility, surgical methods, hormonal therapy, secondary prevention.

СОВРЕМЕННЫЕ ПОДХОДЫ К ХИРУРГИЧЕСКОМУ И ПОСТХИРУРГИЧЕСКОМУ МЕДИКАМЕНТОЗНОМУ ВЕДЕНИЮ ПАЦИЕНТОК С ЭНДОМЕТРИОЗОМ
Резолюция экспертного совета

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В Киеве 8 декабря 2016 прошло заседание экспертного совета по вопросам современных подходов к хирургическому и постхирургическому медикаментозному ведению пациенток с эндометриозом. Эндометриоз – хроническое эстрогенозависимое гинекологическое заболевание, которое требует разработки плана долгосрочного ведения пациентки с целью максимального использования медикаментозного лечения и предотвращения повторных хирургических вмешательств. Лечебная тактика при эндометриозе определяется клиническими симптомами заболевания и включает наблюдение, медикаментозное лечение, хирургическое лечение (консервативное, радикальное), применение вспомогательных репродуктивных технологий. С целью предотвращения рецидивов эндометриоза целесообразно применять комбинированный подход – хирургические методы и гормональную терапию.

В резолюции подробно описана хирургическая тактика ведения больных с эндометриозом в зависимости от клинических симптомов и условий целесообразности данного вмешательства, в соответствии с унифицированным клиническим протоколом «Тактика ведения пациенток с генитальным эндометриозом», утвержденным приказом МЗ Украины №319 от 06.04.2016.

Послеоперационная профилактика рецидивов – важный этап менеджмента пациенток с эндометриозом, поскольку, несмотря на доказанную эффективность хирургического лечения, существует риск возникновения рецидивов эндометриоидных очагов и боли. В резолюции отмечено, что на сегодня отсутствуют четкие критерии оценки рецидива эндометриоза. Подчеркивается, что гормональная терапия может сохранить положительный эффект хирургического лечения в течение длительного времени и минимизировать риск возникновения рецидивов боли и эндометриоидных очагов. Для вторичной профилактики повторного возникновения эндометриоза и ассоциированной с ним боли рекомендуется проводить длительную гормональную терапию (> 6 месяцев). Ключевую роль в назначении послеоперационного медикаментозного лечения играет хирург: именно он определяет его стратегию на первые 6 месяцев после операции при согласовании с врачом амбулаторного звена.

Для лечения женщин с эндометриозом и бесплодием обязательны наличие у хирурга соответствующих навыков и опыта в хирургии бесплодия, а также сотрудничество с центрами репродуктивной медицины. При стойком бесплодии (неэффективности проведенной длительной терапии) неустановленного генеза и подозрении на эндометриоз (наличие болевого синдрома) целесообразно проведение лапароскопии с целью исключения эндометриоза как причины бесплодия и его хирургическое лечения. После проведения операции пациенткам с репродуктивными планами рекомендуется назначить диеногест на 3 месяца, а при инфильтративных формах эндометриоза – минимум на 6 месяцев, с целью минимизации воспалительного процесса.

В целом отмечено, что медикаментозные и хирургические методы лечения эндометриоза следует рассматривать не как конкурирующие, а как сочетанные, которые повышают эффективность лечения и улучшают прогноз заболевания.

Ключевые слова: эндометриоз, бесплодие, хирургические методы, гормональная терапия, вторичная профилактика.