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COMPARATIVE ANALYSIS OF REPRODUCTIVE OUTCOMES AFTER CLASSICAL HYSTEROSCOPIC METROPLASTY AND A MODIFIED METHOD IN WOMEN WITH RPL-SYNDROM

The aim of the study - to conduct a comparative analysis of reproductive outcomes in women with RPL-syndrome after using modified and traditional electrosurgical hysteroscopic metroplasty.

Materials and Methods. 138 patients with primary miscarriage (RPL-syndrome) and/or premature birth participated in the study. The main group (1st clinical) consisted of 88 patients with performed hysteroscopic metroplasty according to the proposed modified technique. The comparative group (2nd clinical) consisted of 50 patients who received surgical treatment according to the classical method of GM. The results regarding the onset of pregnancy and their completion were assessed by interviewing during consultations or according to survey data. Statistical analysis of the obtained results was carried out using the program «Primer Biostatistics» (USA).

Results and Discussion. In the main group, compared to the second group, the frequency of spontaneous miscarriages decreased by 3 times, the frequency of spontaneous pregnancies increased by 20%, and the total frequency of pregnancies and live births increased ($p < 0.05$).

Conclusions. The obtained research results indicate the expediency of implementation and use of the modified hysteroscopic metroplasty method.

Key words: intrauterine septum; hysteroscopic metroplasty; intrauterine adhesions; RPL-syndrome; infertility; miscarriage; mullerian anomalies.

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ПОРІВНЯЛЬНИЙ АНАЛІЗ РЕПРОДУКТИВНИХ НАСЛІДКІВ ПІСЛЯ КЛАСИЧНОЇ ГІСТЕРОСКОПІЧНОЇ МЕТРОПЛАСТИКИ ТА МОДИФІКОВАНОГО МЕТОДУ В ЖІНОК З RPL-СИНДРОМОМ

Мета дослідження – провести порівняльний аналіз репродуктивних наслідків у жінок з RPL-синдромом після використання модифікованої та традиційної електрохірургічної гістероскопічної метропластики.

Матеріали та методи. У дослідженні брали участь 138 пацієнток. Основну групу (I клінічна) склали 88 пацієнток, у яких гістероскопічну метропластику виконували відповідно до запропонованої модифікованої методики. Порівняльну групу (II клінічна) становили 50 пацієнток, які були прооперовані за класичним способом гістероскопічної метропластики. Результати щодо настання вагітності та її завершення оцінювали шляхом опитування під час консультацій або за даними анкетування. Статистичний аналіз отриманих результатів проводили із застосуванням програми «Primer Biostatistics» (USA).

Результати дослідження та їх обговорення. В основній групі порівняно з другою групою частота спонтанних викиднів зменшилась у 3 рази, збільшились частота спонтанних вагітностей на 20 % та загальна частота вагітностей і живонароджень ($p < 0,05$).

Висновки. Отримані результати дослідження вказують на доцільність імплементації та застосування модифікованого способу гістероскопічної метропластики.

Ключові слова: внутрішньоматкова перетинка; гістероскопічна метропластика, внутрішньоматкові синехії; RPL-синдром; безпліддя; невиношування; мюллерові аномалії.

Introduction. Intrauterine septum (IUS) is a congenital malformation of the uterus associated with abnormal resorption of the Müllerian duct during embryogenesis. Its prevalence ranges from 1 to 3% in the population and is associated with reduced fertility, miscarriage and premature birth [1, 2]. Hysteroscopic metroplasty (HM) is an effective but not always safe operation for the treatment of patients with RPL- syndrome associated with IUS. Its performance is aimed at dissection of IUS using various operative techniques: mechanical, laser, and, most frequently, electrosurgical [3,4,5]. The majority of studies confirm the effectiveness of such an operation, but until now there is no unequivocal opinion about the expediency of its performance [6-8, 12-14]. The American Society for Reproductive Medicine (ASRM) guidelines for the treatment of IUS provide for HM in the

case of RPL - syndrome (ASRM, 2016). However, guidelines from the European Society of Human Reproduction and Embryology (ESHRE), the National Institute for Health and Care Excellence (NICE) and the Royal College of Obstetricians and Gynecologists (RCOG) do not support the use of HM until appropriate studies demonstrate its effectiveness (RCOG, 2011; NICE, 2015; ESHRE, 2018) [9,10,11]. Only a few studies have compared different surgical techniques and energies used during HM and their effect on surgical efficacy, but postoperative reproductive outcomes have not yet been evaluated. The improvement of the method of performing HM is of undeniable interest and is of great practical importance, as it can contribute to improving fertility in women of reproductive age. Based on the analysis of the literature and our own experience, we developed a method

of operative treatment of intrauterine membranes of the U2a class (ESHRE/ESGE) in women with RPL - syndrome, which showed positive results in improving reproductive function [copyright of the method No. 123177 dated 01/24/2024 "Modified method of hysteroscopic metroplasty according to I.Z. Gladchuk, V.I. Gladchuk and Kalitsynska Yu.L.").

THE OBJECTIVE of the study is to conduct a comparative analysis of reproductive outcomes in women with RPL- syndrome with the classical and modified method of hysteroscopic metroplasty.

MATERIALS AND METHODS. The selection of patients for a comparative prospective study was carried out randomly according to the type of operation (classical technique or modified technique of HM) in the period from 2018 to 2022 in the gynecological department and in the department of invasive methods of diagnosis and treatment of Multidisciplinary medical Center of ONMedU (clinical base of the Department of Obstetrics and Gynecology of ONMedU). Inclusion criteria were age from 19 to 40 years old with IUM of U2a class (according to ESHRE/ESGE classification) with established diagnosis of primary miscarriage (RPL-syndrome) and/or premature birth. Exclusion criteria were women with clinically insignificant membranes, without a history of RPL-syndrome who had complete U2b class IUM, cervical and vaginal anomalies, as well as patients who required repeated hysteroscopic metroplasty. Two clinical groups were formed. The main group (I Clinical) included 88 patients with performed surgery according to the proposed modified HM method. The comparative group (II clinical) included 50 patients who were

operated on according to the standard method. All women were subjected to general clinical, laboratory and instrumental examinations in accordance with industry standards in the field of health care. Comparative analysis of the studied clinical and anamnestic and preoperative predictors shows the absence of statistically significant differences ($p>0.05$) in patients of both clinical groups (Table 1).

The differences between the modified HM method and the classical method are as follows:

1. Modified HM is performed on the 10-12th day of the menstrual cycle.
2. There is no routine instrumental curettage of the uterine cavity.
3. In contrast to the classical method, which consists only of dissection of the membrane, the modified technique uses the incision-excision technique.
4. The final stage of the proposed method consists in endoscopic curettage of the endometrium with a "cold" loop electrode followed by its endoscopic autotransplantation to the wound surface of the uterine cavity.

All operations were performed under intravenous anesthesia in hospital conditions without additional preoperative hormonal therapy. Antibiotic prophylaxis included administration of 1 g of ceftriaxone intraoperatively in 90% of patients, 10% of patients received 500 mg of levofloxacin, taking into account the allergic history [15]. During all operative interventions, the amount of injected and withdrawn distention fluid was measured to prevent its excessive absorption. HM was completed without any intraoperative or early postoperative

Table 1. **Comparative characteristics of the studied preoperative predictors in women of two clinical groups (n=138)**

Investigated indices	Main group (n=88)		Comparison group (n=50)		Statistical evaluation
Age of patients (years)	27.52±1.59		28.21±1.65		t- Student's test $P>0.05$
Number of pregnancies in history:	Absolute n	%	Absolute n	%	Z is a criterion for comparing two proportions
2	56	63.6±0.55	33	66.0±0.95	Z=-0.098 p=0.922
3	22	25.0±0.49	13	26.0±0.88	Z=-0.074 p=0.941
> 3	10	11.4±0.36	4	8.0±0.37	Z=0.342 p=0.732
AUB (Abnormal uterine bleeding)	10	11.36±0.36	5	10.0±0.60	Z=-0.038 p=0.97
Endometrial polyposis/hyperplasia	26	29.5±0.52	14	28.0±0.90	Z=-0.142 p=0.172
EGE (External genital endometriosis)	12	13.6±0.39	7	14.0±0.69	Z=-0.192 p=0.848
PCOS (Polycystic ovary syndrome)	14	15.9±0.42	7	14.0±0.69	Z=0.052 p=0.958
Uterine myoma	8	9.1±0.33	4	8.0±0.54	Z=-0.094 p=0.925
Membrane size 1/3	53	60.2±0.56	32	64.0±0.96	Z=0.259 p=0.796
1/2	26	29.5±0.52	14	28.0±0.90	Z=-0.008 p=0.993
2/3	9	10.22±0.34	4	8.0±0.48	Z=0.126 p=0.900

complications in any groups under study. The patients were discharged on the day of the procedure.

Outcomes regarding pregnancy onset and completion during the first year after HM were assessed by interview during consultations or by questionnaire data.

The work involved compliance with the concept of informed consent in accordance with the Order of the Ministry of Health of Ukraine No. 29 dated January 21, 2016. Statistical processing of the obtained data was carried out using the program "Primer Biostatistics" (USA). The probability of differences in parametric characteristics in groups was assessed using the Student's test (t-test). During the calculations, statistically significant differences were considered at $p < 0.05$ (99% confidence level (CL)). The study was conducted in compliance with the ethical principles set forth in the Declaration of Helsinki and was approved by the Bioethics Commission of the Odessa National Medical University (protocol No. 18 від 06.12.23).

RESULTS AND DISCUSSION. Reproductive results were studied in 96 patients who tried to conceive after HM during the first year (61 patients from the 1st clinical group and 35 patients from the 2nd clinical group). The other 42 patients were excluded from the study for various reasons, in particular, due to refusal of trying to conceive. The analysis of medical records of women with RPL - syndrome indicates an increase in the frequency of IUS. In 2016, IUSs were detected during hysteroscopies in almost every 10th woman. In 2022, the number of diagnosed IUSs increased to 20%. In our opinion, this is primarily due to the improvement of non-invasive diagnostic methods (3D ultrasound, MRI). Our study confirms the literature data that IUS is one of the frequent causes of miscarriage, premature birth and infertility. Their frequency varies from 1 to 3% in the population, and in women with a history of miscarriage and infertility, the frequency of IUS detection is 5.5-24.5% [16, 17].

Hysteroscopic metroplasty is a reconstructive and plastic surgical intervention aimed at eliminating a congenital defect and creating better conditions for carrying a pregnancy.

Whether the use of a specific instrument or energy during HM will improve reproductive outcome is insufficient and requires further study. Most of the data show improvement in reproductive outcomes after HM, but some authors believe that the chances of a desired pregnancy do not improve. Li W. et al. (2021) found better reproductive potential in the women who underwent HM with scissors than in those who were operated on with a resectoscope [18]. Yang L. et al. (2021) indicate that the use of electrosurgical instruments can cause thermal damage to the myometrium and negatively affect the recovery of the endometrium in the area of IUS resection [19]. In contrast, Alvero R. et al. (2021) found no significant differences between women operated with scissors, argon laser, or resectoscope [14]. Nevertheless, the most common method of HM is considered to be incisional HM. It involves only dissection of the thickness of the membrane to visualize the tubular cells using a mono- or bipolar electrode.

In order to improve reproductive outcomes in women with RPL-syndrome associated with IUS, we performed a modified hysteroscopic metroplasty operation. It involves the use of a combined incision-excision technique followed by autotransplantation of endometrial fragments onto the wound surface. It should be emphasized that the development of the modified technique, first of all, aims at reducing

the frequency of miscarriages and increasing the rate of live birth in women with a history of miscarriage.

There is no doubt that the reproductive consequences of patients with IUS, among other things, depend both on the applied surgical technique and on the level of operative technique and conditions for its implementation. In case of excessive traumatization of the endometrium during surgery, the risk of postoperative intrauterine formation increases significantly, which worsens reproductive expectations.

The choice of HM technique in the patients of both clinical groups was made on a randomized basis. The operations were performed in a specialized center of reconstructive and plastic gynecological surgery by specialists of the highest qualification category, which practically excluded the influence of these factors on any of the studied parameters.

First of all, when using the improved method of HM, there is a decrease in the frequency of miscarriages by almost 3 times - 9.6% compared to the classical method - 33%, which contributes to an increase in the overall rate of live birth in the 1st clinical group - 47 (90.4%), compared to classical incisional technique - 66.7% ($p < 0.05$) (Table 2). According to our research, the frequency of term deliveries in women who underwent GM using modified technique was significantly different from this indicator in the comparison group by almost 30% ($p < 0.05$). In addition, the number of premature births in the main group was lower, but the difference is not statistically significant ($p > 0.05$) (Table 2). Since IUS consists of the fibromuscular tissue and has a reduced blood supply, this can lead to poor implantation and early pregnancy loss. At later stages of gestation, the septum reduces the space for fetal development, which leads to miscarriage, incorrect position of the baby, or premature birth [20, 21]. The developed technique of hysteroscopic metroplasty, which is based on the use of the incision-excision technique, enables to remove completely the tissue of the intrauterine membrane. We assume that this approach contributes to the maximum reconstruction of the uterine cavity, in contrast to the classical technique, where only the dissection of the uterine cavity is performed, and thus increases the reproductive chances of women.

There is a noticeable difference in the overall frequency of pregnancies in the groups under examination. When using the improved HM technique, 52 cases of pregnancy were recorded in the 1st clinical group, compared to 24 cases with the classical incisional technique ($p < 0.05$). We can assume that the results obtained are primarily related to the peculiarities of the modified HM. According to the classical method, HM is performed immediately after menstruation, in the early proliferative phase, not infrequently after previous scraping of the mucous membrane of the uterus, for better visualization of the cavity, which can significantly worsen the postoperative regeneration of the mucous membrane of the uterus. In our opinion, HM should be performed on the 10th-12th day of the menstrual cycle, at the time of the peak level of estradiol (E2) production, at the stage of physiological hyperplasia when the endometrium has the best characteristics for its autotransplantation. The final stage of the modified HM with scratching of the endometrium and its subsequent application to the wound surface of the uterine cavity affects the reduction of the formation of postoperative intrauterine synechiae and improves the period of implantation in the future, as demonstrated by our previous studies [22,23].

Table 2. Comparative characteristics of reproductive consequences after HM in both clinical groups (n=76)

Results	I (n=52)		II (n=24)		p
	n	%	n	%	
Independent pregnancy	36	69.2	10	41.7	P<0.05
IVF	16	30.8	14	58.3	P<0.05
<i>Result of pregnancies</i>					
Urgent childbirth	40	76.9	12	50	P<0.05
Premature birth	7	13.5	4	16.7	P>0.05
Miscarriage	5	9.6	8	33.0	P<0.05
General live birth	47	90.4	16	66.7	P<0.05
<i>The path of birth</i>	47		16		
Independent childbirth	9	19.1	3	18.75	P>0.05
Cesarean section	38	80.9	13	81.25	P>0.05

A statistically significant difference was also found between groups in indices of the method of pregnancy, namely, 36 (69.2%) women of the 1st clinical group became pregnant independently, and 16 (30.8%) women became pregnant through IVF, in contrast to the 2nd clinical group, in which there were 10 (41.7%) cases of spontaneous pregnancy and 14 (58.35%) cases with the help of reproductive technologies ($p<0.05$). We can assume that the results obtained are primarily related to the peculiarities of the conducted modified HM.

Due to the burdensome anamnesis and reconstructive plastic surgery, the majority of women in both clinical groups gave birth by the cesarean section, however, 9 women in the first clinical group and 3 women from the comparison group gave birth physiologically ($p>0.05$).

Today, there is no consensus in the world regarding the treatment strategy for women with RPL-syndrome associated with IUM. Questions about the influence on reproductive outcomes of surgical technique, energy, and instruments during HM remain debatable. Although the number of

supporters of HM to eliminate IUM is rapidly increasing and it is becoming the main, most effective method of treatment for patients with IUM and RPL-syndrome in the anamnesis. At this stage of the study, the proposed HM method demonstrates a number of significant advantages over the standard HM method; however, additional study is needed to confirm the effectiveness of the proposed method. The results of the conducted study indicate the feasibility of implementing and using a modified method of HM and thereby create prospects for further study of the causes and mechanisms of the development of RPL syndrome in women of reproductive age with IUM.

Conclusions. The application of the modified method of hysteroscopic metroplasty in women with RPL syndrome compared to classical HM helps to reduce the frequency of spontaneous miscarriages by 3 times, is accompanied by an increase in the frequency of spontaneous pregnancies by 20% and an increase in the overall frequency of pregnancies and live births.

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