Clinical effectiveness of preconception training in women with sexually transmitted infections after an IVF program

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The objective: to prove the clinical effectiveness of preconception preparation of the women with a history of sexually transmitted infections (STIs) after pre-gravid training before assisted reproductive technology (ART) cycles.

Materials and methods. 115 women received the suggested pre-gravid training, of which 56 women became pregnant after ART programme and were included in the I group and received medical and preventive measures offered by us; 132 women after standard pre-gravid training, of which 55 women became pregnant after ART program and were included in the II group and received generally accepted medical and preventive measures. A clinical analysis of the pregnancy course, childbirth and the condition of newborn children was conducted in 111 women (I and II groups). All patients in the I and II groups had STIs in medical history. Statistical processing of research results was carried out using standard programs “Microsoft Excel 5.0” and “Statistica 8.0”.

Results. The rate of threat of pregnancy interruption was significantly lower in the I group – 6 (10.7 %) patients than in the II group – 19 (34.5 %; p<0.001); missed abortion was determined in 3 (5.3 %) cases in the I group versus 6 (10.9%) cases in the II group; spontaneous pregnancy interruption in the I trimester was in 2 (7.1 %) patients in the I group versus 4 (7.3%) women in the II group. Pregnancy was terminated in 5 (8.9 %) pregnant women in the I group and 10 (18.2 %) – in the II group (p<0.05).

The threat of late abortion in women in the I group was found significantly less than in patients in the II group – 4 (7.8 %) versus 12 (26.7 %) persons, respectively (p<0.05). Fetal growth retardation (FGR) was diagnosed significantly less in the pregnant women of the I group than in pregnant women of the II group – 11 (21.6 %) versus 17 (37.8 %) individuals, respectively (p<0.05). The results of cardiotocography (CTG) demonstrated that the satisfactory fetal state was determined in 40 (78.4 %) pregnant women in the I group, which is statistically significantly more than in the II group – 23 (51.1 %; p<0.05) cases. Doubtful non-stress test data were found in the I group more less – 10 (19.6 %) patients versus 15 (33.3 %) cases the II group (p<0.05). Pathological data of CTG were registered in 1 (2.0 %) pregnant women in the I group versus 7 (15.6%) cases in the II group (p<0.05). The risk of fatal distress in the pregnant women in the I group was 13.9 % (95 % CI 7.8-20.0), RR=0.5 (95% CI 0.16-0.66; p=0.002), which confirms the effect of the pre-gravid complex of medical and preventive measures on the fetal distress reducing in the pregnant women of the I group.

Premature births were observed significantly less in patients in the I group, than in the II group, which amounted to 6 (11.7 %) persons versus 12 (26.7 %) persons (p<0.05). The condition of newborns in the I group was satisfactory in 49 (85.9 %) cases, and the total level of children born with asphyxia in the I group decreased by 2.5 times (p<0.05).

Conclusions. Pathogenetically based pre-gravid preparation and therapy proved to be effective for the onset of pregnancy after ART method and positive pregnancy outcomes in 48.6 % of the women; it reduced the reproductive losses by 2 times, the threat of abortion by 3.2 times, the threat of premature birth by 1.6 times, preeclampsia and fetal growth retardation by 1.5 times, and fetal distress during delivery by 2.2 times.

Keywords: sexually transmitted infections, pre-gravid preparation, pregnancy course, obstetric and perinatal complications.
падів у пацієнток ІІ групи; мимовільне переривання у І триместрі вагітності відбулося у 2 (7,1 %) осіб І групи проти 12 (26,7 %) у ІІ групі. Синдром затримки росту плода у вагітних І групи спостерігався достовірно рідше, ніж у вагітних ІІ групи – 11 (21,6 %) проти 17 (37,8 %) відповідно (p<0,05). Сумнівні дані нестресового тесту рідше спостерігали у І групі – у 10 (19,6 %) пацієнток проти 15 (33,3 %) вагітних ІІ групи, що статистично значуще більше, ніж у ІІ групі – 23 (51,1 %) пацієнток (p<0,05). Сумнівні дані нестресового тесту рідше спостерігали у І групі – у 10 (19,6 %) пацієнток проти 15 (33,3 %) вагітних ІІ групи, що статистично значuche більше, ніж у ІІ групі – 23 (51,1 %) пацієнток (p<0,05).

Висновки. Патогенетично обґрунтована прегравідарна підготовка та терапія виявились ефективними для настання вагітності за допомогою ДРТ та сприятливого результату вагітності у 48,6 % жінок; для знижения репродуктивних втрат – у 2 рази, загрози передчасних пологів – в 3,2 раза, загрози передчасних пологів – в 1,6 раза, прееклампсії та перинатальні ускладнення.

Ключові слова: інфекції, що передаються статевим шляхом, прегравідарна підготовка, перебіг вагітності, акушерські та перинатальні ускладнення.

The long course, frequent exacerbations of chronic processes of the pelvic organs negatively affect the reproductive function of a woman, the course of pregnancy, the outcome of childbirth and the health of the newborn [1–4]. Inflammatory diseases are also one of the reasons for the development of placental dysfunction, fetal growth retardation, intrauterine infection of the fetus. The frequency of intrauterine infection of the fetus occurs in the range of 6–53.6 %, among premature children – up to 70 %. The specific weight of infection in the structure of perinatal mortality is 2–65 %. Profound hormonal changes during pregnancy and altered immunological reactivity can affect the clinical picture of the disease, activate the infection, have an adverse effect on the course and outcome of pregnancy, the fetus and the newborn [5–8].

Women's urogenital infections lead to infectious complications in the form of inflammatory diseases of the pelvic organs and to serious disorders of the reproductive function: tubal infertility and ectopic pregnancy, as well as affect the intrauterine development of the fetus, the outcome of childbirth and the course of the postpartum period [9–13]. The growing significance of intrauterine infection in paternity is associated with the expansion of the range of investigated pathogens in recent years and the emergence of more informative diagnostic methods. On the other hand, a significant increase in the frequency of this pathology may be due to the growth of sexually transmitted infections (STIs) among women of reproductive age. According to a number of studies, infectious diseases are detected in 50–60 % of hospitalized full-term and 70 % of premature children [14–16].

Many infectious and inflammatory diseases during pregnancy have common features: first, infection of the fetus and infant can be caused both by an acute infection of the mother and by the activation of a chronic infection during pregnancy; secondly, a significant proportion of pregnant women’s diseases leading to intrauterine infection is latent or subclinical; thirdly, the activation of persistent infection is possible with any violation of homeostasis in the body of a pregnant woman [17–19].

There are the following ways of pathogen penetration to the fetus and the baby: transplacental path (through the placental barrier to the fetus), ascending (through the cervix and fetal egg membranes), descending (through the fallopian tubes); transmural (through the myometrium and decidual membrane); as well as intranatal (when the fetus passes through the infected birth canal) [3, 15, 16]. If the mother has a sexually transmitted infection (STI) during pregnancy from 10 % to 84 %, infection of the fetus and newborn can occur in any of the mentioned above ways [20, 21].

Clinical features and those of the course of chronic inflammatory diseases have a negative impact on a woman’s body. The long course, frequent exacerbations of chronic processes of the pelvic organs negatively affect the reproductive function of a woman, the course of pregnancy, the outcome of childbirth and the health of the newborn [22–24].

However, research works devoted to the preparation for pregnancy of women with a history of STIs are extremely few and are usually aimed at correcting individual links of the pathological condition. Adequate pathogenetic preregancy training significantly reduces the risks to life and health of a specific woman with a history of sexually transmitted infection and her future child. Taking into account the facts mentioned above, the most important and integral stage is the effectiveness of pre-gravid training of women with infertility who had STIs in a medical history.

The objective: of the study is to prove the clinical effectiveness of preconception training of the women with of sexually transmitted infections (STIs) in a medical history after pregravid training, before assisted reproductive technology (ART) cycles.

MATERIALS AND METHODS

In accordance with the aim set, 247 women with infertility who had a history of STIs and planned to participate in the ART programme were examined: 115 women underwent our suggested pre-gravid training, of which 56 women completed the ART programme with pregnancy, who were included in the 1st group and received medical and preventive measures offered by us; 132 women underwent standard pre-gravid training, of which 55 women in the ART programme ended in pregnancy, they were included in group II and received generally accepted medical and preventive measures.

The generally accepted management of women before and during pregnancy was carried out in accordance with the recommendations and orders of the Ministry
of Health of Ukraine for therapy in group II pregnant women, which included hormonal correction, vitamin therapy, antioxidants, antispasmodics and antiplatelet agents, the use of sedatives, tocolytic drugs, vasoactive drugs and, according to indications, antibacterial and antiviral drugs. The purpose of pre-gravid preparation was to prepare the couple for a successful conception by ART method, a normal course of pregnancy and the birth of a healthy child, by assessing risk factors and eliminating them or reducing their impact based on the implementation of a complex of diagnostic, preventive and therapeutic measures [24].

Pregnant women of group I were prescribed treatment in the preconception period of preparation for the ART program, in the presence of STDs, in accordance with the latest recommendations of the European Union for specialists in sexually transmitted infections (IUSTI, 2018) [24]. During pregnancy, traditional maintenance therapy, prevention of placental dysfunction and treatment of comitant extragenital pathology were carried out at the same time. In the presence of colpitis, local treatment was carried out by sanitizing the cervix and vagina using conventional methods.

Pregnant women who are diagnosed with blood circulation disorders in the “mother-placenta-fetus” system are simultaneously prescribed differential treatment for the correction of the detected disorders. The effectiveness of the treatment was evaluated based on the results of the analysis, clinical signs, dopplerometry indicators, mainly based on the outcome of the pregnancy. To achieve good results of pregnancy management and delivery for women with a history of STIs after ART, it is not enough to solve only one separate problem in reducing obstetric and perinatal losses, the situation requires only a comprehensive approach, where the individual characteristics of each specific woman acquire great importance.

Statistical processing of research results was carried out using standard programs “Microsoft Excel 5.0” and “Statistica 8.0”. Discrepancies at p<0.05 are considered statistically significant [25-26].

The research was carried out in accordance with the principles of the Declaration of Helsinki. The research protocol was approved by the Local Ethics Committee of the institution mentioned in the research work. Women’s informed consent was obtained for the study.

RESULTS AND DISCUSSION

When conducting a statistical analysis, we established that groups I and II obtained while randomization are fully representative of each other. No significant differences related to age, living conditions, reproductive and somatic history were found. In view of the absence of statistically significant differences between all indicators of the subgroups under investigation, it can be stated that the randomization was carried out methodologically correctly.

The effectiveness of ART in women of group I was 56 (48.6 %) cases against 55 (41.6 %) cases in women of group II, p<0.05. The most frequent complication of pregnancy in the examined patients of groups I and II was the threat of termination in the first trimester (Table 1).

However, it should be mentioned that by the end of the first trimester, the phenomenon of threat of termination was observed only in 6 (10.7 %) patients of group I who received pregravidarum complex and treatment, which is statistically significantly less frequent than in women of group II – 19 (34.5 %), p<0.001. Frozen pregnancy in women of group I was 3 (5.3 %) cases against 6 (10.9 %) cases in patients of group II.

Spontaneous termination in the first trimester of pregnancy occurred in patients of the group I in 2 (7.1 %) cases against 4 (7.3 %) cases of women of group II. Isthmic-cervical insufficiency (ICI) was diagnosed in 6 (10.7 %) pregnant women of group I, who received the developed complex of pre-gravid preparation and treatment, against 9 (16.4 %) of pregnant women of group II, but the difference was not reliable p>0.05. Thus, at the beginning of the second trimester of pregnancy, the number of pregnant women in the groups studied was: group I – 51 pregnant women, group II – 45 pregnant women. Pregnancy was terminated in 5 (8.9 %) cases in group I and, accordingly, in 10 (18.2 %) cases in group II of pregnant women, p<0.05. The threat of late abortion in women of group I was found significantly less frequently than in patients of group II, 4 (7.8 %) versus 12 (26.7 %) p<0.05.

Fetal growth retardation syndrome (FGR) in pregnant women of group I was observed significantly less frequently than in pregnant women of group II – 11 (21.6 %) versus 17 (37.8 %), p<0.05. When analyzing the risk of developing the threat of abortion in patients of groups I and II, this indicator was 22.6 % (95 % CI: 10.7–34.5). The relative risk (RR) of the threat of abortion in preg-

### Table 1

<table>
<thead>
<tr>
<th>Indicators</th>
<th>I group, n=56/51</th>
<th>II group, n=55/45</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Threat of interruption</td>
<td>6 (10.7 %)</td>
<td>19 (34.5 %)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Frozen pregnancy</td>
<td>3 (5.3 %)</td>
<td>6 (10.9 %)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Isthmic-Cervical Insufficiency</td>
<td>6 (10.7 %)</td>
<td>9 (16.4 %)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Spontaneous miscarriage</td>
<td>2 (7.1 %)</td>
<td>4 (7.3 %)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Threat of late abortion</td>
<td>4 (7.8 %)</td>
<td>12 (26.7 %)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>The threat of premature birth</td>
<td>5 (9.8 %)</td>
<td>8 (17.8 %)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gestational anemia</td>
<td>13 (25.4 %)</td>
<td>22 (48.5 %)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>4 (7.8 %)</td>
<td>6 (10.9 %)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fetal Growth Retardation</td>
<td>11 (21.6 %)</td>
<td>17 (37.8 %)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Fetal distress</td>
<td>4 (7.8 %)</td>
<td>9 (20.0 %)</td>
<td>&lt;0.05</td>
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</table>
nant women of the first group was 0.35 (95 % CI: 0.22–0.55) in comparison with the control group, p<0.001. The obtained result demonstrates that the frequency of the development of this complication in pregnant women of the group I is three times lower than the frequency of this event in the patients of group II, confirming the statistically significant effect of the pre-gravid complex of treatment and preventive measures on the frequency of threatened termination of pregnancy in the 1st trimester.

The risk of miscarriage up to 12 weeks (frozen pregnancy, spontaneous miscarriage) in patients of groups I and II was 15.3 % (95 % CI: 12.4–18.2), RR=0.5 (95 % CI: 0.27–0.55), p=0.038, which confirms the effect of a complex of medical and preventive measures on reducing the frequency of miscarriage in the 1st trimester. When analyzing the risk of developing the threat of premature birth in pregnant women of groups I and II, the risk of developing this complication was 13.8 % (95 % CI: 9.8–17.8). RR=0.7 (95 % CI: 0.05–0.24), p<0.001, which confirms the effect of a complex of medical and preventive measures on reducing the risk of this complication.

The risk of developing preeclampsia in pregnant women of groups I and II was 9.35 % (95 % CI: 7.8–10.9 %). RR=0.7 (95 % CI: 0.21–0.65), p<0.001, which confirms the effect of the pregravid complex of medical and preventive measures on reducing the frequency of preeclampsia in pregnant women of the first group.

Thus, it was established that patients who received the set of measures developed by us had significantly less complicated pregnancy.

When evaluating the results of ultrasound in group I, whose pregnant women received a pre-gravid complex of medical and preventive measures, echographic changes in the structure of the placenta, pathology in the production of amniotic fluid were detected statistically significantly less often than in group II of pregnant women, p<0.05 (Fig. 1).

During a dopplerometric examination of the uterine-placental-fetal blood circulation in 4 (7.8 %) pregnant women of group I, systolic-diastolic (S/D) increase in both uterine arteries (MA) was found, which is statistically lower than in patients of group II – in 20 (44.4 %), p<0.05 (Table 2).

Early diastolic notch in UrA was recorded in 3 (5.3 %) patients of group I, respectively, which is statistically significantly lower than in pregnant women of group II – 16 (33.6 %), respectively, p<0.05. Zero or reverse blood flow in the umbilical artery (UmA) was not recorded in pregnant women of group I and was observed in 5 (11.1 %) cases in group II of pregnant women. When circulatory decompensation was detected, all patients were delivered urgently. A decrease in the S/D ratio in the middle cerebral artery (MCA) of the fetus was not recorded in pregnant women of both groups.

During CTG, the satisfactory state of the fetus was determined in 40 (78.4 %) pregnant women of group I, which is statistically significantly more than 23 (51.1 %) in group II of pregnant patients (p=0.05) (Fig. 2).

Doubtful non-stress test data were less often observed in 10 (19.6 %) patients of group I compared to 15 (33.3 %) cases in pregnant women of group II, p=0.05. Pathological data of CTG were registered in 1 (2.0 %) in group I against 7 (15.6 %) cases in group II of pregnant women, p<0.05. All patients with a pathological nature of CTG additionally underwent a dopplerometric study of the uterine-placental-fetal blood flow. Based on the studies conducted, fetal distress was diagnosed in 4 (7.8 %) pregnant women of group I and in 9 (20.0 %) patients of group II. The risk of developing distress in pregnant women of the first group was 13.9 % (95 % CI: 7.8–20.0). RR=0.5 (95 % CI: 0.16–0.66), p=0.002, which confirms the effect of the pre-gravid complex of medical and preventive measures on reducing the frequency of fetal distress in pregnant women in group I.
As a result of the research, it was found that structural changes of the placenta, disruption of the utero-placental-fetal blood flow and a decrease in the adaptive and compensatory capabilities of the fetus detected during CTG, fetal distress are statistically significantly less common for pregnant women of group I, who received a pre-gravid complex of therapeutic and preventive drugs measures. Indicators of the functioning of the uterine-placental-fetal blood flow and the state of the fetus in utero were significantly better in pregnant women who received the complex of therapeutic and preventive measures developed.

The pregnant women in research had 51 and 45 deliveries. The largest specific weight of the total number of births in both groups was timely physiological births (Fig. 3). There were significantly fewer premature births observed in patients of group I and amounted to 6 (11.7%) versus 12 (26.7%) in group II, p < 0.05.

Caesarean section was performed in 39 (76.4) patients of group I and 40 (88.9%) women of group II, p < 0.05. In both groups, there is a high percentage of surgical delivery due to treated infertility with a high risk of perinatal pathology and fertilization with the help of ART, but the number of urgent surgical interventions has decreased in the structure of indications.

Progressive fetal distress was an indication for operative delivery by cesarean section in 4 pregnant women of group I, which accounted for 7.8% of cases, against 10 pregnant women of group II, which accounted for 22.2% of cases. Indications for caesarean section consisted of labour abnormalities, fetal distress, and moderate or severe preeclampsia. The postpartum period in patients who received the developed complex of medical measures was uneventful.

During the morphometric and macroscopic examination of the placentas of the women of the groups studied, it was established that the morphometric parameters did not differ statistically significantly, p > 0.05 (Table 3).

Analyzing the condition of newborns after childbirth, it can be said that in 49 (85.9%) cases in group I the condition of children was satisfactory, and the overall level of children born asphyxiated in group I decreased by 2.5 times (p < 0.05). There was neither severe asphyxia, nor intra-amniotic infection, nor, moreover, antenatal death of the fetus in the first group of pregnant women. The rate of fetal growth retardation decreased from 37.8% in group II to 21.6% in group I (p < 0.05), respectively.

According to the data of modern foreign and native literature, the fight against STIs is currently an urgent global health problem, particularly in Ukraine. More than 3,000,000 million new cases of STDs are registered annually in the world. However, experts believe that the actual total number of STDs on our planet is about 1 billion [1–6]. The spread of STDs in the last decade, according to WHO, continues to be significant in the world and cannot but cause alarm. About 400,000 new cases of STIs have been registered in Ukraine in recent years. This puts our country in one of the highest places in terms of the prevalence of STDs in Europe [1–6].

According to the data of Ukrainian and foreign studies on the epidemiology of STDs, the incidence is especially high in the group of people of working and reproductive age. Age 25–40 is an established risk factor for sexually transmitted infections (Table 4).

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It was found that the median indicator of placenta mass and the placental-fetal coefficient in women of group I was statistically greater (0.17) than in the patients of group II (0.15), p < 0.001. Data from the macroscopic examination of placentas were also ambiguous. Abnormalities of the shape of the placenta were not detected. When examining the maternal surface of the placenta, no such changes as hematomas and heart attacks were detected for women of both groups.

51 women of group I gave birth to 57 babies (i.e. 12 of them 6 twins, dichorial diamniotic), 45 women of group II gave birth to 54 babies (i.e. 8 of them 9 twins, dichorial diamniotic). When evaluating the condition of newborns, the median of their weight in group I was significantly higher than in group II, p < 0.05 (Table 4).

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Pathogenetically based pre-pregnancy training and therapy proved to be effective for the onset of pregnancy by the ART method and a favourable pregnancy outcome in 48.6 % of women; reduction of reproductive losses by 2 times, threats of abortion by 3.2 times, threats of premature birth by 1.6 times, preeclampsia and fetal growth retardation by 1.5 times, and fetal distress during childbirth by 2.2 times.

The advantage of STD therapy beyond pregnancy is the prevention of teratogenic and embryotoxic effects of drugs on the fetus, that is, effective antenatal protection of the fetus. Early diagnosis, prevention and treatment of infectious pathology in women before pregnancy, pre-pregnancy preparation and pregnancy planning for women with a history of STIs make it possible to effectively restore reproductive function, reduce the frequency of complications during the gestation period, the severity of the course (duration and frequency of relapses) of the infectious process during pregnancy, prevent severe forms of neonatal infection, reduce perinatal morbidity and mortality. Pre-pregnancy genetic therapy restores a woman’s reproductive function, contributes to the reduction of pregnancy complications and the birth of a healthy, viable newborn, as well as to the reduction of pregnancy losses.

The author declares no conflict of interest.

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