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Prevention and risk prediction of late miscarriages in the second trimester of pregnancy

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Isthmic-cervical insufficiency (ICI) is one of the leading causes of late spontaneous miscarriage and preterm birth during the second trimester of pregnancy. Laparoscopic cerclage is considered one of the modern surgical approaches for the correction of ICI.

Aim – to assess risk factors associated with late miscarriage in the second trimester of pregnancy and to evaluate the effectiveness of preventive measures for improving pregnancy outcomes.

Materials and methods. A prospective study was conducted involving 101 pregnant women with threatened pregnancy loss at 12–28 weeks of gestation (Main group). The Control group consisted of 25 women with physiologically normal pregnancies. The following parameters were assessed: obstetric and gynecological history, gestational age, clinical signs of threatened miscarriage, cervical length, cervical dilatation, and the presence of cervical funneling. Pregnancy outcomes, gestational age at delivery, and perinatal outcomes were also evaluated.

Results. The use of laparoscopic cerclage allowed for prolongation of pregnancy to 32–34 weeks of gestation and beyond, reducing the risk of extremely early preterm birth. No cases of perinatal mortality were observed in the Main group. The obtained results confirm the high effectiveness of laparoscopic cerclage as a method for preventing late miscarriage and preterm birth in high-risk patients. The laparoscopic approach using three trocars demonstrated good clinical efficacy and safety. The absence of differences in neonatal outcomes between delivery methods suggests that, in cases of extreme prematurity, gestational age and antenatal management play a more important role than the mode of delivery itself.

Conclusion. Laparoscopic cerclage is an effective method for the treatment of ICI, contributing to the prolongation of pregnancy in high-risk women. It improves obstetric outcomes in patients with threatened second-trimester pregnancy loss. The choice of delivery method in preterm birth should be based on individual obstetric indications.

The study was carried out in accordance with the principles of the Declaration of Helsinki. The informed consent of the patients was obtained for the study.

No conflict of interest was declared by the author.

Keywords: isthmic-cervical insufficiency, laparoscopic cerclage, preventive measures, risk of pregnancy loss, second-trimester pregnancy.

Профілактика та прогнозування ризику пізніх викиднів у другому триместрі вагітності

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Істміко-цервікальна недостатність (ІЦН) є однією з провідних причин пізніх самовільних викиднів та передчасних пологів у другому триместрі вагітності. Лапароскопічний серкляж вважається одним із сучасних хірургічних підходів до корекції ІЦН.

Мета — оцінити фактори ризику, пов'язані з пізніми викиднями у другому триместрі вагітності, та ефективність профілактичних заходів для покращення результатів вагітності.

Матеріали та методи. Проведено проспективне дослідження за участю 101 вагітної жінки із загрозою втрати вагітності на терміні 12–28 тижнів (основна група). Контрольну групу становили 25 жінок із фізіологічно нормальною вагітністю. Оцінено акушерський та гінекологічний анамнез, гестаційний вік, клінічні ознаки загрози викидня, довжина шийки матки, розкриття шийки матки та наявність воронкоподібного зрощення шийки матки. Також оцінювалися результати вагітності, гестаційний вік на момент пологів та перинатальні результати.

Результати. Використання лапароскопічного серкляжу дало змогу пролонгувати вагітність до 32–34 тижнів вагітності та далі, зменшуючи ризик надзвичайно ранніх передчасних пологів. В основній групі не спостерігалось жодних випадків перинатальної смертності. Отримані результати підтверджують високу ефективність лапароскопічного серкляжу як методу запобігання пізнім викидням та передчасним пологам у пацієнток високого ризику. Лапароскопічний підхід із використанням трьох трокарів продемонстрував хорошу клінічну ефективність та безпеку. Відсутність відмінностей у неонатальних результатах між різними методами розродження свідчить про те, що у випадках крайньої недоношеності гестаційний вік та антенатальне ведення відіграють важливішу роль, ніж сам спосіб розродження.

Висновок. Лапароскопічний серкляж є ефективним методом лікування ІЦН, що сприяє пролонгації вагітності у жінок високого ризику. Він покращує акушерські результати в пацієнток із загрозою втрати вагітності у другому триместрі. Вибір методу розродження при передчасних пологах повинен ґрунтуватися на індивідуальних акушерських показаннях.

Дослідження проведено відповідно до принципів Гельсінської декларації. Для проведення дослідження було отримано інформовану згоду пацієнток.

Автор заявляє про відсутність конфлікту інтересів.

Ключові слова: істміко-цервікальна недостатність, лапароскопічний серкляж, профілактичні заходи, ризик втрати вагітності, вагітність у другому триместрі.

Introduction

Worldwide, perinatal medicine began to form the foundation for improving the health of future generations in many countries at the end of the 20th century. At present, the transition from the primary goal of reducing perinatal mortality to improving the health of the fetus and the newborn has been completed.

The threat of pregnancy loss complicates approximately 35% of pregnancies at various stages of gestation, resulting in the development of placental insufficiency and chronic intrauterine fetal hypoxia. The implementation of preventive methods for this condition plays an important role in reducing the rates of perinatal morbidity and mortality [5,6].

High rates of perinatal morbidity and mortality in preterm births (PTB) (ranging from 30% to 70%) are associated with low birth weight of the newborn, fetal growth restriction, and intrauterine fetal infection [1]. According to the classification of spontaneous pregnancy loss adopted by the World Health Organization, pregnancy losses occurring up to the 22nd week are classified as miscarriages, whereas births occurring from the 22nd completed week up to the 37th week of pregnancy are considered PTB, provided that the fetal body weight exceeds 500 g [7].

Spontaneous miscarriages are classified according to various criteria. Based on gestational age, they are divided into early miscarriages (up to 12 weeks) and late miscarriages (from the 12th to the 22nd week of pregnancy). According to clinical forms, they include threatened miscarriage, inevitable miscarriage, incomplete and complete miscarriage, infected miscarriage or abortion, and missed miscarriage (non-developing pregnancy) [11,12].

According to the classification of the World Health Organization, pregnancy termination is considered inevitable in cases classified as inevitable miscarriage and incomplete miscarriage [2,10]. Based on gestational age and perinatal prognosis for the newborn, PTB are classified as very early PTB at 22–27 weeks of gestation (fetal weight 500–1000 g unfavorable perinatal prognosis), early PTB at 28–33 weeks (fetal weight 1000–1800 g doubtful perinatal prognosis), and PTB at 34–37 weeks (birth weight 1900–2500 g relatively favorable perinatal prognosis) [8].

The frequency of spontaneous pregnancy loss varies between 10% and 20%. Timely and thorough antenatal diagnosis can reduce the statistical incidence of this pathology and contribute to a decrease

in its overall prevalence. The current situation is further aggravated by the deterioration of the general and reproductive health of women of reproductive age. The effectiveness of therapeutic measures remains relatively low, as treatment is usually carried out against the background of clinically evident deviations from the normal course of pregnancy. These factors necessitate the search for new methods to study and address the problems arising during the second trimester of pregnancy.

The aim of the study was to assess risk factors associated with late miscarriage in the second trimester of pregnancy and to evaluate the effectiveness of preventive measures for improving pregnancy outcomes.

Materials and methods of the study

The research was conducted prospectively during the period from 2020 to 2025 at the Department of Obstetrics and Gynecology of the A. Aliyev at the Azerbaijan State Advanced Training Institute for Doctors under the Ministry of Health of the Republic of Azerbaijan and at the Department of Obstetrics and Gynecology of Leyla Medical Center.

A prospective study involving 101 patients was conducted to determine the effect of threatened pregnancy loss during the second trimester on the course of pregnancy and delivery. These patients constituted the Main group.

The women were between 22 and 35 years of age, with a mean age of 28.7 ± 4.06 years. The patients in the Main group were divided into two subgroups: Subgroup 1 included 46 women with threatened miscarriage at 12–21 weeks of gestation, while Subgroup 2 included 55 women with threatened preterm labor at 22–28 weeks of pregnancy.

The Control group consisted of 25 women with physiologically normal pregnancies.

Inclusion criteria were pregnant women in the second trimester (12–28 weeks of gestation) with a threatened pregnancy, aged 22–35 years, who provided written informed consent to participate in the study.

Exclusion criteria included women with malignant diseases of the reproductive system or other organs, stage 5 chronic kidney disease, grade 3 arterial hypertension, age under 22 or over 35 years, and refusal to participate in the study.

At the time of admission to the clinic, the gestational age in all pregnant women was determined using generally accepted methods: based on the first day of the last menstrual period using Negele's for-

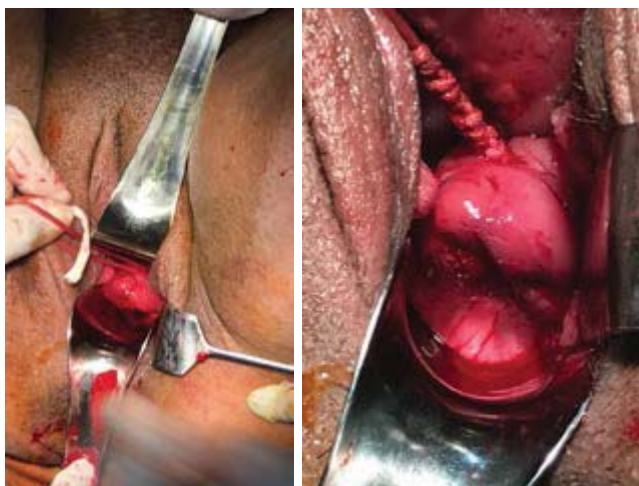


Fig. 1. Vaginal cerclage performed using the MacDonald technique

mula, according to the first perception of fetal movements, and according to the gestational age established at the time of attendance at the antenatal clinic (during the first trimester of pregnancy).

During a thorough medical history assessment, particular attention was paid to socio-economic characteristics, the patient's age, a history of PTB, pregnancies achieved through assisted reproductive technologies (ART), and body mass index (BMI).

Previous extragenital, infectious, viral, autoimmune, and thrombotic diseases were also identified. Obstetric and gynecological history, as well as the characteristics of menstrual and reproductive function, were analyzed in detail. In cases of previous pregnancy loss, the outcomes of earlier pregnancies were evaluated, and in the presence of isthmic-cervical insufficiency (ICI) in the history, the timing of its diagnosis and the methods of its correction were also examined.

The main objective of the treatment carried out in our study was to prolong pregnancy as much as possible up to 32–34 weeks of gestation. Patients with a «true» threat of pregnancy loss (TPL) received medical treatment, including magnesium therapy, tocolytic therapy, and progesterone preparations.

In pregnancies of 24 weeks' gestation and beyond, prophylaxis of fetal respiratory distress syndrome (RDS) with corticosteroids was carried out against the background of tocolytic therapy. The choice of correction method was determined when the diagnosis of ICI was confirmed clinically and by ultrasound, in the absence of contraindications, and was performed either by surgical correction via a vaginal or transabdominal (laparoscopic) approach or by placement of an obstetric pessary.

All patients underwent clinical, laboratory, and transvaginal ultrasound examinations. The following parameters were assessed: obstetric and gynecological history, gestational age, clinical signs of threatened miscarriage, cervical length, cervical dilatation, and the presence of cervical funneling. Pregnancy outcomes, gestational age at delivery, and perinatal outcomes were also evaluated. Surgical correction of ICI, including vaginal and laparoscopic cerclage, was performed according to clinical indications. Laparoscopic cerclage was carried out in 27 patients using a modified three-trocar technique.

Statistical analysis was performed using Statistica for Windows v6.1 (StatSoft Inc., USA). Continuous variables were expressed as mean $\pm$ standard deviation. Categorical variables were presented as absolute numbers and percentages. Group comparisons were conducted using the χ^2 test or Fisher's exact test. A p-value <0.05 was considered statistically significant.

The study was conducted in accordance with the Declaration of Helsinki (2013). The protocol was approved by the Local Ethics Committee of the *Azerbaijan State Advanced Training Institute for Doctors named after A. Aliyev*. All participants provided written informed consent.

Results of the study

During our study, laparoscopic cerclage was performed in 27 patients diagnosed with a threat of pregnancy loss. Cervical cerclage was carried out using the vaginal approach according to the techniques developed by MacDonald, A.I. Lyubimova, and N.M. Mamedalieva.

In our study, the MacDonald technique was preferred, in which a circular purse-string suture was placed on the cervix under intravenous anesthesia up to the 23rd week of gestation. Under aseptic conditions, the cervix was exposed using vaginal specula. The anterior and posterior lips of the cervix were grasped with ring forceps and gently retracted anteriorly and downward. A purse-string suture was placed at the border where the vaginal mucosa of the anterior fornix transitions to the cervix, and the ends of the suture were tied in the anterior fornix of the vagina (Fig. 1).

Mersilene tape was used as the suture material. After surgical correction of ICI via the vaginal approach, the patient was allowed to mobilize and get out of bed. On the 2nd-3rd postoperative day, a follow-up examination of the cervix was performed us-

ing vaginal specula, and the vagina and cervix were treated under aseptic conditions with a 3% hydrogen peroxide solution, benzyldimethyl miristoylammonium chloride monohydrate, and chlorhexidine. Depending on the results of bacteriological and microscopic examinations, vaginal sanitation was performed on an outpatient basis in a dynamic follow-up, and the sutures were usually removed at 37 weeks of gestation.

In cases where several unsuccessful vaginal cerclage procedures and pessary placement have been performed, and despite the use of tocolytics, the pregnancy has still resulted in miscarriage or PTB, laparoscopic cerclage is offered to the patient.

Direct indications for laparoscopic cerclage include patients with cervical amputation, trachelectomy (after organ-preserving surgery for invasive cervical cancer), deep cervical conization, cervical scarring, cervical excision, congenital short cervix, and congenital anatomical cervical defects. Laparoscopic cerclage differs from other cerclage methods in that it can be performed both before pregnancy and during pregnancy. Laparoscopic cerclage is typically carried out up to the end of the first trimester.

Under general anesthesia, in the dorsal lithotomy position and under aseptic conditions, three trocars (one 5.0 mm and two 10.0 mm) are inserted into the abdominal cavity. After insufflation of the abdominal cavity, the vesicouterine peritoneum is dissected in a transverse direction using a laparoscopic hook. The urinary bladder is then gently pushed downward using laparoscopic instruments. In our practice, no uterine manipulator was used, whereas the use of uterine manipulators is reported in the international literature [1,5,6].

In pregnant patients undergoing laparoscopic cerclage, fetal heart rate is checked immediately after the effects of anesthesia have worn off. In non-pregnant patients, the passage of the Mersilene tape through the cervix is assessed by cervicospscopy using a hysteroscope. In the laparoscopic cerclage procedures performed in our study, visualization of the Mersilene tape was not observed after surgery.

Delivery is performed by cesarean section (CS) when it occurs at the appropriate gestational age. Laparoscopic transabdominal cerclage (LTAC) is performed worldwide using a standard laparoscopic technique with four trocars. In our practice, LTAC was performed using a standard laparoscopic technique with three trocars (Fig. 2).



Fig. 2. Performance of laparoscopic transabdominal cerclage using three trocars (personal study)

Worldwide, patients usually remain in inpatient care for 5–7 days after surgery. In our study, however, patients were discharged home after 24 hours following cerclage, under outpatient follow-up. In modern practice, the possibility of placing a laparoscopic cerclage prior to conception is being considered, which reduces the risk of pregnancy loss associated with suture placement during pregnancy. Laparoscopic correction of ICI is performed between 10–11 and 15–16 weeks of gestation.

One of the important and still unresolved issues in PTB is the choice of delivery strategy. At present, there is no consensus among obstetricians and gynecologists regarding which mode of delivery is optimal for preterm infants [2,11]. There are both proponents and opponents of operative delivery by CS and vaginal delivery. The possibility of prolonging pregnancy beyond 28 weeks and reducing the incidence of extremely early PTB significantly improves the perinatal and long-term outcomes of preterm delivery. To study the optimal delivery tactics in cases of PTB, 55 pregnancy histories with preterm delivery were analyzed.

Of these, $50.9 \pm 6.7\%$ (28 cases) of deliveries occurred via the vaginal route, while $49.1 \pm 6.7\%$ (27 cases) were completed by CS. It should also be noted that no cases of perinatal mortality were observed in the studied group, which was most likely due to the exclusion of extremely low birth weight (ELBW) infants from the study, as well as the complicated course of pregnancy. During the analysis of overall perinatal outcomes at 26–28 weeks of gestation, we did not detect any statistically significant

Table

Perinatal outcomes in newborns at 26–28 weeks of gestation according to mode of delivery

Indicator	Vaginal delivery (n=28)	Cesarean section (n=27)	Fisher's exact test, p
Birth hypoxia (Apgar score <7)	7 (25.0±9.0%)	8 (29.6±9.0%)	>0.05
Respiratory distress syndrome	8 (28.6±8.1%)	9 (33.3 ± 9.0%)	>0.05
Continuous positive airway pressure (CPAP) therapy required	5 (17.8±7.3%)	7 (25.9±8.3%)	>0.05
Mechanical ventilation	3 (10.7±5.9%)	2 (7.4%)	>0.05
Cerebral ischemia	19 (67.9±8.8%)	20 (74.0±8.4%)	>0.05
Intraventricular hemorrhage	2 (7.14%)	1 (3.70%)	>0.05

differences between the groups of children depending on the mode of delivery (Table).

Table 1 presents perinatal outcomes of newborns delivered at 26–28 weeks of gestation depending on the mode of delivery (vaginal delivery versus CS). In general, the analysis demonstrated no statistically significant differences between the compared groups for any of the evaluated neonatal outcomes (all $p>0.05$ according to Fisher's exact test).

Birth hypoxia, defined as an Apgar score below 7, was observed in 25.0±9.0% (7 cases) of newborns in the vaginal delivery group and in 29.6±9.0% (8 cases) in the CS group. Although the frequency was slightly higher in the CS group, the difference was not statistically significant ($p>0.05$), indicating comparable neonatal adaptation at birth between the two delivery methods.

RDS was recorded in 28.6±8.1% (8 cases) of newborns delivered vaginally and in 33.3±9.0% (9 cases) of those delivered by CS, also without statistically significant differences ($p>0.05$). This suggests that the mode of delivery did not significantly influence the incidence of respiratory morbidity in this gestational age group.

The need for respiratory support using CPAP was required in 17.8±7.3% (5 cases) of the vaginal delivery group and in 25.9±8.3% (7 cases) of the CS group. Although CPAP usage was somewhat more frequent following CS, the difference did not reach statistical significance ($p>0.05$).

Adaptive support ventilation (ASV) was required in 10.7±5.9% (3 cases) of newborns after vaginal delivery and in 7.4% (2 cases) after CS, again showing no statistically significant difference ($p>0.05$). This indicates a similar need for intensive respiratory support regardless of delivery mode.

Cerebral ischemia was one of the most frequently observed complications, occurring in 67.9±8.8% (19 cases) in the vaginal delivery group and in

74.0±8.4% (20 cases) in the CS group. Despite the high incidence in both groups, no statistically significant difference was found ($p>0.05$), suggesting that delivery mode did not influence this outcome.

Intraventricular hemorrhage (IVH) was relatively rare, detected in 7.14% (2 cases) of vaginal deliveries and 3.70% (1 case) of cesarean deliveries. As with other parameters, the difference was not statistically significant ($p>0.05$).

Overall, the findings indicate that at 26–28 weeks of gestation, neonatal outcomes do not significantly differ between vaginal and cesarean delivery groups, suggesting that the mode of delivery alone may not be a determining factor in short-term perinatal morbidity within this cohort.

Discussion

The present study addresses modern approaches to the prevention and treatment of pregnancy complications associated with ICI, second-trimester threatened miscarriage, and the management of PTB with assessment of perinatal outcomes depending on the mode of delivery. Special attention was given to laparoscopic cerclage as a highly effective surgical method for correcting ICI, as well as to the selection of optimal obstetric tactics in preterm delivery at 26–28 weeks of gestation.

An important aspect of this study is the use of laparoscopic cerclage as one of the key methods for preventing late spontaneous miscarriage and PTB in patients with ICI. Our findings demonstrate a high clinical effectiveness of this intervention, reflected in the ability to prolong pregnancy to viable gestational ages (32–34 weeks and beyond) and in a reduction in extremely early PTB.

In the international literature, laparoscopic cerclage is considered a more anatomically sound and reliable alternative to traditional vaginal cerclage, particularly in patients with cervical anatomical de-

fects, after conization or trachelectomy, or after failure of vaginal correction techniques [2–4,8,9]. According to several authors, including international reviews and meta-analyses, LTAC is associated with a higher rate of pregnancy prolongation and a reduced risk of late pregnancy loss compared with vaginal techniques, especially in high-risk groups [7,11,12].

In our study, the use of laparoscopic cerclage allowed satisfactory perinatal outcomes even in patients with severe forms of ICI and an unfavorable obstetric history. It should be noted that the absence of perinatal mortality in the main group is likely related both to the use of modern surgical correction techniques and to careful dynamic monitoring and timely therapeutic support.

Of particular importance is the fact that the use of a laparoscopic approach, including a modified technique with three trocars, demonstrated comparable efficacy to traditionally described methods while being less invasive and potentially associated with reduced surgical trauma. These findings are consistent with reports from other authors indicating the safety and reproducibility of laparoscopic cerclage in experienced surgical centers [10–12].

Thus, laparoscopic cerclage should be considered an effective method for preventing late miscarriage and PTB in high-risk patients, especially when vaginal correction methods are ineffective. Its use, combined with an individualized pregnancy management strategy, significantly improves perinatal outcomes and reduces the incidence of severe complications associated with ICI.

In the present study, perinatal outcomes in newborns delivered at 26–28 weeks of gestation were analyzed according to the mode of delivery. The results demonstrated no statistically significant differences between vaginal delivery and CS groups in terms of birth hypoxia, RDS, need for respiratory support, cerebral ischemia, and IVH. This indicates that, at this gestational age, the mode of delivery itself is not a determining factor in early neonatal outcomes.

These findings are consistent with data from several international studies, according to which elective or emergency CS does not lead to a significant improvement in short-term neonatal outcomes in very preterm infants compared with vaginal delivery when appropriate obstetric management is provided [7,10–12]. In particular, studies by C. Crump et al. [2] and several observational cohort studies have shown that reductions in neonatal morbidity with

cesarean delivery are not consistent and are often attenuated after adjustment for gestational age, birth weight, and antenatal therapy. Similar conclusions have been reported in meta-analyses, which found no convincing evidence of superiority of CS in preterm neonates in the absence of strict obstetric indications.

At the same time, some authors report potential benefits of operative delivery in specific clinical situations such as breech presentation, severe fetal distress, or ELBW [2–4,8,10]. However, these benefits are not universal and depend on multiple factors, including maternal condition, presence of infection, use of antenatal corticosteroids, and the level of neonatal care. In our study, despite a slightly higher incidence of RDS and CPAP requirement in the CS group, the differences were not statistically significant, which is consistent with literature data regarding the uncertain impact of delivery mode on respiratory outcomes in preterm infants.

A particularly high incidence of cerebral ischemia was observed in both groups, confirming data from other authors regarding the leading role of prematurity as the main risk factor for neurological complications [1,7,10–12]. Immaturity of cerebral autoregulation mechanisms and high vulnerability of brain tissue at 26–28 weeks of gestation likely play a more important role than the mode of delivery. Similarly, the low incidence of IVH and the absence of significant differences between groups further support the multifactorial nature of this complication.

Thus, the results indicate that the choice of delivery mode in PTB at 26–28 weeks should be strictly individualized and based primarily on obstetric indications rather than on a routine preference for CS. The absence of significant differences in neonatal outcomes between the compared groups is consistent with current evidence that gestational age and antenatal management are the primary determinants of neonatal prognosis rather than the delivery method itself.

Further large-scale prospective studies and randomized clinical trials are required to more precisely determine the impact of delivery mode on both short-term and long-term neurodevelopmental outcomes in infants born at extremely and very early gestational ages.

Conclusions

Among etiological factors of pregnancy loss, ICI plays a major role as one of the leading causes of

pregnancy termination in the second trimester. It is recognized as a significant obstetric complication affecting pregnancy outcomes.

In addition to clinically evident cases of ICI and a history of recurrent pregnancy loss, an increasing number of pregnant women are considered to be at high risk for the development of this condition. These include women with polyhydramnios, multiple pregnancy, fetal macrosomia, and congenital connective tissue disorders associated with structural weakness of the cervix and impaired competence of the internal os.

For the assessment of cervical status during pregnancy, vaginal examination remains an important

diagnostic method, allowing evaluation of cervical position, length, consistency, condition of the external os, presence of previous trauma or scarring, and degree of cervical dilatation. Transvaginal ultrasound is also considered one of the most informative diagnostic tools for detecting ICI, and its criteria are widely used in clinical practice.

Thus, ICI often leads to late spontaneous pregnancy loss and significantly contributes to adverse perinatal outcomes. Timely diagnosis, along with appropriate surgical and conservative management, may improve pregnancy outcomes and reduce perinatal complications.

No conflict of interest was declared by the author.

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