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Оценка риска спонтанных преждевременных родов у беременных с акушерским пессарием

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Обоснование. Этиология преждевременных родов многофакторная, включающая как материнские, так и плодовые осложнения на фоне действия функционально ослабленных вариантов множества генов, поэтому преждевременные роды рассматривают как большой акушерский синдром. Один из анатомических компонентов данного синдрома — короткая шейка матки, и в качестве профилактики преждевременных родов у данных пациенток применяют акушерский пессарий.

Цель — выявить факторы риска, приводящие к спонтанным преждевременным родам у беременных, которым установлен акушерский пессарий.

Материалы и методы. Проведено проспективное открытое рандомизированное когортное исследование, в которое вошли 189 женщин с одноплодной беременностью с короткой шейкой матки (<25 ‰ по шкале L.J. Salomon) и угрозой прерывания беременности во II и в III триместрах с акушерским пессарием Dr. Arabin (ФРГ). Было проанализировано 183 параметра и определены основные факторы риска, приводящие к спонтанным преждевременным родам, на основании исходов беременностей.

Результаты. В зависимости от исходов беременности все пациентки были разделены на две группы: в первую вошли 167 женщин со срочными родами, во вторую — 19 беременных со спонтанными преждевременными родами. Основными факторами риска реализации спонтанных преждевременных родов при одноплодной беременности по мере убывания были: по шкале Бишоп ≥7 баллов (p = 0,00032; ОШ 12,38; 95 % ДИ 3,50–43,87), по модифицированной шкале Штейнберга ≥8 баллов (p = 0,00056; ОШ 10,55; 95 % ДИ 3,09–36,03), длина шейки матки ≤15 мм по трансвагинальной цервикометрии (p < 0,001; ОШ 7,94; 95 % ДИ 2,83–22,26), преждевременные роды в анамнезе (p = 0,00128; ОШ 6,91; 95 % ДИ 2,32–20,56), хроническая плацентарная недостаточность (p = 0,00307; ОШ 5,06; 95 % ДИ 1,82–14,01), аномалия развития полового аппарата (p = 0,07452; ОШ 5,03; 95 % ДИ 1,15–22,06), лечебные манипуляции на шейке матки в анамнезе (p = 0,07003; ОШ 2,90; 95 % ДИ 1,05–8,00). В результате многофакторного анализа было показано, что частота спонтанных преждевременных родов в 5 раз выше у беременных при наличии сразу трех факторов: длина шейки матки ≤15 мм, ≥8 баллов по модифицированной шкале Штейнберга и ≥7 баллов по шкале Бишоп (83,33 % спонтанных преждевременных родов по сравнению с 16,67 % срочных родов (p < 0,05; ОШ 59,29; 95 % ДИ 6,47–543,29).

Заключение. Среди пациенток с короткой шейкой матки и акушерским пессарием определены группы высокого риска по реализации спонтанных преждевременных родов.

Ключевые слова: спонтанные преждевременные роды; факторы риска; короткая шейка матки; акушерский пессарий Dr. Arabin; истмико-цервикальная недостаточность.

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Assessment of the risk of spontaneous preterm birth in pregnant women with the Dr. Arabin cervical pessary

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BACKGROUND: Preterm birth has a multifactorial etiology, including both maternal and fetal complications, amid the effect of functionally impaired variants of multiple genes. Preterm birth is therefore considered as the "major obstetric syndrome." One of the anatomical components of this syndrome is a short cervix, and a cervical pessary is used as a prevention of preterm birth in these patients.

AIM: The aim of this study was to identify risk factors for spontaneous preterm birth in pregnant women who received a cervical pessary.

MATERIALS AND METHODS: This prospective, open, randomized cohort study included 189 women with a singleton pregnancy and a short cervix (<25‰ according to the Salomon scale) and a threatened miscarriage / preterm birth in the second and third trimesters trimester, who received the Dr. Arabin cervical pessary. We analyzed 183 parameters and identified the main risk factors leading to spontaneous preterm birth based on pregnancy outcomes.

RESULTS: Based on the pregnancy outcomes, all patients were categorized into two main groups: group I included 167 women with term birth and group II consisted of 19 pregnant women with spontaneous preterm birth. The main risk factors for spontaneous preterm birth in singleton pregnancies in descending order were: the Bishop score ⩾7 points (p = 0.00032, OR 12.38, 95 % CI [3.50–43.87]), the modified Steinberg score ⩾8 points (p = 0.00056, OR 10.55, 95% CI [3.09–36.03]), cervical length ⩽15 mm by transvaginal cervicometry (p < 0.001, OR 7.94, 95% CI [2.83–22.26]), history of preterm birth (p = 0.00128, OR 6.91, 95% CI [2.32–20.56]), chronic placental insufficiency (p = 0.00307, OR 5.06, 95 % CI [1.82–14.01]), genital anomalies (p = 0.07452, OR 5.03, 95% CI [1.15–22.06]), and history of surgical manipulations on the cervix (p = 0.07003, OR 2.90, 95% CI [1.05–8.00]). In multivariate analysis, the risk of spontaneous preterm birth was five times higher in pregnant women with the concomitant presence of three risk factors: cervical length ⩽15 mm, the modified Steinberg score ⩾8 points, and the Bishop score ⩾7 points (83.33% of spontaneous preterm birth compared to 16.67% of term birth; p < 0.05, OR 59.29, 95% CI [6.47–543.29]).

CONCLUSIONS: Among patients with a short cervix and the Dr. Arabin cervical pessary, we have identified groups at higher risk for spontaneous preterm birth.

Keywords: spontaneous preterm birth; risk factors; short cervix; Dr. Arabin cervical pessary; cervical insufficiency.

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ECO•VECTOR

BACKGROUND

Preterm birth (PB) is a major obstetric syndrome that is the leading cause of perinatal morbidity and mortality worldwide [1–8]. The etiology of PB is multifactorial. It includes both maternal and fetal complications; thus, this condition can have different clinical presentations. In our practice, we are mainly faced with three routes of spontaneous preterm birth (SPB) development. In case 1, during uterine contractions, the uterine cervix changes structurally and shortens, and the classic clinical presentation of childbirth occurs. Case 2 is characterized by softening, dilatation, and shortening of the cervix without uterine activity. Moreover, the clinical manifestations are not apparent, and a painless, progressive dilatation of the cervix is usually noted, leading to prolapse, infection, and preterm rupture of the membranes, termination of pregnancy, or PB (classic cervical insufficiency [CI]). In case 3, preterm rupture of the membranes occurs with a long cervix and the absence of uterine activity.

In recent years, various biophysical, biological, and clinical markers have been widely studied to identify women at a high risk of SPB, which enables the development of new approaches not only to the treatment but also to the prevention of SPB (such as the timely use of progesterone, an obstetric pessary, or cerclage) and fetal respiratory distress syndrome [9–12].

Despite the various risk factors for PB, their contribution prevents the successful prolongation of pregnancy nowadays. The incidence of PB remains high, that is, 5%–18% in different countries.

In most cases, the causes of PB are complex. One of the causes is a short uterine cervix. Lots of data have been published on the factors resulting in a short cervix. A short cervix is inherently a syndrome and can be provoked by various causes, such as reduced progesterone activity/levels, congenital short cervix, surgical treatment of cervical pathology, intra-amniotic infection/inflammation, CI of various etiologies, history of PB, age of the pregnant woman (<20 years; >35 years), low body mass index (<19.8 kg/m^2), and ethnicity (African-American or Afro-Caribbean) [8, 13].

The measurement of the cervical length using transvaginal ultrasound (US) is a simple and effective screening method that enables the formation of PB groups. The International Federation of Gynecology and Obstetrics working group on best practices in maternal and fetal medicine has advocated compulsory screening of pregnant women to assess cervical length by transvaginal US in the second trimester as an effective method that can reduce the incidence of PB in pregnant women with short cervix [1, 2]. Similarly, the European Association for Perinatal Medicine has approved universal cervical length screening as a current strategy for detecting PB [3].

However, some international societies do not recommend routine cervical length screening [4–7, 14]. Moreover, the American College of Obstetricians and Gynecologists and the Society for Maternal and Fetal Medicine acknowledge that such a screening strategy may be reconsidered [5–7].

In routine screening, a cervical length of ⩽25 mm is accepted as the standard cutoff for preventive measures. However, the cervical length is known to depend on both the gestational age and the number of fetuses. Thus, according to the Salomon scale, at week 16 of pregnancy, the length of the cervix of 38 mm is short; however, it corresponds to normal values at week 27 of pregnancy and later [15]. This percentile table was developed for singleton pregnancies. This scale is not appropriate for cases of multiple fetations, as there are additional risk factors for PB, and other cases of a short cervix are typical. Thus, when the cervix is ⩽25 mm, preventive measures may be too late and therefore not effective enough.

In connection with the foregoing, the treatment for PB in most cases is catching up in nature and does not lead to the expected result. The standard therapy for threatening PB mainly consists of several stages, namely, the pharmacological regulation of the contractile function of the uterus, correction of cervical incompetence, sanitation of concomitant infection and bacterial vaginosis, protective regimen, stress therapy, and prevention of fetal distress syndrome, and all this takes time. The Russian and international experience suggests that, nowadays, despite the promoted monotherapy of the threat of BP, the effective suppression of the contractile activity of the uterus and further prolongation of pregnancy are possible only using a comprehensive approach.

With the shortening of the cervix, either vaginal progesterone or an obstetric pessary is recommended. The efficacy of the two treatment approaches has been extensively studied.

The history of the use of pessaries goes back thousands of years. Following modernization, pessaries are also widely used nowadays. However, the results of many studies are contradictory, and there is still no consensus and no unambiguous answer to the questions of practitioners regarding the criteria for placement, efficiency, and safety of obstetric pessaries.

Thus, in their systematic review and meta-analysis, Conde-Agudelo et al. (2020) showed that current data do not provide evidence on the efficiency of obstetric pessaries in preventing PB or improving perinatal outcomes in singleton or twin pregnancies in the case of a short cervix [16].

In a meta-analysis, Jin et al. (2019) revealed that compared with expectant management, the placement of an obstetric pessary can prolong pregnancy and reduce the amount of tocolytic drugs and glucocorticoids [17].

In Italy, Saccone et al. (2017) conducted a parallel-group randomized clinical trial and revealed that in the obstetric

pessary group, the incidence of SPB at a term less than 34 weeks of pregnancy was significantly lower than that of the control group (odds ratio [OR] 0.36; 95% confidence interval [CI] 0.54–0.87) [18].

The problem of evaluating the efficiency of an obstetric pessary for PB prevention consists in the fact that only one factor (cervical length) is considered during placement, whereas the rest of the well-known risk factors for PB are ignored.

The study aimed to identify risk factors leading to SPB in pregnant women with singleton pregnancies and a short cervix who received an obstetric pessary.

MATERIALS AND METHODS

Our prospective, open, randomized cohort study included 189 female patients with a singleton pregnancy, a short cervix (<25‰ according to the L.J. Salomon scale), and a threatened miscarriage in the second and third trimesters, who were using an obstetric pessary (Arabin). Pregnancy outcomes and risk factors leading to SPB were analyzed. A total of 183 parameters of general somatic and reproductive health of pregnant women and biophysical methods were compared.

Depending on the pregnancy outcomes, all patients were distributed into two groups. Group 1 included 167 female patients with term delivery. In 22 women, the pregnancy ended with PB, which included 3 pregnant women with induced PB, who were excluded from further study, and 19 pregnant women with SPB (group 2).

All women lived in the same climatic and geographical conditions in St. Petersburg and the North-West region. All 189 pregnant women were registered in an antenatal clinic and regularly visited a doctor. The average period of registration in the antenatal clinic of the examined pregnant women was 10.59 ± 3.05 weeks.

Upon hospital admission, pregnant women underwent both a bimanual vaginal examination and transvaginal US cervicometry for cervical assessment. CI was also scored according to the scale developed by Savelyeva et al. based on the Steinberg scale, where CI correction was indicated with a total of 7–8 points or more [19] (Table 1) and assessment of the degree of cervical maturity according to the 10-point Bishop scale (Table 2).

In most of the examined pregnant women, structural changes in the cervix (shortening, softening, and dilatation of the internal os) occurred during the uterine activity. In all patients, PB prevention was comprehensive and dependent on the severity of symptoms and gestational age. According to the order of the Ministry of Health of the Russian Federation dated November 1, 2012, No. 572n, the pessary was placed only after the cessation of uterine activity, sanitation of the vagina in the biocenosis impairment, and prevention of fetal distress syndrome.

Of the 13 possible options for obstetric pessaries, Arabin pessary was chosen according to the table developed by Sichinava (Table 3).

Table 1. Cervical insufficiency rating scale based on the modified Steinberg scale

Sign	Score, points		
	0	1	2
Cervical location	Significantly posteriorly	Posteriorly	Central
Cervical consistency	Dense	Softened	Soft
Location of the presenting part of the fetus	Above the pelvic inlet	Pressed against the pelvic inlet	Segment at the pelvic inlet
Cervical length according to transvaginal US	Norm	3–2 cm	⩽2 cm
Internal os by transvaginal US	Closed	<0.9 cm	⩾0.9 cm
Hyperandrogenism during pregnancy	No	–	Revealed
Late spontaneous miscarriage, history of CI	No	1	⩾2, CI

Note. CI, cervical insufficiency; US, ultrasound.

Table 2. Assessment of the degree of cervical maturity according to the Bishop scale

Parameter	Score		
	0	1	2
Position of the cervix in relation to the axis pelvis plane	Displaced to the sacrum	Between the sacrum and the axis pelvis plane	Along the axis of the pelvis
Cervical length, cm	⩾2	1–2	⩽1
Consistency of the cervix	Dense	Softened	Soft
Dilatation of the external os, cm	Closed	1	⩾2
Location of the presenting part of the fetus	Movable above the pelvic inlet	Pressed against the pelvic inlet	Pressed to or fixed at the pelvic inlet

Table 3. Size selection table of Arabin ASQ pessary for the second trimester and later term

Clinical situations including transvaginal sonography	Outer diameter, mm		Height, mm				Inner diameter, mm	
	65	70	17	21	25	30	32	35
Short cervix, second trimester, singleton, no conization, primiparity	✓			✓			✓	
Short cervix, second trimester, singleton, no conization, repeated labor		✓		✓			✓	
Short cervix, second trimester, singleton, conization, primiparity	✓			✓				✓
Short cervix, second trimester, singleton, conization, repeated labor		✓		✓				✓
Short cervix, second trimester, multiparous, no conization, primiparity	✓				✓		✓	
Short cervix, second trimester, multiparous, no conization, repeated labor		✓			✓		✓	
Short cervix, second trimester, multiparous, conization, primiparity	✓				✓			✓
Short cervix, second trimester, multiparous, conization, repeated labor		✓			✓			✓
Short cervix, second trimester, V- or U-shaped internal os		✓	✓					✓

OP was removed ahead of the schedule in cases of preterm rupture of membranes, bloody discharge from the genital tract, and/or development of labor activity. In all other pregnant women, OP was removed after week 37.

RESULTS

Pregnancy ended in term delivery in 167 (88.36%) patients. PB occurred in 22 (11.64%) pregnant women, including SPB in 19 (10.05%) patients. PB was induced in 3 (1.59%) women who were excluded from further study.

The age of all examined pregnant women ranged from 22 to 49 years and averaged 32.06 ± 4.89 years. The mean age of the patients in the two groups was comparable (p = 0.867). The initial mean weight of the examined pregnant women in the two groups was comparable (69.35 ± 12.14 and 70.68 ± 21.23 kg; p = 0.680). The mean body mass index was 24.92 ± 4.66 kg/m^2. The examined pregnant women in the two groups did not differ significantly in body mass index (p = 0.381).

The menstrual function was analyzed, and results revealed no significant difference between the groups in terms of the average age of menarche, nature of the menstrual cycle regularity, and incidence of menstrual irregularities (p > 0.05). The average age of the sexual debut of patients in the two groups was significantly different, and it was 18.12 ± 2.51 years in group 1 and 17.26 ± 1.41 years in group 2 (p = 0.146).

As regards the outcomes of previous pregnancies, a history of PB was registered in 7.78% of the patients in group 1, which differed significantly from that in group 2 with 36.84% (p = 0.00128; OR 6.91; 95% CI 2.32–20.56). In the two groups, a history of miscarriage was high. Moreover, 68.42% of patients in group 2 had a history of miscarriage, and in group 1, this figure was slightly lower, at 47.90% (p = 0.14631; OR 2.36; 95% CI 0.85–6.49). The outcomes of previous pregnancies in the two groups are presented in Table 4.

The gynecological history of the two groups was comparable (Table 5). Moreover, abnormalities in the development

Table 4. Outcomes of previous pregnancies in the two groups of examined women

Indicator	Group 1 (n = 167)		Group 2 (n = 19)		p
	n	%	n	%	
Preterm delivery	13	7.78	7	36.84	0.00128
Spontaneous miscarriage	75	44.91	8	42.11	>0.05
Missed miscarriage	47	28.14	5	26.32	>0.05
Induced termination of pregnancy	51	30.54	7	36.84	>0.05
Curettage of the uterine cavity	95	56.89	10	52.63	>0.05
Vacuum aspiration of the ovum	13	7.78	1	5.26	>0.05
Drug-induced termination of pregnancy	6	3.59	1	5.26	>0.05
Ectopic pregnancy	14	8.38	1	5.26	>0.05
Miscarriage	80	47.90	13	68.42	0.14631

Table 5. Gynecological diseases and surgeries in the examined pregnant women

Nosological form	Group 1 (*n* = 167)		Group 2 (*n* = 19)		*p*
	n	%	*n*	%	
Gynecological diseases					
Cervical ectopia	107	64.07	11	57.89	>0.05
Chronic salpingoophoritis	21	12.57	3	15.79	>0.05
Chlamydia infection	27	16.17	4	21.05	>0.05
Ureaplasma infection	63	37.72	8	42.10	>0.05
Mycoplasma infection	11	6.57	0	0	>0.05
Candidal vaginitis	9	5.39	0	0	>0.05
Primary infertility	20	11.98	1	5.26	>0.05
Secondary infertility	31	18.56	3	15.79	>0.05
Impaired development of the genitals	6	3.59	3	15.79	0.07452
Surgical interventions					
Surgical interventions on the uterus and appendages (laparoscopy)	62	37.13	5	26.32	>0.05
Conservative myomectomy	11	6.59	0	0	>0.05
Hysteroscopy	55	32.93	4	21.05	>0.05
Polypectomy (endometrium or cervical canal)	23	13.77	1	5.26	>0.05
History of therapeutic manipulations on the cervix	28	16.77	7	36.84	0.07003

of the genitals were more common in group 2 compared with those in group 1 (15.79% and 3.59%; $p = 0.07452$; OR 5.03; 95% CI 1.15–22.06). Previous therapeutic manipulations on the cervix were performed ⩾2 times in patients with SPB (36.84% and 16.77%; $p = 0.07003$; OR 2.90; 95% CI 1.05–8.00).

Moreover, the incidence of extragenital diseases was not significantly different between the two groups ($p > 0.05$). However, group 2 recorded a high incidence of chronic cystitis (36.84%), which was two times higher than that in group 1 (17.96%) ($p = 0.09895$; OR 2.66; 95% CI 0.97–7.33). Data on the analysis of extragenital diseases in the studied patients are presented in Table 6.

The current pregnancy in most women (n = 157) occurred spontaneously (83.07%), and 32 (16.93%) patients had assisted reproductive technologies. Pregnancy occurred following assisted reproductive technologies in 16.17% in group 1 and 21.05% in group 2 ($p > 0.05$), which indicated that assisted reproductive technologies are not a risk factor for SPB.

Among the current pregnancy complications in both groups, a high incidence of threatened miscarriage in all trimesters was registered (up to 52.63%). Gestational diabetes mellitus was diagnosed ⩾2 times in group 1 than in group 2. Chronic placental insufficiency (CPI) was significantly more common in the group with SPB ($n = 8$; 42.10%) than in the group with term delivery (21% cases; 12.57%) ($p = 0.00307$; OR 5.06; 95% CI 1.82–14.01), which confirmed the fetal and placental risk factors for SPB. CI at the time of obstetric pessary placement was detected in 136 pregnant women, which included 94.74% of patients in group 2 and 70.66% in group 1 ($p = 0.049$; OR 7.47; CI 0.97–57.54). Table 7 presents the complications of the current pregnancy of the examined pregnant women.

Bacteriological culture of the cervicovaginal contents of the examined pregnant women did not reveal a significant difference between the groups ($p > 0.05$); therefore, infections of the cervicovaginal contents were not a risk factor for PB in the groups of the examined pregnant women. Isolated cases of impaired biocenosis were registered in both groups.

On bimanual vaginal examination, the average length of the cervix was 17.90 ± 3.49 mm in group 1 and 16.32 ± 4.03 mm in group 2 ($p = 0.066$). According to transvaginal US cervicometry, the average lengths of the cervix at the time of obstetric pessary placement were 24.54 ± 6.54 mm in group 1 and 18.30 ± 7.69 mm in group 2, that is, the lengths were significantly different between the groups ($p < 0.001$). Pregnant women with cervical length ⩽15 mm had a higher risk of SPB than those with >15 mm ($p < 0.001$; OR 7.94; 95% CI 2.83–22.26).

The scores according to the modified Steinberg and Bishop scales at the time of obstetric pessary placement differed significantly from each other. Thus, the mean scores according to the modified Steinberg scale were 4.52 ± 1.63 in group 1 and 6.37 ± 2.63 in group 2 ($p < 0.001$). The average scores on the Bishop scale were 4.04 ± 1.33 in group 1 and 5.32 ± 1.92 in group 2 ($p < 0.001$).

The average gestational age during obstetric pessary placement in the two groups was comparable, with 26.09 ± 4.33 weeks in group 1 and 24.58 ± 3.98 weeks in group 2 ($p = 0.147$). The duration of hospitalization in groups 1 and 2 (12.34 ± 8.73 and 17.26 ± 12.63 days, respectively) was significantly different ($p = 0.028$).

Table 6. Structure of extragenital diseases in the examined pregnant women

Extragenital diseases	Group 1 (*n* = 167)		Group 1 (*n* = 19)		*p*
	n	%	*n*	%	
Diseases of the urinary system					
Chronic pyelonephritis	27	16.17	4	21.05	>0.05
Chronic cystitis	30	17.96	7	36.84	0.09895
Urolithiasis	10	5.99	3	15.79	>0.05
Diseases of the digestive system					
Chronic gastritis	43	26.75	3	15.79	>0.05
Chronic cholecystitis	7	4.19	1	5.26	>0.05
Chronic pancreatitis	2	1.20	1	5.26	>0.05
Biliary dyskinesia	25	14.97	1	5.26	>0.05
Chronic tonsillitis	23	13.77	2	10.53	>0.05
Diseases of the cardiovascular system					
Hypotensive-type vegetovascular dysfunction	13	7.78	2	10.53	>0.05
Hypertensive-type vegetovascular dysfunction	16	9.58	1	5.26	>0.05
Varicose veins	51	30.54	5	26.32	>0.05
Hereditary thrombophilia	32	19.16	1	5.26	>0.05
Myopia	67	40.12	5	26.32	>0.05
Autoimmune thyroiditis	51	30.54	4	21.05	>0.05

Table 7. Complications of the current pregnancy in the examined pregnant women

Indicator	Group 1 (*n* = 167)		Group 2 (*n* = 19)		*p*
	n	%	*n*	%	
Threatened miscarriage					
Trimester I	78	46.71	8	42.10	>0.05
Trimester II	80	48.86	10	52.63	>0.05
Trimester III	67	40.12	9	47.37	>0.05
CI	118	70.66	18	94.74	>0.05
GDM	54	32.34	3	15.79	>0.05
CPI	21	12.57	8	42.10	0.00307
Oligohydramnios	9	5.39	0	0	>0.05
Polyhydramnios	20	11.98	0	0	>0.05
ARVI	31	18.56	4	21.05	>0.05

Note. CI, cervical insufficiency; GDM, gestational diabetes mellitus; CPI, chronic placental insufficiency; ARVI, acute respiratory viral infection.

The average period of pregnancy prolongation was significantly different between groups 1 and 2 (12.77 ± 4.68 and 9.38 ± 3.89 weeks, respectively) ($p = 0.003$). The average gestational age at the time of obstetric pessary removal was 37.36 ± 1.18 weeks in group 1 and 33.80 ± 2.49 weeks in group 2 ($p < 0.001$). After the obstetric pessary removal, the average interval of delivery was 9.77 ± 8.92 days in group 1 and 1.16 ± 3.00 days in group 2 ($p < 0.001$). This was attributed to the removal of the obstetric pessary ahead of schedule due to the development of labor, preterm rupture of membranes, or patient complaints in the SPB group.

In group 2, no very early PBs were recorded (22–$27^{6}/_{7}$ weeks). Childbirth at a gestational age of 28–$33^{6}/_{7}$ weeks occurred in 8 (42.11%) pregnant women and at a term of 34–$36^{6}/_{7}$ weeks in 11 (57.89%) (Table 8).

Vaginal delivery was registered in 119 (71.26%) pregnant women in group 1 and in 14 (73.68%) cases in group 2 ($p > 0.05$). In the SPB group, 5 (26.32%) women underwent an emergency cesarean section. In the group with term delivery, 48 (28.74%) pregnant women underwent cesarean section, including 18 (10.78%) elective cases and 30 (17.96%) emergency cases.

Preterm rupture of the membranes was registered in 34 (20.36%) female patients in group 1 and 6 (31.58%) female patients in group 2 ($p > 0.05$). Chorioamnionitis and fever during childbirth were not registered in any groups.

Table 8. Placement and efficiency of the Arabin obstetric pessary

Indicator	Group 1 (*n* = 167)	Group 2 (*n* = 19)	*p*
Average gestational age during pessary placement, weeks	26.09 ± 4.33	24.58 ± 3.98	0.147
Duration of hospitalization, days	12.34 ± 8.73	17.26 ± 12.63	**0.028**
Prolongation of pregnancy, weeks	12.77 ± 4.68	9.38 ± 3.89	**0.003**
Minimum, weeks	3.29	3.43	–
Maximum, weeks	25.14	17.57	–
Gestational age during pessary removal, weeks	37.36 ± 1.18	33.80 ± 2.49	**<0.001**
Interval from the pessary removal to the onset of labor, days	9.77 ± 8.92	1.16 ± 3.00	**<0.001**
Minimum, days	0	0	–
Maximum, days	47	11	–
Average term of delivery, weeks	38.86 ± 1.59	33.96 ± 2.49	**<0.001**
Minimum, weeks	37	29.57	–
Maximum, weeks	41	36.86	–

Table 9. Risk factors for spontaneous preterm birth occurrence

	Risk factors	OR	CI	*p*
1	Bishop scale ⩾7 points	12.38	3.50–43.87	0.00032
2	Modified Steinberg scale ⩾8 points	10.55	3.09–36.03	0.00056
3	Cervical length ⩽15 mm by cervicometry	7.94	2.83–22.26	<0.001
4	PB in history	6.91	2.32–20.56	0.00128
5	CPI	5.06	1.82–14.01	0.00307
6	Impaired development of the genitals	5.03	1.15–22.06	0.07452
7	Medical manipulations on the cervix in history	2.90	1.05–8.00	0.07003

Note. CPI, chronic placental insufficiency; PB, preterm birth; OR, odds ratio; CI, confidence interval.

Thus, we have identified seven main risk factors of SPB during singleton pregnancy in pregnant women who used an Arabin obstetric pessary (Table 9).

A multivariate analysis established that the incidence of SPB was five times higher in pregnant women having three factors at once, namely, cervical length ⩽15 mm, modified Steinberg scale score ⩾8, and Bishop scale score ⩾7 points (83.33% of SPB compared with 16.67% of term deliveries, $p < 0.05$, OR 59.29, 95% CI 6.47–543.29).

DISCUSSION

A detailed analysis of the course and outcomes of pregnancy and childbirth in patients of high risk groups identified seven factors that affect the occurrence of SPB. These risk factors can conditionally be divided into anamnestic and factors related to the current pregnancy.

One of the main risk factors for SPB during the current pregnancy was a cervical length of ⩽15 mm according to cervicometry. This indicator refers to the extremely short cervix and serves as an immediate indication for the comprehensive treatment of PB. However, in most cases, cervix length of ⩽15 mm is detected late, only on the second US screening. Patients at risk of PB should undergo cervicometry every 2–4 weeks to not miss the extreme shortening of the cervix and to perform timely correction with Arabin obstetric pessary. A direct relationship was found between the cervical length measured by transvaginal US cervicometry at weeks 16–24 of pregnancy and the gestational age at the time of delivery [12]. According to the clinical recommendations of the Ministry of Health of the Russian Federation "Preterm birth" of 2020, cervical length of ⩽25 mm at a term up to 34 weeks of pregnancy is a predictor of PB. At week 20 of pregnancy, cervical length of ⩽25 mm is associated with a 6-fold increase in the risk of PB. Up to week 34, in singleton pregnancies, cervical length of ⩽25 mm had a sensitivity of 76%, specificity of 68%, positive predictive value of 20%, and negative predictive value of 96% for the diagnosis of PB [20–22]. Souza et al. (2020) conducted a prospective multicenter cohort study in five Brazilian specialized maternity hospitals. According to them, a short cervix is a risk factor for SPB [23]. An "extremely" short cervix is a high risk factor for spontaneous PB and is a predictive measurable indicator of threatening PB.

When assessing the probability of SPB on the Bishop and Steinberg scales, the incidence of SPB changes depending on the score obtained on these scales. Our data revealed that the risk of SPB increases with modified Steinberg scale score of ⩾8 points and Bishop scale of ⩾7 points. According to the literature, a high Bishop scale score indicates preterm

cervical ripening, which is also associated with an increased probability of PB [24, 25]. Accordingly, a high modified Steinberg scale score, which is an augmented version of the Bishop scale for assessing the degree of CI, is also associated with an increase in the probability of PB.

Our multivariate analysis revealed that the incidence of SPB is five times higher in pregnant women having three factors at once, namely, cervical length of ⩽15 mm, modified Steinberg scale score of ⩾8 points, and Bishop scale score of ⩾7 points.

According to our data, CPI is a risk factor for SPB, which indicates the relationship between SPB and the fetus–placental complex. Other researchers obtained similar results [26]. According to Katkov et al. (2017), true PB was significantly more common in primigravida, whereas the most common gestational complication in these pregnant women was chronic fetoplacental insufficiency with OR of 14.5 (0.8–247.8), which suggests a relationship between the occurrence of true PB and fetal–placental factor [27].

Based on history data, the practitioner can include the patient in a risk group for SPB. Our results revealed that a history of PB is an anamnestic risk factor for SPB significantly more often. Many researchers have obtained the same results [28–33]. Other scientists consider a history of SPB a major risk factor for PB. PB often relapses at a similar gestational age, and patients who have not had term delivery between PB and the current pregnancy and patients who have had several PBs in a row are at risk [34]. According to Laughon et al. (2014), a history of induced PB increases the risk of repeated PB by 23%. Essentially, this group has an increased risk of not only induced but also term PB [35]. Thus, one of the main risk factors for SPB is a history of PB, which is confirmed by other researchers. According to their results, anamnestic risk factors for SPB include an abnormal development of the genitals. Different authors believe that abnormalities in genital development increase the risk of PB. Genital abnormalities such as bicornuate uterus, unicornuate uterus, and complete didelphia most probably do not impair fertility, but are associated with complications throughout the pregnancy, depending on the type of abnormality. Female patients with bicornuate and unicornuate uterus have an increased risk of miscarriage, PB, and malpresentation, whereas female patients with complete didelphia have only a moderately increased risk of PB [36–42].

In our opinion, a history of therapeutic manipulations on the cervix is also one of anamnestic risk factors for SPB. PB is significantly more common in female patients with a history of surgery on the cervix (conization, diathermocoagulation, etc.), which leads to the development of anatomical CI. Loop cervical electrosurgery predisposes to PB. Loop electrosurgical excision conization increased the risk of PB, especially in female patients without a history of PB [43–45].

CONCLUSION

High risk groups for SPB were identified among patients with short cervix and obstetric pessary. Despite the comprehensive treatment of PB and placement of an obstetric pessary, in the presence of the seven main risk factors associated with the occurrence of SPB, its incidence is high. In this group, the development of algorithms for preconception preparation, pregnancy management for three trimesters, and prevention and treatment of threatened miscarriage is required.

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