

ORIGINAL PAPER ΕΡΕΥΝΗΤΙΚΗ ΕΡΓΑΣΙΑ

The effect of a pessary in women with a short cervix

OBJECTIVE To investigate a possible relationship between preterm birth (PTB) prevention via pessary insertion and fetal heart rate variability (HRV), term of birth, neonatal biometry, and Apgar score in women with a short cervix (ShC). **METHOD** A total of 64 patients with threatened preterm delivery and ShC between 22 and 30 weeks of gestation were enrolled in the study. Thirty patients treated with acute tocolysis, chronic use of nifedipine, progesterone, and cervical pessary insertion were included in group I. Thirty-four pregnant women treated with acute, and chronic tocolytics and progesterone were included in group II. All patients included in the study had no personal history of spontaneous miscarriages or PTB. HRV parameters were obtained from an RR-interval time series recorded from the maternal abdominal wall fetal non-invasive electrocardiography (FNI-ECG). The study protocol also included several parameters: term at birth, neonatal body weight, body length, head circumference, and Apgar score. **RESULTS** The data on fetal HRV, term at birth, neonatal anthropometry, and Apgar score revealed certain regularities. The mean gestational term at birth was significantly higher in group I. This fact demonstrated that pessary was a useful part of the therapeutic strategy in patients with threatened PTB. The prolongation of pregnancy until the stage of fetal complete development reflected the statistically significant difference of neonatal biometry variables and a tendency to a statistically significant difference in Apgar score between the representatives of groups I and II. The logistic regression model with term of birth showed the relationship with Apgar score and the pessary insertion. **CONCLUSIONS** Pessary was an efficient supplement to tocolytics and progesterone in women with threatened PTB. The insertion of pessary contributed to pregnancy prolongation.

Preterm birth (PTB) remains a significant problem, with both short- and long-term projections on newborns' health. A decreased cervical length (<25–30 mm) during the second trimester as measured via transvaginal ultrasound, is a well-established predictive marker for PTB. There are several known interventions for the prevention of PTB: cerclage, vaginal progesterone, and pessary.¹ Cerclage is conventionally used in cases of cervical insufficiency (incompetence) due to morphological weakness of the circular muscle layer. The rate for this pathology is not higher than 1% of all pregnancies.² In contrast, most cases of short cervix (ShC) cases are associated with an increased uterine tone,³ and autonomic dysfunction is also involved in the scenario of PTB.⁴ Several studies have demonstrated the efficacy of progesterone in asymptomatic pregnant women with ShC.^{5–7} However, the utility of pessary remains controversial and disputable.^{8–10} Pessary was found to

increase perinatal morbidity and mortality in one study¹¹ and increased vaginal discharge has also been observed in pessary-treated patients.¹² The indications for pessary use during pregnancy are not clearly defined. Tocolysis was found to be a meaningful factor for pessary efficiency.¹³ Therefore, the women with a ShC after tocolysis could be a target population for a pessary. The necessity of testing the hypothesis on pessary as an efficient supplement to tocolytics is rather obvious.

The fetal programming theory of adulthood diseases explains the effect of the disturbed uterine environment during the antepartum period.¹⁴ Fetal neurological maturation is an inevitable stage in the process of preparation for extrauterine life. Fetal non-invasive electrocardiography (FNI-ECG) is a prospective method for assessing fetal health and autonomic function.¹⁵ Fetal heart rate variability (HRV)

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ΑΡΧΕΙΑ ΕΛΛΗΝΙΚΗΣ ΙΑΤΡΙΚΗΣ 2026, 43(Συμπλ 1):63–69

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Η επίδραση ενός κολλπικού
υποστηρίγματος στις γυναίκες
με βραχύ τράχηλο

Περίληψη στο τέλος του άρθρου

Key words

Fetal growth and maturation
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detected via FNI-ECG is known as a marker of fetal growth and surveillance.¹⁶

This research was focused on the detection of a possible relationship between PTB prevention via pessary insertion, maternal and fetal HRV, term of birth, neonatal biometry, and Apgar score in women with a ShC.

MATERIAL AND METHOD

Participants

In a total of 64 patients with threatened preterm delivery and ShC at 22–30 weeks of gestation, were enrolled in the study. The 30 patients treated with acute tocolysis, chronic use of nifedipine, progesterone, and cervical pessary insertion were included in group I. The 34 pregnant women treated with acute, and chronic tocolytics, and progesterone were included in group II. All patients included in the study have no personal history of spontaneous miscarriages or PTB. The therapeutic course lasted until 36 weeks of gestation in the study population.

Study design

This descriptive cross-sectional study was performed among pregnant women admitted to Kharkiv Municipal Perinatal Center between 1 January 2024 and 30 September 2024. Participants were randomly selected from the department of maternal-fetal medicine. The research was carried out as part of the project led by the Department of Obstetrics and Gynecology No 3 of Kharkiv National Medical University (0123U104315), titled "Developing of a system for predicting, preventing, and treating pregnancy, labor, and postpartum complications in women affected by wartime stress". Eligible participants were informed about the study's methodology, aims, objectives, indications, and eventual complications before enrollment.

The fetal HRV variables were obtained from an RR-interval time series registered from the maternal abdominal wall via FNI-ECG. The registration of FNI-ECG was performed after the acute tocolysis was completed. The equipment "Cardiolab Baby Card" (Scientific Research Center "KhAI-Medica", Ukraine) was used in the study. The registration was carried out over 30–60 minutes. The stress index was selected for evaluation among all linear HRV variables. $SI = AMo (\%) / (2 \times Mo \times Var)$; $Var = NN_{max} - NN_{min}$; AMo (the most frequent value of NN interval or the highest column in the histogram), with the number of NN intervals included in the pocket corresponding to the mode being measured in percentages (%). The obtained fetal RR interval time series was transformed into cardiocotographic (CTG) tracing. The following CTG parameters were determined: short-term variation (STV) and long-term variation (LTV). The variables of AC/DC (acceleration capacity/deceleration capacity) were also detected.¹⁷ The study protocol also included several parameters: term at birth, neonatal body weight, body length, head circumference, and Apgar score.

The ShC was diagnosed according to ultrasound measurements.

Criteria

Inclusion criteria were threatened pre-term delivery, ShC. Exclusion criteria were chromosomal abnormalities, multiple pregnancy, preexisting medical disorders like diabetes mellitus, metabolic syndrome, cardiac diseases, renal disease, and thyrotoxicosis. The data was obtained from the hospital automation system.

Statistical analysis

The Statistical Package for Social Sciences (SPSS) program (IBM SPSS Statistics for Windows, IBM Corp, Armonk, NY), version 28.0, was used for statistical analysis. Results were presented as means and standard deviations for numerical variables, and frequencies and percentages for categorical data. The suitability of numerical variables to normal distribution was evaluated using skewness values and histograms. An independent sample t-test was used in comparing numerical variables fitting normal distribution. Variables that did not conform to normal distribution were analyzed by the Mann-Whitney U test. The Chi-square or Fisher's exact test was used for comparing categorical variables. Depending on their distribution, Spearman or Pearson correlation analysis was used to assess the relationships between numerical variables. For multivariate examinations, a logistic regression analysis with the entered model was used. A p-value of <0.05 was considered sufficient for statistical significance.

RESULTS

The mean age of the patients was comparable between the two study groups: 23.6 ± 4.8 in group I and 24.1 ± 5.9 ($p > 0.05$) in group II. The mean gestational term at inclusion was 26.8 ± 3.0 and 27.1 ± 4.2 in groups I and II, respectively ($p > 0.05$). The mean term at NIF-ECG registration was not different: 28.4 ± 3.1 and 28.2 ± 2.7 in the pessary group and comparison group ($p > 0.05$). The data on maternal and fetal HRV, term at birth, neonatal anthropometry, and Apgar score revealed certain regularities (tab. 1). No statistically significant differences in maternal and fetal AC/DC, SI, STV, and LTV were found. The mean gestational term at birth and the parameters of neonatal biometry were significantly higher in the pessary group.

The investigation of the relationship between detected variables showed a moderate positive correlation between fetal AC/DC and Apgar score (tab. 2). The parameters of correlation in pair fetal AC versus Apgar score ($r = 0.34$; $p = 0.034$), fetal DC versus Apgar score ($r = 0.37$; $p = 0.019$) were significant. No relationship between neonatal parameters and other fetal HRV variables was detected.

The relationship between several maternal and fetal

Table 1. The variables of fetal HRV, neonatal anthropometry, and Apgar score in the study population.

Variable, units of measure	Intervention	Mean	SD	Minimum	Maximum	p
AC maternal	Pessary	8.45	2.12	4.25	12.17	0.7341
	Standard	8.7	3.63	3.54	17.44	
DC maternal	Pessary	8.7	2.14	5.11	13.58	0.7675
	Standard	8.5	3.2	3.9	17.13	
SI maternal	Pessary	145.32	82.03	32.0	430.0	0.0872
	Standard	197.83	153.15	34.0	744.0	
STV, ms	Pessary	6.65	2.44	1.7	12.3	0.6313
	Standard	6.98	3.03	1.2	13.0	
LTV, ms	Pessary	34.42	12.32	12.3	71.0	0.6199
	Standard	36.04	13.68	9.3	58.7	
Term at birth, weeks	Pessary	38.05	2.87	27.0	41.0	0.0001*
	Standard	34.84	3.37	26.0	39.0	
Neonatal body weight, g	Pessary	3333.5	1011.48	440.0	5530.0	<0.0001*
	Standard	2294.74	853.32	410.0	3500.0	
Neonatal body length, cm	Pessary	52.0	7.22	29.0	62.0	0.0003*
	Standard	44.84	7.64	27.0	56.0	
Neonatal head circumference, cm	Pessary	33.55	3.97	19.0	38.0	0.0327*
	Standard	31.32	4.19	19.0	36.0	
Apgar score, points	Pessary	7.7	2.08	0	9.0	0.0684
	Standard	6.74	2.05	0	9.0	

*The differences were statistically significant ($p < 0.05$)

HRV: Heart rate variability

HRV variables was found (tab. 3). The negative moderate or weak correlation in pairs: maternal SI versus fetal AC ($r = -0.42$; $p < 0.001$), maternal SI versus fetal DC ($r = -0.37$; $p = 0.001$), and maternal SI versus STV ($r = -0.27$; $p = 0.22$) demonstrated the coupling of maternal and fetal autonomic tone.

The logistic regression model with the term of birth showed the relationship between the Apgar score and pessary insertion (tab. 4). This model was found to be meaningful. The use of a pessary contributed to the increased Apgar score.

DISCUSSION

Fetuses in both study groups demonstrated similar levels of autonomic function and neurological maturation.¹⁸ Tocolysis contributed to fetal well-being, as well as its intra-uterine growth and development. This fact demonstrated that a pessary was a useful part of the therapeutic strategy in patients with threatened PTB. The prolongation of preg-

nancy to the stage of fetal complete development reflected a statistically significant difference in neonatal biometry variables and a tendency towards a statistically significant difference in Apgar scores between the representatives of group I and group II. The obtained results showed the considerable use of pessary insertion in women with ShC. Several previous studies demonstrated controversial findings.¹⁹⁻²² The issue was that the differentiation of the study group population following a complicated anamnesis was not performed in these studies. Our research detected that a pessary could improve perinatal outcomes in women with threatened PTB. However, the issue of the efficiency of a pessary in cervical insufficiency is still open.

The linear correlation between fetal AC/DC and Apgar score supported the prospect of AC/DC in diagnosing fetal deterioration.²³ The link between fetal HRV variables and neonatal biometric parameters was not found. Probably, the possible coupling of fetal growth parameters and HRV variables was disturbed in threatened PTB. The

Table 2. A linear correlation between fetal HRV variables, term at birth, neonatal anthropometry, and Apgar score in the study population.

Variable	Correlation											
AC fetal	r	1	0.86	-0.65	0.85	0.84	0.22	0.06	0.16	0.23	0.34	
	p		<0.001*	<0.001*	<0.001*	<0.001*	0.183	0.717	0.317	0.155	0.034*	
DC fetal	r	0.86	1	-0.63	0.9	0.84	0.2	0.05	0.15	0.21	0.37	
	p	<0.001*		<0.001*	<0.001*	<0.001*	0.226	0.746	0.36	0.208	0.019*	
SI fetal	r	-0.65	-0.63	1	-0.73	-0.8	-0.1	0.07	-0.09	-0.14	-0.24	
	p	<0.001*	<0.001*		<0.001*	<0.001*	0.543	0.675	0.569	0.382	0.144	
STV	r	0.85	0.9	-0.73	1	0.96	0.1	0.02	0.14	0.2	0.28	
	p	<0.001*	<0.001*	<0.001*		<0.001*	0.53	0.913	0.389	0.222	0.09	
LTV	r	0.84	0.84	-0.8	0.96	1	0.06	-0.03	0.1	0.16	0.23	
	p	<0.001*	<0.001*	<0.001*	<0.001*		0.695	0.857	0.551	0.319	0.157	
Term at birth	r	0.22	0.2	-0.1	0.1	0.06	1	0.85	0.83	0.68	0.73	
	p	0.183	0.226	0.543	0.53	0.695		<0.001*	<0.001*	<0.001*	<0.001*	
Neonatal body weight	r	0.06	0.05	0.07	0.02	-0.03	0.85	1	0.92	0.84	0.68	
	p	0.717	0.746	0.675	0.913	0.857	<0.001*		<0.001*	<0.001*	<0.001*	
Neonatal body length	r	0.16	0.15	-0.09	0.14	0.1	0.83	0.92	1	0.85	0.74	
	p	0.317	0.36	0.569	0.389	0.551	<0.001*	<0.001*		<0.001*	<0.001*	
Head circum-ference	r	0.23	0.21	-0.14	0.2	0.16	0.68	0.84	0.85	1	0.72	
	p	0.155	0.208	0.382	0.222	0.319	<0.001*	<0.001*	<0.001*		<0.001*	
Apgar score	r	0.34	0.37	-0.24	0.28	0.23	0.73	0.68	0.74	0.72	1	
	p	0.034*	0.019*	0.144	0.09	0.157	<0.001*	<0.001*	<0.001*	<0.001*		

*The differences were statistically significant (p<0.05)

HRV: Heart rate variability

Table 3. A linear correlation between maternal and fetal HRV in the study population.

Variable	Correlation	AC maternal	DC maternal	AC fetal	DC fetal	SI maternal	SI fetal	STV	LTV
AC maternal	r	1	0.95	0.19	0.15	-0.71	-0.01	0.05	0
	p		<0.001*	0.115	0.204	<0.001*	0.943	0.685	0.981
DC maternal	r	0.95	1	0.21	0.18	-0.78	0.01	0.07	-0.02
	p	<0.001*		0.079	0.132	<0.001*	0.923	0.581	0.84
AC fetal	r	0.19	0.21	1	0.91	-0.42	-0.64	0.91	0.81
	p	0.115	0.079		<0.001*	<0.001*	<0.001*	<0.001*	<0.001*
DC fetal	r	0.15	0.18	0.91	1	-0.37	-0.63	0.91	0.83
	p	0.204	0.132	<0.001*		0.001*	<0.001*	<0.001*	<0.001*
SI maternal	r	-0.71	-0.78	-0.42	-0.37	1	0.05	-0.27	-0.11
	p	<0.001*	<0.001*	<0.001*	0.001*		0.674	0.022*	0.342
SI fetal	r	-0.01	0.01	-0.64	-0.63	0.05	1	-0.74	-0.84
	p	0.943	0.923	<0.001*	<0.001*	0.674		<0.001*	<0.001*
STV	r	0.05	0.07	0.91	0.91	-0.27	-0.74	1	0.9
	p	0.685	0.581	<0.001*	<0.001*	0.022*	<0.001*		<0.001*
LTV	r	0	-0.02	0.81	0.83	-0.11	-0.84	0.9	1
	p	0.981	0.84	<0.001*	<0.001*	0.342	<0.001*	<0.001*	

*The differences were statistically significant (p<0.05)

HRV: Heart rate variability

Table 4. The logistic regression model with term of birth.

Unstandardized coefficients	Standardized coefficients		Standard error	t	p	95% confidence interval for B	
	B	Beta				Lower bound	Upper bound
Model							
(Constant)	26.51		5.12	5.18	<0.001	16.0	37.02
AC maternal	0.36	0.34	0.18	1.94	0.058	-0.01	0.73
DC maternal	-0.39	-0.34	0.2	-1.91	0.061	-0.8	0.02
SI maternal	0	0.01	0	0.08	0.933	0	0
AC fetal	0.75	0.12	0.97	0.77	0.447	-1.24	2.74
DC fetal	0.35	0.07	0.89	0.39	0.698	-1.47	2.17
SI fetal	0	-0.19	0	-1.8	0.082	0	0
STV	-0.14	-0.11	0.32	-0.44	0.663	-0.81	0.52
LTV	-0.03	-0.1	0.05	-0.52	0.605	-0.13	0.08
Neonatal body weight	0	0.16	0	0.66	0.512	0	0
Neonatal body length	0.18	0.43	0.12	1.57	0.127	-0.06	0.42
Neonatal head circumference	-0.06	-0.07	0.2	-0.29	0.774	-0.47	0.36
Apgar score	0.6	0.36	0.26	2.34	0.027	0.07	1.13
PTB prevention pessary	1.11	0.16	0.55	2.03	0.033	-0.01	2.22

PTB: Preterm birth

known relationship between maternal and fetal autonomic tone was supported.^{14,24} The coupling between maternal sympathetic tone and fetal HRV demonstrated the role of autonomic dysfunction in preterm birth. Maternal increased sympathetic activity negatively affected fetal HRV in women with ShC. The linear correlation between several variables of HRV or between the term at birth and neonatal parameters was rather logical. Thus, the prolongation of pregnancy in threatened PTB is an axiom and a milestone of modern obstetrics.²⁵⁻²⁷

Contemporary strategies for preventing major obstetrical syndromes are grounded in evidence-based approaches.²⁸⁻³⁰ Our study demonstrated the excellent efficiency of a pessary insertion in managing threatened PTB. The use of a pessary contributed to enhanced fetal growth and functional maturation. As a result, theoretical value of the results was supported practically. Therefore, PTB

prevention was effective in the pessary group. However, this study does not represent the final step in the process of identifying the most effective therapeutic intervention. Probably, the tocolytics, progesterone, and pessary are the main parts of the PTB prevention in women without complicated anamnesis.^{31,32} Further research is required to validate this hypothesis.

In conclusion, pessary was an efficient supplement to tocolytics and progesterone in women with threatened PTB. The pessary insertion contributed to pregnancy prolongation.

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ΠΕΡΙΛΗΨΗ

Η επίδραση ενός κολπικού υποστηρίγματος στις γυναίκες με βραχύ τράχηλο

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ΣΚΟΠΟΣ Η διερεύνηση μιας πιθανής σχέσης μεταξύ της πρόληψης του πρόωρου τοκετού (PTB) μέσω εισαγωγής κολπικού υποστηρίγματος και της μεταβλητότητας του καρδιακού ρυθμού του εμβρύου (HRV), της ημερομηνίας τοκετού, της νεογνικής βιομετρίας και της βαθμολογίας Apgar σε γυναίκες με βραχύ τράχηλο (ShC). **ΥΛΙΚΟ-ΜΕΘΟΔΟΣ** Συγκεντρώθηκαν συνολικά 64 ασθενείς με απειλούμενο πρόωρο τοκετό και ShC στις 22–30 εβδομάδες κύησης. Οι 30 ασθενείς που υποβλήθηκαν σε οξεία τοκολυτική θεραπεία, χρόνια χρήση νιφεδιπίνης, προγεστερόνης και εισαγωγή υποστηρίγματος συμπεριλήφθηκαν στην Ομάδα Ι. Οι 34 έγκυες γυναίκες που υποβλήθηκαν σε οξεία και χρόνια τοκολυτικά και προγεστερόνη συμπεριλήφθηκαν στην Ομάδα ΙΙ. Όλες οι ασθενείς που περιλήφθηκαν στη μελέτη δεν είχαν προσωπικό ιστορικό καθ' έξιν αποβολών ή PTB. Οι μεταβολές του καρδιακού ρυθμού του εμβρύου (HRV) ελήφθησαν από μια χρονοσειρά διακυμάνσεων RR που καταγράφηκε από το κοιλιακό τοίχωμα της μητέρας μέσω μη επεμβατικής ηλεκτροκαρδιογραφίας του εμβρύου (NIF-ECG). Το πρωτόκολλο μελέτης περιλάμβανε επίσης αρκετές παραμέτρους, όπως ημερομηνία τοκετού, σωματικό βάρος νεογνού, σωματικό μήκος, περίμετρος κεφαλής και βαθμολογία Apgar. **ΑΠΟΤΕΛΕΣΜΑΤΑ** Τα δεδομένα σχετικά με τη μεταβλητότητα του καρδιακού ρυθμού του εμβρύου, την ημερομηνία γέννησης και την ανθρωπομετρία των νεογνών, καθώς και τη βαθμολογία Apgar, αποκάλυψαν ορισμένες κανονικότητες. Ο μέσος όρος του γονικού χρόνου γέννησης ήταν σημαντικά μεγαλύτερος στην Ομάδα Ι. Αυτό το γεγονός έδειξε ότι το κολπικό υποστήριγμα ήταν χρήσιμο μέρος της θεραπευτικής στρατηγικής σε ασθενείς με απειλούμενη πρόωρη γέννηση. Η παράταση της εγκυμοσύνης μέχρι το στάδιο της πλήρους ανάπτυξης του εμβρύου αντικατοπτρίζει τη στατιστικά σημαντική διαφορά στις βιομετρικές μεταβλητές των νεογνών και μια τάση για στατιστικά σημαντική διαφορά στη βαθμολογία Apgar μεταξύ των εκπροσώπων των Ομάδων Ι και ΙΙ. Το μοντέλο λογιστικής παλινδρόμησης με τον χρόνο γέννησης έδειξε τη σχέση με τη βαθμολογία Apgar και την εισαγωγή της κολπικής υποστήριξης. **ΣΥΜΠΕΡΑΣΜΑΤΑ** Η κολπική υποστήριξη ήταν ένα αποτελεσματικό συμπλήρωμα στα τοκολυτικά και στην προγεστερόνη σε γυναίκες με απειλούμενη πρόωρη γέννηση. Η εισαγωγή του κυλίνδρου συνέβαλε στην παράταση της εγκυμοσύνης.

Λέξεις ευρετηρίου: Ανάπτυξη και ωρίμανση του εμβρύου, Κύλινδρος, Προληπτικές παρεμβάσεις, Πρόωρη γέννηση

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