Effectiveness of a cervical pessary in prolongation of pregnancy after an arrested episode of preterm labor: a systematic review and individual patient data meta-analysis

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BACKGROUND: Randomized controlled Trials (RCTs) show conflicting results on the effectiveness of a cervical pessary after an arrested episode of preterm labor (PTL) aiming to prolong pregnancy.

OBJECTIVE: To assess the effectiveness of a cervical pessary in prolongation of pregnancy after an arrested episode of PTL by utilizing individual participant data (IPD) meta-analysis.

DATA SOURCES: Databases Central, Embase, Medline, and clinical trial databases (ClinicalTrials.gov, ISRCTN, EU-CTR) were searched from inception until January 2024.

STUDY ELIGIBILITY CRITERIA: Randomized controlled trials investigating individuals between 24^{+0} and 34^{+0} weeks of gestation with an arrested episode of PTL and who were subsequently randomized to cervical pessary or no intervention.

STUDY APPRAISAL AND SYNTHESIS METHODS: Studies were assessed for data integrity and risk of bias. Main outcomes were prolongation of pregnancy >7 days, interval between randomization and delivery, and a composite of adverse neonatal outcome. A one-step meta-analysis approach was employed, and the intention-to-treat principle was applied.

RESULTS: Four RCTs had IPD available. In singleton pregnancies (total *N*=546; 275 individuals in the pessary group, 271 individuals in the control group), pessary placement did not decrease delivery risk within 7 days (relative risks [RR] 0.87; 95% confidence intervals [CI] 0.40—1.9), prolong pregnancy (mean differences 4.5 days; 95% CI −0.08 to 9.0), nor reduce the risk of adverse neonatal outcomes (RR 0.95; 95% CI 0.53—1.7). The incidence of readmissions for a new episode of PTL was significantly less frequent in the cervical pessary group (RR 0.66, 95% CI 0.50—0.85). Two studies investigating multiple pregnancies (*N*=167, 84 individuals in the pessary group, 83 individuals in the control group) were identified, showing contradictory results that could not be explained by study differences. Therefore, merging IPD and pooling of was uninformative.

CONCLUSION: In individuals with a singleton pregnancy with an episode of PTL between 24 and 34 weeks of gestational age, pessary placement does not prevent delivery within 7 days, preterm birth, or neonatal outcomes. A pessary might reduce the probability of readmissions for PTL.

El resumen está disponible en Español al final del artículo.

Key words: arrested, ceased, cervical pessary, individual participant data meta-analysis, pessary, preterm birth, preterm labor, threatened

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Tweetable Statement: Placement of a cervical pessary after an arrested episode of preterm labor does not have a beneficial effect on prolongation of pregnancy or maternal and neonatal outcomes.

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AJOG MFM at a Glance

Why was this study conducted?

Findings from this study will help to clarify the effectiveness of cervical pessary placement after an arrested episode of preterm labor.

Key findings

Placement of a cervical pessary after an arrested episode of preterm labor does not prolong latency time nor decreases the risk of a composite adverse neonatal outcome in singleton pregnancies.

What does this add to what is known?

This is the first individual patient data meta-analysis (IPDMA) performed on the effectiveness of a cervical pessary in the prolongation of pregnancy after an arrested episode of preterm labor. Since current literature is showing contradictory results, the use of IPDMA methodology will help to answer the controversies in the literature.

Introduction

Spontaneous preterm birth (PTB), defined as delivery before 37 weeks of gestation, is the leading cause of neonatal and childhood morbidity and mortality. Worldwide, over 14 million children are born preterm annually, and the rate of PTB appears to be increasing.[1,2] Preterm birth is accountable for 15% of all childhood deaths under the age of five.[3] Survivors of PTB are at increased rates of severe neonatal morbidity[4] and long-term medical and social complications.[5]

Spontaneous preterm labor (PTL) is the most common clinical presentation of patients who deliver preterm.[6,7] Approximately 10% of all pregnant patients experience an episode of PTL and require hospital admittance.[8] Most of these patients do not deliver during the first admission and contractions cease. Those who remain pregnant form a subgroup at high risk for spontaneous PTB throughout pregnancy.[8,9] For this reason, there has been considerable interest in potential maintenance therapies to reduce the risk of PTB after an arrested episode of PTL. The effectiveness of treatments such as maintenance tocolysis or progesterone is still debatable and is currently not recommended in most guidelines.[9,10]

An alternative maintenance therapy for these patients could be the insertion of a cervical pessary. Although the exact mechanism of a cervical pessary and prevention of PTB is still unknown, it is suggested to increase the utero-cervical angle, reducing pressure on the internal ostium and membranes.[11] Others describe the cervical pessary may prevent more dilatation of the internal ostium.[12] It is also hypothesized that the cervical mucus plug is retained by supporting the cervical tissue and preventing cervical effacement, which in turn prevents ascending infections and subsequent preterm delivery.[13,14]

EDITOR'S CHOICE

Despite several recently published randomized controlled trials (RCTs), the effectiveness of the cervical pessary for prolongation of pregnancy after an arrested episode of PTL remains controversial.[15] This controversy in literature is due to the varying results and the limited statistical power of each individual study. To increase the statistical power and allow for better classification of subgroups based on participant and intervention-level characteristics, an individual participant data (IPD) meta-analysis (IPDMA) methodology can be utilized. An IPDMA can provide a more precise estimate of its effectiveness by pooling data from multiple studies.

Therefore, the objective of this study is to assess the effectiveness of a cervical pessary in patients who did not deliver after an episode of PTL between 24 and 34 weeks of gestational age (GA) by utilizing an IPDMA.

Methods

This IPDMA followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for IPD (PRISMA-IPD) statement.[16] The study was registered with the PROSPERO International Prospective Register of Systematic Reviews (CRD #42020205735) before data collection started.

Study identification: information sources and search strategy

In August 2020, an electronic search in Central, Embase, and Medline was executed to identify published RCTs eligible for inclusion. This search was updated January 2024. Clinical trial registries, including ClinicalTrials.gov and the International Clinical Trials Registry Platform (ICTRP), were searched to identify ongoing studies. A search strategy containing the following keywords: "pessary," "preterm labor," and "randomized controlled trial" was constructed by a medical librarian. No restrictions were applied to include any eligible RCT.

Two review authors (SB and AdR) independently assessed all potentially eligible studies identified by the search. The complete electronic search from MEDLINE, Embase, Cochrane, and Central is shown in Table A.

Study selection and eligibility criteria

Inclusion criteria were applied at study level. Studies eligible for inclusion were RCTs reporting on individuals between 24 and 34 weeks of GA, singleton or twin pregnancy, with intact membranes, and who did not deliver 48 hours after admittance for an episode of PTL. Initial admission had to select high-risk individuals based on cervical length measurement, a biomarker (eg, fetal fibronectin or other), or a combination of both to allow for the intervention. The intervention was randomization to either pessary placement or no treatment. Studies evaluating any type of pessary were considered. Cluster-randomized RCTs and quasi-random design studies were excluded. Furthermore, trials including individuals with clinical signs of intrauterine infection,

obstetric indication for immediate delivery (signs of fetal distress, abruption, cord prolapse, or advanced labor), or with a confirmed fetal abnormality were excluded.

Assessment of trustworthiness (data integrity)

Data integrity of studies was assessed with a recently developed screening tool (Table B).[17,18] If necessary, trialists were contacted and asked to provide additional outcomes and explain uncertainties. Studies were excluded if research data integrity could not be confirmed.

Assessment of risk of bias

The risk of bias in included studies was assessed by two authors (SB and AdR) using the Cochrane Risk of Bias 2 tool for RCTs.[19] Each domain was judged and categorized as "low risk," "high risk" or "some concerns." Disagreements were resolved through discussion with a third author (FH).

Data collection

Corresponding authors of eligible studies were contacted to participate in this IPDMA. Authors who were willing to participate were provided with the protocol and data analysis plan. The protocol and data analysis plan was approved by all authors. A data-sharing agreement with participating authors was signed in compliance with the European Union General Data Protection Regulation (GDPR), including a statement for terms of data access, handling, analysis, and storage. Authors were asked to provide fully anonymized IPD. Data was checked for internal consistency, extreme values, missing items, errors, and consistency with published reports. When discrepancies were found within the database or with the published results, they were presented to the study's principal investigator and all finalized data for each trial was verified and approved by the individual trialists.

If the required IPD could not be retrieved, the published data was collected and incorporated into a standardized aggregated meta-analysis. Trials that could not provide data on outcomes of interest or did report big protocol violations, such as more than 20% exclusions of individuals after randomization or incomplete reporting of reasons for withdrawals and protocol violations, were excluded from the analysis.

Finally, authors of ongoing trials were contacted and asked for preliminary outcomes to be included in the aggregated meta-analysis.

Ethics statement

All RCTs included in this IPDMA had received country-specific ethical approval for the study and each participant gave informed written consent. Details can be found in these original manuscripts. For this IPDMA, there was no specific public or patient involvement.

Outcomes measures

Main outcomes were the prolongation of pregnancy after an arrested episode of PTL for more than 7 days, the interval in days between randomization and delivery, and a composite of adverse neonatal (mortality and morbidity) outcomes. This included neonatal sepsis, stillbirth, neonatal death, respiratory distress syndrome, or necrotizing enterocolitis.

Secondary maternal outcomes include rates of spontaneous PTB before 37, 34, 32 and 28 weeks of GA, prolongation of pregnancy >14 days, GA at delivery, preterm prelabor rupture of membranes (PPROM), maternal infection or inflammation (chorioamnionitis), antepartum hemorrhage, length of maternal hospital stay admission in days, number of readmissions for an episode of PTL, mode of delivery, side effects of pessary and significant maternal adverse effects.

Secondary neonatal outcomes include birthweight, neonatal intensive care unit admission, length of neonatal hospital stay, intrauterine fetal demise, neonatal death, perinatal death, neonatal morbidity.

Statistical analysis

A two-stage approach was used. Aggregated analysis was used to estimate explainable heterogeneity of treatment effect between trials by generating forest plots.

For the main and each of the secondary outcomes, a one-step linear modelling approach that included the IPD from all eligible trials was employed. An intention-to-treat approach was used to analyze all available individuals according to the treatment group which they were randomly allocated to.

Treatment effect was adjusted on study level by adding study as covariate to the analyses. This allows for correction of between study differences and was applied as a fixed effect.

For binary outcomes, relative risks (RR) with two-sided P values and 95% confidence intervals (CI) were calculated using log-binomial regression models (log-link function). If the model does not converge, outcome reference class will be swapped, or log Poisson regression models with robust variance estimation will be used (logit-link function). For continuous outcomes, linear regression models were used, and results were presented as mean differences (MD) with two-sided P values and 95% CIs. Generalized estimating equations were only used to take correlations into account between outcomes due to multiple births (two children related to one mother). The default independence working matrix and a robust "sandwich" type variance estimator for clustering was used. There were no adjustments for multiple comparisons.

Analyses were performed using IBM SPSS Statistics version 28.0.1.1.

Subgroup analysis

Subgroup analyses were prespecified in the protocol. Subgroup analyses were planned for the following: individuals enrolled before versus after 28 weeks of GA and before versus after 32 weeks of GA, individuals with a cervical length with 15 mm cut-off value, cervical dilation, funneling, urinary tract infection, amniocentesis (to rule out chorioamnionitis), history of cervical surgery, types of pessary, number of tocolysis and finally, subgroups based on obstetric history.

Subgroup analyses were performed for main outcomes only. Subgroup

effects were investigated using an interaction term between the subgroup and treatment in the regression model. If an interaction was found to be significant ($p < 0.05$), a stratified analysis was performed to investigate the effect of cervical pessary in different subgroup strata.

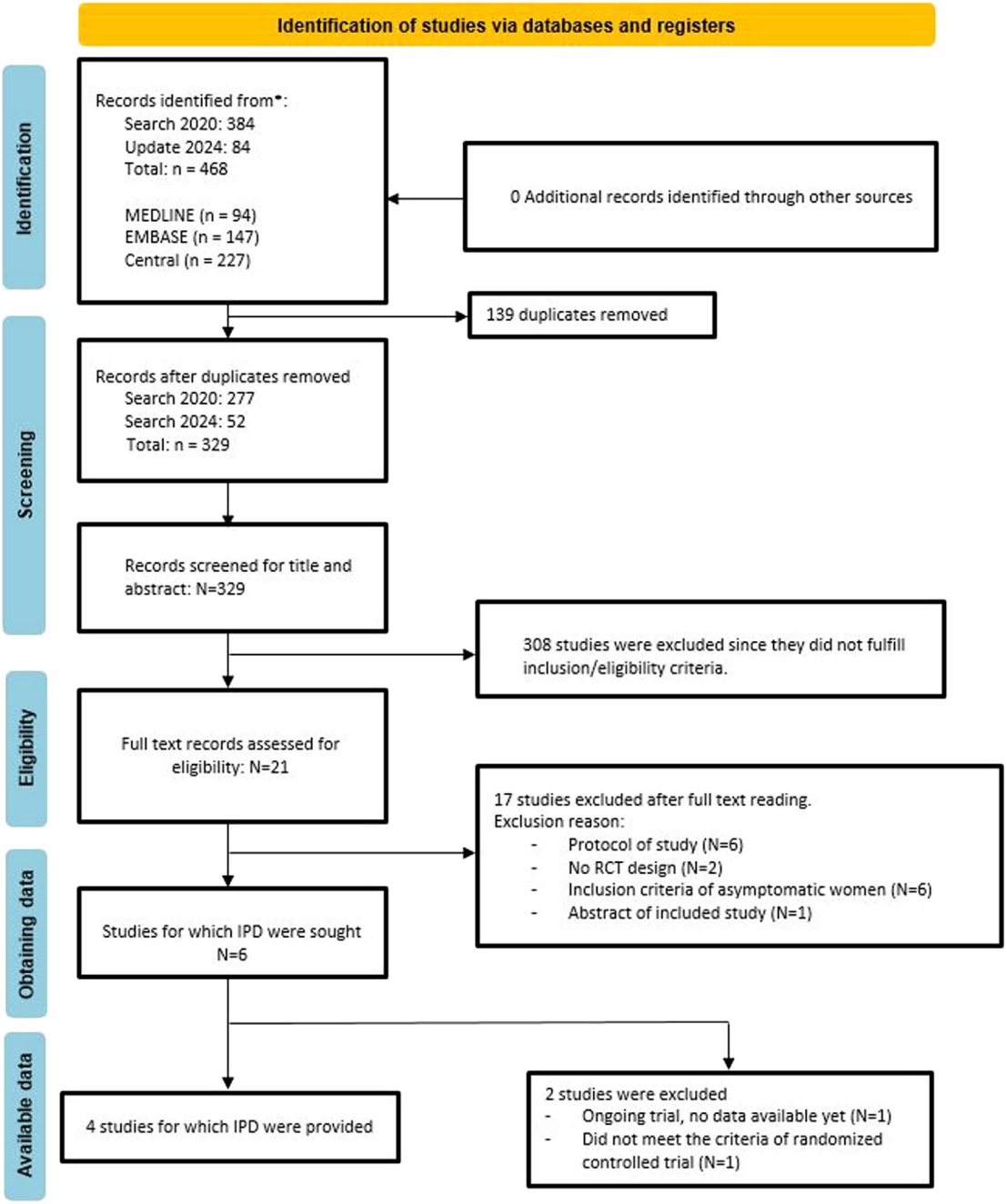
Results

Study selection

At September 11, 2020, the initial search was performed. The search was updated on January 24, 2024. After full-text analysis, six RCTs[20–25] were eligible for inclusion (n=982 individuals). See Figure 1 for the PRISMA flow diagram.

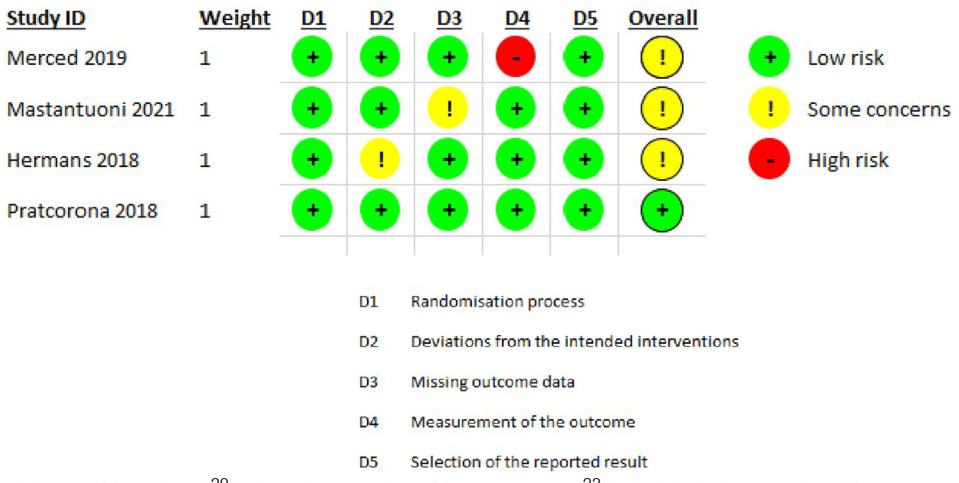
Two studies were excluded; one study[25] had no IPD or preliminary results for an aggregated meta-analysis available, as this study was ongoing. Another study was excluded based on

FIGURE 1
PRISMA flow diagram



Breuking. Effectiveness of a cervical pessary in prolongation of pregnancy after an arrested episode of preterm labor. Am J Obstet Gynecol MFM 2025.

FIGURE 2
Risk of bias of included studies in IPDMA



Overview of study populations: • Merced et al[20] included twins only. • Mastantuoni et al[23] included singletons only. • Hermans et al[22] included both singletons and twins. • Pratcorona et al[21] included singletons only.

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data trustworthiness.[24] In this study, significant differences in baseline characteristics were found. When asked for an explanation, the original authors declared that these differences were the result of nonrandom allocation of individuals. Hence, this study no longer met the requirements of an RCT.

The authors of the remaining four RCTs were willing to share IPD. Two studies included singleton pregnancies[21,23], one study included singleton and twin pregnancies[22] and one study included twin pregnancies only.[20] Hence, data included 546 individuals with singleton pregnancies (275 pessary versus 271 expectant management) and 168 individuals with twin pregnancies (85 pessary versus 83 expectant management).

IPD integrity

After checking data for internal consistency, a few discrepancies with the published results of individual studies were found. These discrepancies were mainly due to different rounding procedures applied by the authors or a coding error that resulted in numbers being inverted and did not affect outcomes of the primary studies. Those discrepancies were resolved after contact with the principal investigator of the original study.

Risk of bias within studies

The risk of bias of the four included studies is shown in Figure 2. Overall, Pratcorona et al (including singletons only) scored low risk of bias in all domains[21] and three studies were scored as "some concerns."[20,22,23] Among them, Hermans et al[22] (including both singletons and multiples) was rated with "some concerns" due to deviations in the intervention group and was stopped before enrollment was completed for futility. Mastantuoni et al[23] (including singletons only) was rated similar for being concluded before completion due to a low enrollment and an anticipated long trial duration. The study of Merced et al[20] (including multiples only) had concerns over discrepancies between the database and published results, however, this was resolved after contact with the authors.

Study characteristics

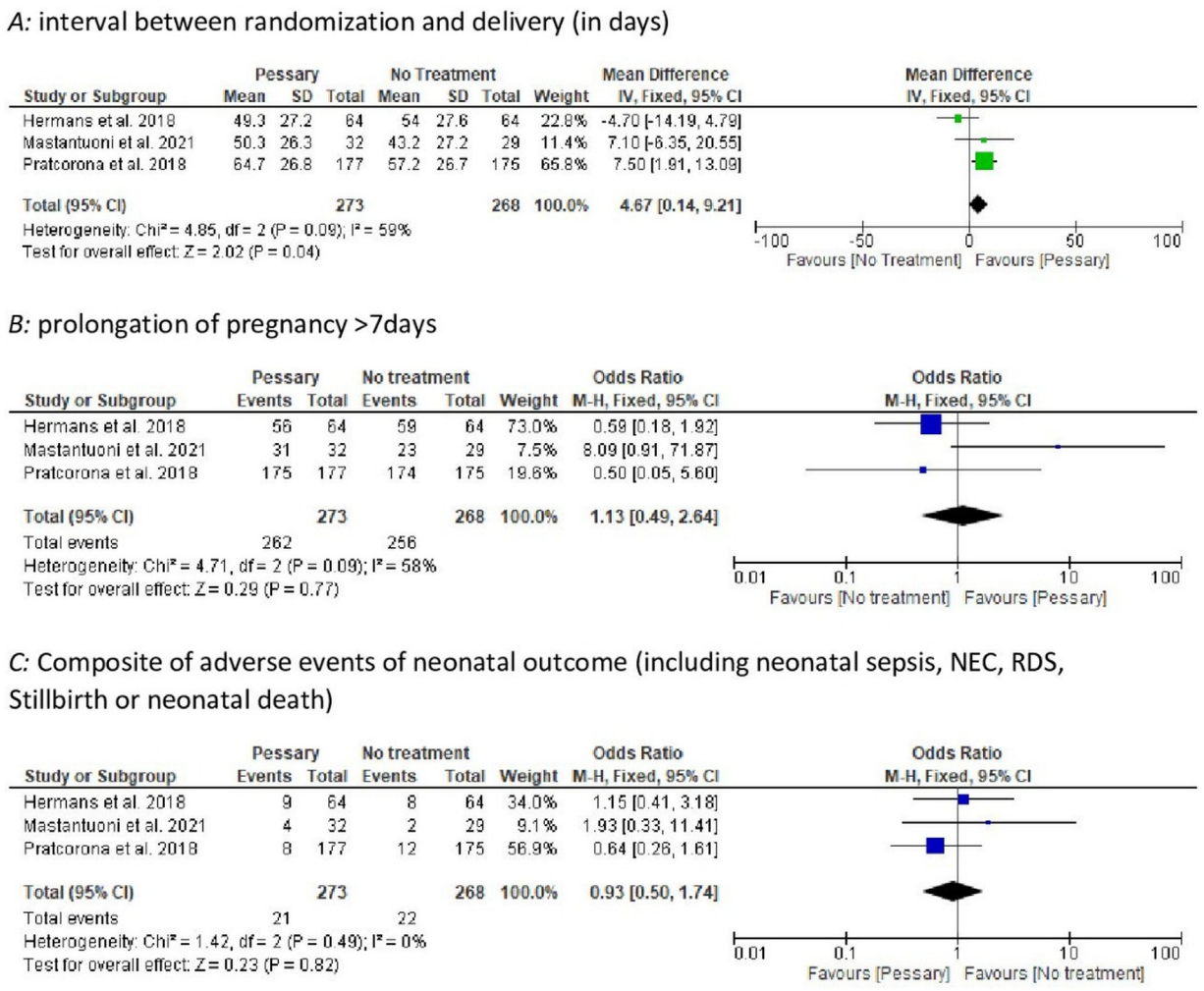
Table C provides key study and participant characteristics of included studies. All studies compared placement of an Arabin pessary versus expectant management according to local protocol to investigate the prolongation of pregnancy. Main protocol differences, including different cut-off values for cervical length, between studies are shown in Tables C and D.

Results for individuals with a singleton pregnancy

Three studies (N=546 individuals) were included in the analysis of singleton pregnancies, with 275 individuals in the pessary group and 271 individuals allocated to the control group. An aggregated meta-analysis revealed that pessary placement had a positive effect on prolongation of pregnancy with 54.8 days versus 51.5 days in the control group, resulting in a MD of 4.7 days (Figure 3, A; 95% CI 0.14−9.2; I^2=59%; P=.04). The analysis did not show a significant effect in prolongation of pregnancy for more than 7 days (Figure 3, B; RR 1.1, 95% CI 0.49−2.6; I^2=58%; P=.77) or in composite of adverse events or neonatal outcomes (Figure 3, C: RR 0.93, 95% CI 0.50−1.74; I^2=0%; P=.82) when comparing a cervical pessary versus expectant management.

When analyzing IPD, baseline characteristics were similar between the intervention and control group

FIGURE 3
Aggregate meta-analysis of primary outcomes for included studies investigating singletons, comparing pessary placement after an episode of PTL with expectant management



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(Table 1). Treatment with a cervical pessary did not demonstrate a significant effect on the main outcomes; delivery <7 days after randomization (RR 0.87; 95% CI 0.40−1.9), interval between randomization and delivery (MD 4.5 days; 95% CI −0.076 to 9.0), and no difference in composite neonatal outcomes (RR 0.95; 95% CI 0.53−1.7), as shown in Table 2. Placement of a cervical pessary after an arrested episode of PTL did not have a significant effect on secondary or neonatal outcomes. Only the incidence of readmissions for a new episode of PTL was significantly less frequent in the cervical pessary group (RR 0.66, 95% CI 0.50−0.85).

When examining the side effects and safety of the pessary, only one adverse event was observed in the pessary group. There were no differences in adverse neonatal outcomes between both groups (Table 2). Pooling data for PPROM was not feasible due to limited availability since this outcome was reported in only one study (Table E).[21]

Results for individuals with a twin pregnancy

Baseline characteristics for the twin pregnancies are presented in Table 3. For twin pregnancies, only two eligible studies (N=167 individuals) were available, including 84 individuals in the pessary group and 83 in the expectant management group. Analysis with an IPDMA was attempted, however, the contradictory effects of treatment in each study could not be explained by differences in study protocol or population. Therefore, analyzing effect estimates of these studies together was deemed uninformative with the risk of finding false treatment effects.

Subgroup analysis

Predefined subgroup analyses are described in Table F. Not all preplanned subgroup analyses could be executed, as not all outcomes were available within included studies. For available

TABLE 1
Baseline characteristics singletons

Variable	Pessary *N*=275	Expectant management *N*=271	*P* value
Maternal age at randomization (y)	***N=275*** 29.2±5.5	***N=271*** 29.9±5.9	.15
BMI (kg/m^2)	***N=268*** 24.7±4.4	***N=257*** 24.8±4.8	.94
Parity - Primigravida - Multiparous with no history of PTB - Multiparous with history of PTB	***N=275*** 148 (53.8) 88 (32.0) 39 (14.2)	***N=271*** 143 (52.8) 91 (33.6) 37 (13.7)	.92
Smoking - Yes (or stopped in first trimester) - No	***N=264*** 60 (22.7) 204 (77.3)	***N=263*** *53 (20.2)* *210 (79.8)*	.62
Ethnicity - Caucasian - Non-Caucasian	***N=266*** 174 (65.4) 92 (34.6)	***N=262*** 169 (64.5) 93 (35.5)	.83
Use of assisted reproduction techniques[a]	***N=64*** 6 (9.4)	***N=64*** 8 (12.5)	.57
History of cervical surgery[b]	***N=96*** 6 (6.3)	***N=93*** 8 (8.5)	.54
Pregnancy characteristics			
Gestational age at randomization (wk)	***N=275*** 28.5±2.8	***N=271*** 28.9±2.8	.13
Cervical length at randomization (mm)	***N=275*** 16.8±6.3	***N=271*** 16.5±7.0	.64
Funneling present at randomization	***N=233*** 56 (24.0)	***N=228*** 50 (21.9)	.59
Tocolysis given[c]	***N=275*** 255 (92.7)	***N=271*** 256 (94.5)	.41
Antenatal steroid administration	***N=275*** 271 (98.5)	***N=271*** 268 (98.9)	.72
Amniocentesis to exclude chorioamnionitis before randomization[d]	***N=275*** 179 (65.1)	***N=271*** 178 (65.7)	.88

Values are given as numbers (percentage) or mean±standard deviation.

BMI, body mass index; *PTB*, preterm birth.

[a] Available only for the data from Hermans et al; [b] Available only for the data from Hermans et al and Mastantuoni et al; [c] Number of doses only available for the data from Hermans et al; [d] Amniocentesis was only performed in the study from Pratcorona et al.

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subgroups, no significant *P* values for interaction were found.

A posthoc subgroup analysis excluding individuals who did not receive tocolysis showed no significant differences in the main outcomes (Table G).

Discussion

Main findings

This IPDMA demonstrated that placement of a cervical pessary in individuals with a singleton pregnancy between 24 and 34 weeks of GA after an arrested episode of PTL did not prolong pregnancy nor reduced the risk for a composite of adverse neonatal outcomes. While cervical pessary did reduce the probability of readmissions for PTL, no other clinically relevant differences were observed for secondary maternal or neonatal outcomes. Analysis of twin pregnancies was not feasible due to heterogeneity in treatment effects among the included studies.

Strengths and limitations

This is the first IPDMA investigating the effectiveness of a cervical pessary in high-risk pregnant patients who did not deliver after an episode of PTL. The IPDMA method is known for its robustness in analyzing treatment effects in

TABLE 2
Primary and secondary outcomes singletons

Variable	Pessary *N*=273[a]	Expectant management *N*=268[b]	Risk ratio or mean difference (95% CI)	*P* value
Primary outcome				
Delivery <7 d after randomization Yes No	***N*=273** 11 (4.0) 262 (96.0)	***N*=268** 12 (4.5) 256 (95.5)	0.87 (0.40–1.9)	.31
Interval between randomization and delivery (d)	***N*=273** 59.3±27.7	***N*=268** 54.9±27.1	4.5 (−0.076 to 9.0)[c]	.054
Composite of neonatal outcome[d]	***N*=273** 21 (7.7)	***N*=268** 22 (8.2)	0.95 (0.53–1.7)	.85
Secondary maternal outcomes				
Any PTB <37 wk	***N*=273** 72 (26.4)	***N*=268** 76 (28.4)	0.98 (0.75–1.3)	.89
Spontaneous PTB <37 wk[e]	***N*=240** 53 (22.1)	***N*=238** 65 (27.3)	0.85 (0.62–1.2)	.30
Any PTB <34 wk	***N*=273** 43 (15.8)	***N*=268** 40 (14.9)	1.1 (0.72–1.6)	.75
Spontaneous PTB <34 wk[e]	***N*=241** 33 (13.7)	***N*=239** 32 (13.4)	1.0 (0.66–1.6)	.88
Any PTB <32 wk	***N*=273** 32 (11.7)	***N*=268** 28 (10.4)	1.1 (0.70–1.8)	.61
Spontaneous PTB <32 wk[e]	***N*=241** 25 (10.4)	***N*=239** 24 (10.0)	1.0 (0.61–1.8)	.88
Any PTB <28 wk	***N*=273** 8 (2.9)	***N*=268** 10 (3.7)	0.77 (0.31–1.9)	.77
Spontaneous PTB <28 wk[e]	***N*=241** 5 (2.1)	***N*=239** 7 (2.9)	0.71 (0.23–2.2)	.55
Delivery <14 d after randomization Yes No	***N*=273** 21 (7.7) 252 (92.3)	***N*=268** 19 (7.1) 249 (92.9)	1.1 (0.59–1.9)	.82
Gestational age at delivery (wk)	***N*=273** 37.0±3.4	***N*=268** 36.8±3.4	0.26 (−0.30 to 0.83)[c]	.36
PPROM (y/n)[f]	NA	NA	NA	NA
Maternal infection or inflammation (chorioamnionitis)	***N*=264** 7 (2.7)	***N*=257** 5 (1.9)	1.4 (0.44–4.3)	.59
Number of readmissions for an episode of PTL —No readmission —One or more	***N*=241** 196 (81.3) 45 (18.7)	***N*=234** 157 (67.1) 77 (32.9)	0.66 (0.50–0.85)	**.001**
Mode of delivery —Vaginal —Instrumental —Cesarean delivery (all types)	***N*=273** 209 (76.6) 11 (4.0) 53 (19.4)	***N*=268** 200 (74.6) 20 (7.5) 48 (17.9)	 1.0 (0.93–1.1) 0.54 (0.26–1.1) 1.1 (0.76–1.5)	 .63 .091 .67
Significant maternal adverse effects[g]	***N*=232** 1 (0.4)	***N*=196** 0 (0.0)	NA	NA
Secondary perinatal outcomes				
Birthweight <2500 gram	***N*=273** 52 (19.0)	***N*=268** 53 (19.8)	1.0 (0.71–1.4)	.99
Birthweight <1500 gram	***N*=273** 21 (7.7)	***N*=268** 23 (8.6)	0.90 (0.51–1.6)	.70

(continued)

TABLE 2
Primary and secondary outcomes singletons *(continued)*

Variable	Pessary *N*=273[a]	Expectant management *N*=268[b]	Risk ratio or mean difference (95% CI)	*P* value
Birthweight in grams	***N=273*** 2987±804	***N=268*** 2892±759	96.7(−32.7 to 226.0)[d]	.14
NICU admission[h]	***N=79*** 21 (26.6)	***N=68*** 14 (20.6)	1.3 (0.73−2.4)	.37
Intrauterine fetal demise[i]	***N=273*** 1 (0.4)	***N=268*** 0 (0.0)	NA	NA
Perinatal death[j]	***N=273*** 1 (0.4)	***N=268*** 2 (0.7)	0.50 (0.046−5.4)	.58
Neonatal death[k]	***N=273*** 0 (0.0)	***N=268*** 2 (0.7)	NA	NA
Need for mechanical ventilation	NA	NA	NA	NA
Respiratory distress syndrome (RDS)	***N=255*** 14 (5.5)	***N=245*** 14 (5.7)	0.94 (0.47−1.9)	.87
Bronchopulmonary dysplasia (BPD)[l]	***N=80*** 0 (0.0)	***N=70*** 2 (2.9)	NA	NA
Intraventricular hemorrhage (IVH)	***N=257*** 1 (0.4)	***N=246*** 1 (0.4)	0.91 (0.059−13.8)	.94
Periventricular leukomalacia (PVL)	***N=225*** 0 (0.0)	***N=217*** 0 (0.0)	NA	NA
Necrotizing enterocolitis (NEC)	***N=257*** 7 (2.7)	***N=246*** 9 (3.7)	0.77 (0.29−2.0)	.59
Neonatal sepsis	***N=257*** 4 (1.6)	***N=246*** 2 (0.8)	1.8 (0.34−9.2)	.50
Retinopathy of prematurity	***N=255*** 1 (0.4)	***N=243*** 0 (0.0)	NA	NA

Values are given as numbers (percentage) or mean±standard deviation, RR is adjusted for RCT.

NA, not applicable; *PTB*, preterm birth.

In the *P*-value column, when a number is bold, that means that the number is significant.

[a] Two patients lost to follow-up in intervention group; [b] Three patients lost to follow-up in expectant management group; [c] Mean difference; [d] Including neonatal sepsis, necrotizing enterocolitis, respiratory distress syndrome, stillbirth, perinatal death; [e] Only data available from studies Hermans et al and Pratcorona et al; [f] Data on PPROM are only available in Pratcorona et al; not reported in Mastantuoni et al, and in Hermans et al, only PPROM before 30 weeks is reported; [g] Significant maternal adverse effect defined as heavy bleeding, cervical tear, uterine rupture; [h] Only data available from studies Hermans et al and Mastantuoni et al; [i] Intrauterine fetal demise: intrapartum or antepartum death; [j] Perinatal death: fetal and neonatal death; [k] Neonatal death: defined as death within 28 days after birth.

Breuking. Effectiveness of a cervical pessary in prolongation of pregnancy after an arrested episode of preterm labor. Am J Obstet Gynecol MFM 2025.

relevant treatment effects within clinically relevant subgroups.[26,27]

Also, since the validity of data in RCTs matter to the accountability of medical practice, an extensive analysis of data integrity was performed, that resulted in exclusion of a study that turned out not be an RCT. This highlights the need for caution in studies with data uncertainties about trustworthiness in the process of revising clinical guideline recommendations, since substantial bias can be introduced.

A limitation of this IPDMA is that two included studies were concluded prior to achieving the required sample size. Hermans et al[22] was stopped for futility, while Mastantuoni et al[23] ended early due to slow enrollment rates and the anticipation of an extended trial duration. Nevertheless, the statistical power of this IPMDA is enhanced by certain characteristics, such as high-quality data and a large sample size, enabling an appropriate classification of the beneficial effects of a cervical pessary.

Also, differences in inclusion criteria across studies could contribute to variability in risk profiles within the study populations (Table C). For example, the studies Pratcorona et al[21] and Mastantuoni et al[23] selected patients solely based on cervical length with different cut-off values based on GA. The study of Hermans et al[22] used an algorithm of cervical length and fetal fibronectin to identify patients at high risk. However, subgroup analysis of different cervical lengths at time of inclusion did not demonstrate a significant interaction for the main outcomes. For the fibronectin test, subgroup analysis could not be performed due to lack of events in this group (Table F).

TABLE 3
Baseline characteristics twins

Variable	Pessary *N*=84	Expectant management *N*=83	*P* value
Maternal age at randomization (y)	***N=84*** 35.7±4.8	***N=83*** 34.6±5.8	.17
BMI (kg/m^2)	***N=79*** 24.4±2.0	***N=77*** 24.4±2.6	.18
Chronicity - Monochorionic	***N=84*** 16 (19.0)	***N=83*** 19 (22.9)	.54
Parity - Primigravida - Multiparous with no history of PTB - Multiparous with history of PTB	***N=84*** 43 (51.2) 31 (36.9) 10 (11.9)	***N=83*** 40 (48.2) 31 (37.3) 12 (14.5)	.87
Smoking - Yes (or stopped in first trimester) - No	***N=83*** 12 (14.5) 71 (85.5)	***N=80*** *9 (11.3)* *71 (88.7)*	.49
Ethnicity - Caucasian - Non-Caucasian	***N=81*** 50 (61.7) 31 (38.3)	***N=81*** 52 (64.2) 29 (35.8)	.75
Use of assisted reproduction techniques	***N=84*** 23 (27.4)	***N=83*** 24 (28.9)	.83
History of cervical surgery[a]	***N=17*** 0 (0.0)	***N=18*** 0 (0.0)	NA
Pregnancy characteristics			
Gestational age at randomization (wk)	***N=84*** 28.2±2.9	***N=83*** 28.9±3.0	.16
Cervical length at randomization (mm)	***N=84*** 11.3±5.5	***N=83*** 12.2±5.2	.41
Funneling present at randomization	***N=81*** 15 (18.5)	***N=82*** 16 (19.5)	.87
Tocolysis given[b]	***N=84*** 84 (100.0)	***N=83*** 83 (100.0)	NA
Antenatal steroid administration	***N=84*** 84 (100.0)	***N=82*** 82 (100.0)	NA
Amniocentesis to exclude chorioamnionitis before randomization[c]	***N=84*** 67 (79.8)	***N=83*** 65 (78.3)	.81

Values are given as numbers (percentage) or mean±standard deviation.

BMI, body mass index; *PTB*, preterm birth.

In the *P*-value column, when a number is bold, that means that the number is significant.

[a] Available only for the data from Hermans et al; [b] Number of doses only available for the data from Hermans et al; [c] Amniocentesis was only performed in the study from Pratcorona et al.

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Another limitation is the inability to evaluate the training in pessary insertion and management in this IPDMA, as this has proven to be crucial for effectiveness.[28,29]

Moreover, due to the nature of the intervention, the included RCTs were not able to blind treating personnel or individuals. However, the main outcomes of this IPDMA were objective measures and thus mitigating potential influence on the outcomes arising from the absence of blinding procedures.

Comparison with existing literature

The results of the included studies in this IPDMA are contradictory between studies. Hermans et al[22] and Mastantuoni et al[23] found no beneficial effect of cervical pessary placement in singleton pregnancies and the reduction of PTB <37 weeks or in any other maternal or neonatal outcome. Contrary to this, Pratcorona et al[21] reported significant reductions in PTB <37 weeks, recurrence of threatened PTL and PPROM with pessary use.

For twin pregnancies, only two studies were eligible, with conflicting results of treatment effect. Merced et al[20] found a significantly lower spontaneous PTB rate <34 weeks after pessary placement. Hermans et al[22] reported contrasting results, finding no significant differences in maternal or neonatal outcomes with pessary placement in twins and even observed a favorable trend toward expectant management.

When examining the risk profile for PTB across different countries, the baseline risk of PTB among the countries included in this IPD is equivalent.[2] However, the heterogeneity in primary analyses and variation in results for both singletons and multiples may be caused by differences in participant selection and clinical practice (Table D).

Individuals in the Spanish studies (Merced et al[20] and Pratcorona et al[21]) underwent amniocentesis to detect subclinical chorioamnionitis, which led to exclusion from the study if present. Hermans et al[22] and Mastantuoni et al[23] did not employ amniocentesis to rule out subclinical chorioamnionitis. Since asymptomatic intra-uterine infection increases the risk of PTB,[30] this may have caused baseline risk differences between study populations. Despite apparent differences in pregnancy prolongation between individuals receiving pessary versus expectant management, with a MD of 7.42 days (95% CI 1.82 −13.03) for those with amniocentesis and −1.08 days (95% CI −8.91 to 6.75) for those without, the interaction *P* value was not statistically significant (Table F; *P*=.08). Secondly, there was no significant interaction of amniocentesis on all other main outcomes.

Moreover, the Spanish studies excluded patients with cervical dilatation. Although Hermans et al[22] and Mastantuoni et al[23] did not use this specific exclusion criterion, they did not include patients with cervical dilation, so this difference did not contribute to differences in risk profiles.

Therefore, it could only be hypothesized that the study population of the studies conducted in Spain may have had a lower risk profile, contributing to the more beneficial effect found for the cervical pessary. However, the exact cause of the heterogeneity in treatment effects could not be identified.

In the study of Mastantuoni et al,[23] all individuals, irrespective of allocation, received progesterone. Nevertheless, a recent systematic review demonstrated progesterone has no effect for prolongation of pregnancy after an arrested episode of PTL.[31] Additionally, tocolysis was only administered based on clinician opinion, resulting in half of the individuals not receiving tocolysis. It could be debated whether these individuals were experiencing an episode of PTL. However, a posthoc subgroup analysis of only individuals who received tocolysis showed no difference.

The safety of pessary use was confirmed in all trials included in this IPDMA, with no associated maternal or fetal adverse effects identified.

This IPDMA showed a significant effect in favor of the pessary to reduce the risk of readmission after an arrested episode of PTL. This effect may be due to the inability of blinding, providing individuals a sense of reassurance, leading to reduced stress, anxiety, and fewer hospital visits.[32] Additionally, this sense of reassurance might have influenced the treating clinician to different clinical management. However, this theory remains hypothetical. Nonetheless, the reduction in re-hospitalizations could have meaningful implications for maternal mental health and may also contribute to lower healthcare costs associated with repeated hospitalizations. Although we found a significant difference in readmissions for threatened PTL, this did not reduce the main outcomes.

Previous RCTs investigating the use of a cervical pessary in asymptomatic individuals with midtrimester short cervical length have shown contradictory results regarding its effectiveness in preventing PTB.[33−35] In this IPDMA, all included individuals were symptomatic with signs of PTL. It is important to note that the mechanism and pathways leading to PTB in symptomatic individuals might differ from the ones who are asymptomatic, with cervical insufficiency especially playing a role in cervical shortening,[36,37] leading to a different treatment effect of pessary placement. Or, it could be suggested that a pessary might be less effective in symptomatic individuals as it has passed the "window of opportunity" with the process of cervical shortening, softening, and dilation unavoidably starting.[38,39]

Conclusions and implication

In singleton pregnancies, placement of a cervical pessary after an arrested episode of PTL does not have a significant effect on the prolongation of pregnancy nor decreasing the risk of composite adverse neonatal outcomes. Placement of pessary seems to reduce the probability of readmissions for PTL. Based on current evidence, the use of a cervical pessary to prolong pregnancy following an arrested episode of PTL cannot be recommended in singleton pregnancies. ■

CRediT authorship contribution statement

Sofie H. Breuking: Writing − original draft, Visualization, Validation, Resources, Project administration, Investigation, Formal analysis, Data curation, Conceptualization. **Annemijn A. De Ruigh:** Writing − review & editing, Validation, Project administration, Investigation, Formal analysis, Data curation, Conceptualization. **Carme Merced:** Writing − review & editing, Conceptualization. **Rik Van Eekelen:** Writing − review & editing, Software, Methodology, Formal analysis. **Madelon Van Wely:** Software, Methodology, Formal analysis. **Charlotte E. Van Dijk:** Writing − review & editing, Conceptualization. **Laia Pratcorona:** Writing − review & editing, Conceptualization. **Elena Carreras:** Writing − review & editing. **Ben W. Mol:** Writing − review & editing, Validation, Supervision, Conceptualization. **Gabriele Saccone:** Writing − review & editing. **Eva Pajkrt:** Writing − review & editing, Validation, Supervision, Data curation, Conceptualization. **Maria Goya:** Writing − review & editing, Conceptualization. **Frederik J. Hermans:** Writing − review & editing, Validation, Supervision, Data curation, Conceptualization. ■

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.ajogmf.2025.101690.

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Eficacia del pesario cervical en la prolongación del embarazo tras un episodio detenido de trabajo de parto pretérmino: revisión sistemática y metaanálisis con datos individuales de pacientes

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ANTECEDENTES
Los ensayos clínicos aleatorizados (ECA) han mostrado resultados contradictorios sobre la eficacia del pesario cervical para prolongar el embarazo tras un episodio detenido de trabajo de parto pretérmino (TPP).

OBJETIVO
Evaluar la efectividad del pesario cervical en la prolongación del embarazo después de un episodio detenido de TPP, utilizando un metaanálisis con datos individuales de participantes (IPD, por sus siglas en inglés).

FUENTES DE DATOS
Se realizaron búsquedas desde el inicio hasta enero de 2024 en las bases de datos CENTRAL, Embase, Medline y registros de ensayos clínicos (ClinicalTrials.gov, ISRCTN, EU-CTR).

CRITERIOS DE ELEGIBILIDAD DEL ESTUDIO
Ensayos clínicos aleatorizados que incluyeran personas embarazadas entre las 24+0 y 34+0 semanas de gestación con un episodio detenido de TPP, posteriormente aleatorizadas a pesario cervical o sin intervención.

EVALUACIÓN DEL ESTUDIO Y MÉTODOS DE SÍNTESIS
Se evaluó la integridad de los datos y el riesgo de sesgo. Los desenlaces principales fueron la prolongación del embarazo >7 días, el intervalo entre la aleatorización y el parto, y un desenlace neonatal adverso compuesto. Se utilizó un enfoque de metaanálisis en un solo paso, aplicando el principio de intención de tratar.

RESULTADOS
Se contó con datos individuales de cuatro ECA. En embarazos únicos (N=546; 275 en el grupo con pesario, 271 en el grupo control), el uso del pesario no redujo el riesgo de parto dentro de los 7 días (riesgo relativo [RR]: 0.87; IC 95%: 0.40–1.9), no prolongó significativamente la gestación (diferencia media: 4.5 días; IC 95%: −0.08 a 9.0), ni disminuyó el riesgo de desenlaces neonatales adversos (RR: 0.95; IC 95%: 0.53–1.7). Sin embargo, la tasa de reingresos hospitalarios por un nuevo episodio de TPP fue significativamente menor en el grupo del pesario cervical (RR: 0.66; IC 95%: 0.50–0.85).
Se identificaron dos estudios sobre embarazos múltiples (N=167; 84 en el grupo con pesario, 83 en el grupo control), cuyos resultados fueron contradictorios y no explicables por diferencias metodológicas, por lo que el agrupamiento de IPD fue poco informativo.

CONCLUSIÓN
En personas con embarazo único y un episodio de TPP entre las 24 y 34 semanas de gestación, el uso de pesario cervical no reduce el riesgo de parto en los 7 días posteriores, ni mejora la prolongación del embarazo o los desenlaces neonatales. No obstante, puede disminuir la probabilidad de reingresos por nuevos episodios de TPP.

Palabras clave
Pesario cervical, trabajo de parto pretérmino, parto pretérmino, episodio detenido, metaanálisis con datos individuales, amenaza de parto pretérmino.