

The risk of recurrent preterm birth after spontaneous preterm birth between 16-28 weeks of gestation: A national observational cohort study

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Abstract

Background: Previous spontaneous preterm birth (sPTB) is an important risk factor for recurrent PTB, yet consensus on the lower limit of PTB is lacking. This complicates the identification of patients at risk for recurrent PTB. **Objectives:** To assess the risk of recurrent preterm birth following spontaneous extreme PTB between 16⁺⁰ - 27⁺⁶ weeks and the association with the interpregnancy interval. **Design:** A nationwide retrospective cohort study. **Setting:** Data from the Perinatal Registry of the Netherlands. **Population:** Nulliparous women with a singleton pregnancy that ended in sPTB between 16⁺⁰ and 27⁺⁶ weeks of gestation without congenital anomalies or antenatal death between 2010-2014 and had a subsequent pregnancy in the 5 years following. **Main outcome measures:** Recurrent preterm birth < 37 weeks. **Results:** 1011 women with linked pregnancies were included. The risk of PTB < 37 weeks with prior spontaneous birth between 16⁺⁰-19⁺⁶, 20⁺⁰-23⁺⁶, and 24⁺⁰-27⁺⁶ weeks was respectively 19.0%, 29.5% and 27.6%. The risk of subsequent PTB < 24 weeks was 5.7%, 7.2% and 4.3%. A short interpregnancy interval of 0-3 months was associated with increased odds for recurrent PTB < 32 weeks (OR 2.3 95% CI 1.4-3.7) and PTB < 37 weeks (OR 1.8 95% CI 1.2-2.6). **Conclusion:** Patients with previous sPTB from 16 weeks GA onwards are at high risk for recurrent PTB and should be regarded as such in the consideration of preventive measures to prevent recurrent adverse pregnancy outcomes.

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Short title: Recurrence risk after spontaneous PTB from 16 weeks onwards.

Abstract

Background : Previous spontaneous preterm birth (sPTB) is an important risk factor for recurrent PTB, yet consensus on the lower limit of PTB is lacking. This complicates the identification of patients at risk for recurrent PTB.

Objectives: To assess the risk of recurrent preterm birth following spontaneous extreme PTB between 16⁺⁰ - 27⁺⁶ weeks and the association with the interpregnancy interval.

Design : A nationwide retrospective cohort study.

Setting : Data from the Perinatal Registry of the Netherlands.

Population : Nulliparous women with a singleton pregnancy that ended in sPTB between 16⁺⁰ and 27⁺⁶ weeks of gestation without congenital anomalies or antenatal death between 2010-2014 and had a subsequent pregnancy in the 5 years following.

Main outcome measures: Recurrent preterm birth < 37 weeks.

Results : 1011 women with linked pregnancies were included. The risk of PTB < 37 weeks with prior spontaneous birth between 16⁺⁰-19⁺⁶, 20⁺⁰-23⁺⁶, and 24⁺⁰-27⁺⁶ weeks was respectively 19.0%, 29.5% and 27.6%. The risk of subsequent PTB < 24 weeks was 5.7%, 7.2% and 4.3%. A short interpregnancy interval of 0-3 months was associated with increased odds for recurrent PTB < 32 weeks (OR 2.3 95% CI 1.4-3.7) and PTB < 37 weeks (OR 1.8 95% CI 1.2-2.6).

Conclusion : Patients with previous sPTB from 16 weeks GA onwards are at high risk for recurrent PTB and should be regarded as such in the consideration of preventive measures to prevent recurrent adverse pregnancy outcomes.

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Keywords: preterm birth, recurrent preterm birth, mid trimester loss, mid pregnancy loss, interpregnancy interval, preterm labor

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Introduction

Preterm birth (PTB) is in quantity and severity one of the most important cause of neonatal mortality and morbidity.^{1,2} An important challenge in the prevention of PTB is the recognition of patients at risk, because effective preventive measures such as cervical cerclage and the administration of progesterone are available.³

Previous spontaneous preterm birth (sPTB) has proven to be an important risk factor for recurrent PTB, yet the lower limit of the gestational age of prior birth at which the recurrent risk is increased is not well defined.⁴⁻⁶ The widely used WHO definition of PTB distinguishes between extremely preterm (<28 weeks), very preterm (28-32 weeks) and moderate or late preterm (32-37 weeks), but is limited by lacking a lower limit of gestational age. The upper limit of 37 weeks is widely used across various countries, but the lower limit varies between 20, 22 and 28 weeks for respectively the USA⁷, Europe⁸ and China⁹. Therefore, there is no general consensus on the gestational age demarcation between miscarriage and extreme PTB. This complicates a clear assessment of which patients are at risk for subsequent or recurrent PTB, especially for patients with previous birth around 20 weeks. Yet, especially in these patients, early recognition of risk factors will contribute to early intervention in the management of preventing PTB.

Objective: In this study we will assess the recurrence risk of total PTB per gestational age group, following sPTB between 16⁺⁰- 27⁺⁶ weeks. In addition, we will assess the role of interpregnancy interval in this association.

Material & Methods

Study design and population

We conducted a nationwide cohort study with data from the national Perinatal Registry of the Netherlands (PERINED). This registry contains data on pregnancy, delivery and neonatal outcome and covers 97% of all deliveries after 16 weeks of gestation in the Netherlands.¹⁰ The PERINED database is obtained by linkage of three registries: the midwifery registry (LVR-1), obstetrics registry (LVR-2) and the neonatology registry (LNR). Permission for usage of the PERINED data with the purpose of this study was obtained on July, 13 2021 (approval number 21.13).

We extracted the data of registered pregnancies that ended in birth > 16 weeks of gestation between 2010 and 2014 (index pregnancies). We excluded pregnancies from primiparous or multiparous women, multiple pregnancies, pregnancies with birth > 28 weeks of gestation or pregnancies with an induced start of labor. Subsequently, the included pregnancies were linked with a 5 year cohort in primiparous women. This was done separately for each year with a subsequent 5-year cohort in the years 2010-2019. The 3 deterministic linkage keys were date of birth of the mother, data of previous birth/ birth date of the child and 4-digit zip code. Linkage was possible if two out of three variables were available of which maternal birth day was one of them. After linkage of prior birth and subsequent birth, prior pregnancies that were complicated with antenatal diagnosed IUFD and/or congenital anomalies were excluded from the sPTB index group in the analysis.

Outcomes

Primary outcome of this study was the recurrent risk rate of PTB before 37 weeks of gestation. Secondary outcomes included the recurrent risk of PTB < 24 and PTB < 32 weeks. The recurrent risks are reported for the total group as well as subdivided into prior sPTB between 16⁺⁰-19⁺⁶, 20⁺⁰-23⁺⁶ and 24⁺⁰-27⁺⁶ weeks of gestation.

Covariates

The interpregnancy interval (IPI) is defined as the interval between prior birth and conception date of the subsequent pregnancy using the expected due date and gestational age. The IPI was subdivided into 0-3, 3-6, 6-12, 12-36 and >36 months. Gestational age was based on crown-rump-length (CRL) during early fetal sonography. Assisted reproductive technology (ART) yes/no. Birth weight is shown in grams. Low social economic status (SES) of a neighborhood was defined based on income, paid jobs and education. Low SES (most deprived) was defined as SES at the lowest quintile.

Statistical analysis

Following the linkage between nulliparous women with previous sPTB and primiparous women with an on-going pregnancy after 16 weeks of gestation, the baseline characteristics of the first pregnancy were described and tested for the three spontaneous PTB groups of the index population; chi-square for categorical variables and anova for continues variables.

Logistic regression analysis was performed to assess the association between the gestational age at prior birth and the PTB pregnancy outcomes of the subsequent pregnancy. PTB rates are expressed per 100 births. Odds ratios (OR) and 95% confidence intervals (C.I.) were calculated separately for the three outcome groups (PTB < 24 weeks, PTB < 32 weeks and PTB < 37 weeks) in the subsequent pregnancy, with prior birth between 24+0 – 27+6 weeks as the reference. Analysis was adjusted for maternal characteristics (age, ethnicity, low SES), neonatal characteristics (fetal sex) and obstetrics characteristics (interpregnancy interval).

A separate analysis was conducted to assess the association between the interpregnancy interval, gestational age at prior birth and the recurrent risk. The interpregnancy interval was subdivided into groups of 0-3, 4-6, 7-12, 13-36 and >37 months, with 13-36 months as the reference.

Linkage and analysis were performed using SAS, version 9.4.

Core outcome set

A core outcome set was not used.

Patient involvement

There was no public or patient involvement in this retrospective cohort study.

Results

Study population

Out of 981,353 registered births in 2010-2014, we identified 4728 nulliparous women with a singleton pregnancy that ended in PTB between 16^{+0} - 27^{+6} weeks. From these, 2434 pregnancies were induced or ended with an elective cesarean section and were excluded. In total, 2294 prior births were included for linkage (Figure 1).

After linkage with a cohort of 1,782,991 primiparous births, 1285 of the included 2294 women with prior sPTB could be linked with a subsequent pregnancy that ended in a birth after 16 weeks of gestation. Prior pregnancies complicated by an antenatal diagnoses of intra-uterine fetal death (IUFD) (n=127) or fetal congenital abnormalities (n=159) (together n=274, numbers do not add up due to overlap in diagnosis) were excluded from the prior sPTB pregnancies after linkage. Ultimately, we were able to include the perinatal outcomes of 1011 linked pregnancies in this study. The flow chart of inclusion and exclusion per year is shown in figure 1.

Patient characteristics of the index pregnancy are shown in table 1 and are shown separately for women with prior sPTB between 16^{+0} - 19^{+6} , 20^{+0} - 23^{+6} and 24^{+0} - 27^{+6} weeks of gestation. The number of patients in each group was respectively 342, 346 and 323. The proportion of women with a western ethnicity differed significantly between groups, with the highest proportion of women with an ethnicity other than a western ethnicity in the group with birth between 16^{+0} and 19^{+6} . Despite an almost equal number of male fetuses (n=511) and female fetuses (n=500) in the overall group, the proportion of male fetuses being born between 16^{+0} - 19^{+6} weeks (35.7%) was significantly lower compared to 20^{+0} - 23^{+6} (59.5%) and 24^{+0} - 27^{+6} (56.7%) weeks (p<0.001). Maternal age, ART involvement and low SES did not differ significantly between the sPTB groups.

Outcomes

The recurrence rate of PTB < 37 weeks in women with prior birth between 16^{+0} - 19^{+6} was 19.0% (95% CI 15.0%-23.6%). Women with prior birth between 20^{+0} - 23^{+6} weeks had a recurrence rate of PTB < 37 weeks of 29.5% (95% CI 24.7% - 34.6%) and women with prior birth between 24^{+0} - 27^{+6} weeks had a recurrence rate of PTB < 37 weeks of 27.6% (95% CI 22.8% - 32.8%). The recurrent rates for PTB < 24, < 32 and < 37 weeks with 95%-confidence intervals are shown in table 2. For the three groups, odds for PTB < 24 and PTB < 32 weeks did not differ significantly between groups (Supplementary table 1). Figure 2 shows the risk of recurrent preterm birth per week of gestational age groups in prior sPTB birth.

Interpregnancy interval Compared to the reference group with an interpregnancy interval of 13-36 months, an interval of 0-3 months was found to be associated with significantly increased odds for PTB < 32 weeks (OR 2.3 95% CI 1.4-3.7) and PTB < 37 weeks (OR 1.8 95% CI 1.2-2.6). The odds per interval groups are shown in table 3. Compared to women with prior birth at a viable gestational age > 24 weeks, women with previous pre-viable birth between 16^{+0} - 19^{+6} , 20^{+0} - 23^{+6} weeks were more likely to have a short interpregnancy interval < 3 months (14.2% vs respectively 19.6% and 28.0%). (supplementary table 2)

Discussion

Main findings

The aim of this study was to assess the risk of recurrent preterm birth following spontaneous preterm birth between 16^{+0} - 27^{+6} weeks. We found that, at all gestational ages, patients with previous sPTB from 16

weeks onwards are at high risk for recurrent preterm birth.

A short interpregnancy interval of 0-3 months was associated with an increased risk of subsequent preterm birth < 37 and < 32 weeks. Short intervals were more common in patients with prior sPTB < 24 weeks. Since in the Netherlands no active support is offered to neonates born before 24 weeks, these births inevitably end in perinatal death. Therefore, parents might pursue a subsequent pregnancy shortly after the immature birth.

Interpretation

Multiple studies assessed the association between obstetric history and the risk for subsequent PTB and found higher risks of PTB following recurrent miscarriage or prior PTB < 37 weeks.^{6,11–18} Limited research assessed the subsequent risk after birth between 16-24 weeks and a cohort comparison is complicated by international differences in terminology and registration. One study by Goldenberg et al. ('93) found a recurrent PTB rate of 39% in women who gave birth between 13-24 weeks, which increased to 62% if the prior birth was between 19-22 weeks.¹² Edlow et. al. ('07) found that women with prior birth between 14-24 weeks were 10.8 times more likely to experience subsequent second-trimester loss or PTB compared to those with previous full-term delivery.¹³ A third study from Denmark ('17) reported a recurrence rate of 7.3% following birth between 16 and 28 weeks, but this rate varied significantly depending on the characteristics of the previous birth (fetal anomaly, multiple gestation, or intrauterine fetal demise), complicating a comparison with our findings.¹¹

Our results confirm that sPTB between 16-28 weeks is associated with a high risk for subsequent PTB, with an emphasis that the risk is also high in women with prior sPTB between 16⁺0-19⁺6 weeks. Women with prior birth at 16⁺0-19⁺6 weeks of gestation had a recurrent risk for PTB < 32 and < 37 weeks of respectively 5.8% and 11.7%, which is high compared to 1.0% and 5.5% in a general Dutch population of multiparous women with singleton and multiple pregnancies in 2021 (www.peristat.nl). Therefore, the obstetric history of women with prior birth between 16⁺0-19⁺6 weeks might deserve equal consideration in a risk assessment for subsequent PTB. Labelling spontaneous birth at this gestational age range as a miscarriage, may underestimate the risk for subsequent PTB. Using terminology that acknowledges the increased risk, by classifying birth between 16-20 weeks as PTB instead of miscarriage, could enhance the recognition, approach and preventive treatment of patients at risk.

The high recurrent risk after births at low gestational ages raises questions whether the subsequent risk may also be increased after birth at gestational ages below 16 weeks. If so, women with a previous miscarriages just below 16 weeks might be misidentified as patients at at-risk for subsequent PTB. Accurate national registration is vital to assess PTB risk following births at 13-15 weeks. All pregnant women in the Netherlands are advised to contact a midwife or general practitioner before 10 weeks of pregnancy, allowing for precise gestational age determination via ultrasound. Therefore, gestational age at which a (late) miscarriage might occur should be easy to determine. Registering these pregnancy outcomes will help PTB risk evaluation. If an increased PTB risk is found, further research is needed to assess whether and which preventive measures improve subsequent pregnancy outcomes.

Strengths and limitations

This study used data from the perinatal registry in the Netherlands, covering >97% of births.¹⁰ The large sample size with data from multiple consecutive years enabled a detailed assessment on subsequent PTB risk by gestational age and allowed for analysis on the interpregnancy interval. However, due to non-mandatory registration for births until 24 weeks, underrepresentation is likely for prior births between 16-24 weeks and also for the recurrence risk in that range.

In the index pregnancy selection, we excluded induced births, focusing on spontaneous and unknown start of labor. Excluding pregnancies complicated by congenital abnormalities or IUFD in the index pregnancy, likely removed inaccurately registered induced deliveries. However, we cannot rule out the possibility that the index pregnancy cohort might still include induced births, potentially underestimating the risk of subsequent

PTB after sPTB. Our subsequent cohort lacks distinction for high initial PTB risk (e.g., multiples, congenital issues, IUFD). Therefore, the risk is most likely lower for uncomplicated singletons. Still, our PTB rates remain notably high, even compared to national figures encompassing all pregnancies.

No data were available regarding the use of preventive measures in the subsequent pregnancy. In the Netherlands, patients with previous sPTB < 34 weeks of gestation are typically offered preventive progesterone treatment, additional cervical length screening and potentially receive interventions such as a cervical cerclage.¹⁹ Therefore, it is plausible that a significant portion of our study population received preventive treatment in the subsequent pregnancy, which could underestimate the actual risk faced by patients. However, there may be limited awareness regarding the increased risk following PTB around 16 weeks, resulting in fewer or no preventive measures and therefore providing a representative risk estimate for this subgroup.

No core outcome set (COS) could be used in the design of this study because of limited availability of the required outcome measures in the national perinatal registry.

Out of 2,294 women with prior sPTB, we successfully linked 1,285 nulliparous women to a subsequent pregnancy in a primiparous cohort. No linkage could be established in 1009 women, possibly due to insufficient matching variables. For example, if the birth record of the subsequent pregnancy did not include the date of the prior birth and if ZIP code changed over time, there would insufficient matching variables to establish a linkage. Other reasons could include no subsequent pregnancy within the 5-year timeframe, cases where the only pregnancy within the 5-year timeframe resulted in a miscarriage or termination before 16 weeks, or misreported subsequent births as nulliparous births. Also, 172 patients from the index cohort were excluded due to the antenatal diagnosis of IUFD, which might involve cases of IUFD due to fetal distress from extreme preterm labor. Given its likelier occurrence before 24 weeks, the group of patients with prior birth between 16-24 weeks may not be entirely represented.

Conclusions

Patients with previous spontaneous preterm birth from 16 weeks onwards are at high risk for recurrent preterm birth and should be considered and treated as such with preventive measures. A short interpregnancy interval of 0-3 months was associated with a significantly increased risk for subsequent PTB and should be actively discouraged in these patients.

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Contribution to Authorship MAB and EIK proposed the research idea; MAB, EIK, AR and ALG were responsible for the design of the study. AR was responsible for retrieving the data from PERINED for the purposes of this study and analysis of retrieved data; ALG drafted the manuscript; AR, EIK, BMK, EP, MAO and MAB reviewed all versions of the article and contributed to the interpretation of the results. All authors were sent the paper as prepared for submission and approved the final version.

Ethics approval Permission for usage of the PERINED data with the purpose of this study was obtained on July, 13 2021 (approval number 21.13).

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