



Low risk of adverse obstetrical and perinatal outcome in pregnancies complicated by asthma: A case control study



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ABSTRACT

Background: Asthma in pregnancy have been associated with an increased risk of pregnancy complications. Our aim was to estimate incidence and describe risk factors for adverse obstetrical and perinatal outcomes in pregnant women with asthma.

Methods: Women enrolled in the Management of Asthma during Pregnancy (MAP) program were each matched with three controls (i.e. consecutive women giving birth at our obstetrical service). Asthma severity was classified according to treatment step. Data on obstetrical and perinatal outcomes were obtained from medical records. Logistic regression analysis was applied, and findings expressed as odds ratios (OR) unadjusted and adjusted (adj) for BMI, age, parity, smoking, ethnicity and marital status.

Results: Nine-hundred-thirty-nine pregnancies in women with asthma (i.e. cases) were compared to 2.782 controls. Overall, the incidence of complications was low, although women with asthma had a statistically significant higher risk of pre-eclampsia (5% vs. 3%, OR_{adj} 1.60, 95% CI 1.07–2.38; $p = 0.02$) and small for gestational age neonates (SGA) (OR_{adj} 1.30, 95% CI 1.10–1.54; $p < 0.01$) compared to controls. Compared to mild asthma, more severe asthma was associated with a higher risk of SGA (60% vs 53%, OR_{adj} 1.30, 95% CI 1.10–1.54; $p < 0.01$). Women with asthma exacerbation during pregnancy tended to have a higher risk of severe pre-eclampsia (OR_{adj} 3.33 95% CI 0.96–11.65, $p = 0.06$) compared to pregnancies without any exacerbations.

Conclusion: The overall risk of adverse obstetrical and perinatal outcomes in pregnancies complicated by asthma is low compared to non-asthmatic women. Our observations suggest that enrollment into an asthma management program has a positive impact on overall pregnancy outcome.

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1. Introduction

Asthma is a common respiratory disorder among women of child-bearing age [1], which has been associated with an increased risk of pregnancy complications and adverse perinatal outcomes, but the observations published so far are conflicting [2]. While several studies have reported an association between maternal asthma and adverse pregnancy outcome such as pre-eclampsia [3,4], gestational diabetes [5,6], placenta praevia [4], premature rupture of the membranes (PROM) [5], postpartum hemorrhage [5,7], anemia [7], caesarean delivery [7–11], malformations [12],

small for gestational age (SGA) [10,13,14], low birth weight (LBW) [11,15,16], and preterm delivery [4,15], others have not found an association [11,16–19]. In general, larger database studies have reported increased risks [4,5,13,14], whereas smaller clinical prospective studies have not found significantly increased risks [6,7,18,20,21]. This discrepancy may be caused by variation in study size, regular follow-up visits in prospective studies, and lack of information on asthma characteristics, including severity, treatment and incidence of exacerbations [15]. Due to these conflicting results, prospective studies of large cohorts are needed to clarify the association between asthma, asthma severity and pregnancy outcome.

The aim of the present study was, therefore, to investigate the effect of maternal asthma, including asthma severity and occurrence of exacerbations, on obstetrical and perinatal outcomes in a case-control study of a large sample of pregnant women.

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2. Materials and methods

2.1. Material

The prospective cohort study, the Management of Asthma during Pregnancy (MAP) program, was initiated in 2007, and since then pregnant women have consecutively been recruited through the Department of Gynecology and Obstetrics, Hvidovre Hospital. All pregnant women referred to Hvidovre Hospital (approximately 7,000 per year, corresponding to 10% of infants born in Denmark) are informed about the study as part of the welcome letter from the Department of Gynecology and Obstetrics. The letter includes an invitation to participate in the MAP-program together with an e-mail address for response (astmaoggraviditet@regionh.dk). All women who accepted the invitation were, irrespective of time point during pregnancy, given a scheduled appointment (by letter) at the out-patient clinic, Department of Pulmonary Medicine.

In the present analysis, only women who fulfilled all of the following inclusion criteria were included: 1) Current diagnosis of asthma (defined according to the GINA-guidelines [22]), 2) Current prescribed treatment with at least rescue bronchodilator, 3) First visit to the outpatient clinic at the Department of Pulmonary Medicine within the first 18 weeks of pregnancy, and 4) age 17–50 years old. The participants were prospectively followed from recruitment and seen approximately every 4 weeks during pregnancy and 3 months postpartum; if necessary, patients were also seen at unscheduled visits. Case history, incl. age at diagnosis, tobacco exposure and acute exacerbations (previously and/or during first trimester of pregnancy) were obtained, attention was also paid to adherence and device technique. Medication use and exacerbation incidence were confirmed by pharmacy records. Level of asthma control was, according to GINA guidelines [22], assessed on the basis of history of day- and night-time symptoms, use of rescue medication together with objective assessment, incl. spirometry and level of fractional exhaled nitric oxide ($F_{E}NO$). The adjustment of medication was done in accordance with what was later described by Powell et al. [23] to maintain the women under tight asthma control.

Each case was matched to three controls. The controls were the three consecutive women giving birth at Hvidovre Hospital. Data on obstetrical and perinatal outcomes were extracted from the patient's medical records.

2.2. Ethics statement

This study was performed in accordance with the Helsinki II declaration, and according to Danish legislation. The study was approved by the Research Ethics Committee of the Capital Region of Denmark (H-D-2007-0051) and permission has also been obtained from the Danish Data Protection Agency (2007-41-0770).

3. Definitions and methods

3.1. Definitions

The severity of asthma was categorized as mild or moderate/severe based on the prescribed level of treatment according to the GINA guidelines [22], with mild asthma defined as treatment step 1 or 2 and moderate/severe asthma as disease that required step 3, 4 or 5 treatments [22]. Exacerbations were defined according to the official American Thoracic Society/European Respiratory Society guidelines on asthma control and exacerbations [24], and categorized as mild (defined as exacerbations managed by an increase in therapy, but not requiring oral corticosteroids) or severe (defined as exacerbations requiring hospital admission, emergency

department treatment and/or a rescue course of systemic corticosteroid).

Body Mass Index (BMI) was calculated based on self-reported pre-pregnancy bodyweight in kilograms divided by height in m^2 at the first visit. Immigrants were defined as patients born in non-western countries.

Low birth weight (LBW) was defined as birth weight 1000–2500 g, very low birth weight (VLBW) as less than or equal to 1000 g, and macrosomia as birth weight more than 4500 g irrespective of gestational age.

The gestational age (GA) of the infant was calculated from the nuchal translucency scan at week 12–14, or if this was not performed, from the first day of the last menstrual period. Preterm birth was defined as delivery between GA 32 and 37 weeks, very preterm birth between GA 28 and 32 weeks and extremely preterm birth as delivery before 28 weeks of gestation. Post-term pregnancy was defined as a pregnancy exceeding 42 weeks of pregnancy.

Each infant's z score, the deviation of the measured fetal weight from the expected fetal weight for each gestational age and sex using published ultrasonically estimated fetal weights, was calculated and expressed as standard deviations [25]. Small for gestational age (SGA) was defined as birth weight z-score ≤ -2 and large for gestational age (LGA) as z-score $\geq +2$.

Apgar score was evaluated after 5 min, and the cut-off point was set to 7 [26]. Fetal malformations and chromosomal abnormality included spina bifida, cleft lip, tongue-tie, hydro nephrosis, Down's syndrome, and talipes equinovarus. Instrumental delivery was defined as vaginal delivery using vacuum extraction or forceps.

Pregnancy complications were recorded according to The International Classification of Diseases 10 (ICD-10), including pre-eclampsia/eclampsia (O14-15), gestational diabetes (O24), gestational hypertension (O13), premature rupture of membranes (PROM) (O42), and anemia (D64.9). Psychiatric co-morbidity included mental and behavioral disorders, incl. mental development disorders (F00–F99).

3.2. Statistical analysis

Data analyses were performed using SAS Enterprise Guide 7.1. Continuous data were analyzed using the two-tailed Student t-test. Binary outcomes were analyzed using the chi-square test. Logistic regression analysis was used to estimate odds ratio (OR) as the measure of association, with 95% confidence intervals (CI). The crude OR and OR adjusted for potential confounding variables were estimated, with the following included as potential confounding variables: pregnancy maternal age and BMI (continuous variables), primiparity, smoking at onset of pregnancy, immigrant status and cohabitating with the child's father (categorical variables). A p-value < 0.05 was considered significant.

4. Results

4.1. Baseline characteristics

Over a 7-year period, 1018 pregnancies (i.e. cases) in 986 women with asthma were enrolled prospectively. However, 80 cases were excluded due to delivery at another hospital, leaving 938 for analysis. Of the 2820 women in the control group, 42 were excluded due to missing data in the medical records, leaving 2778 for analysis. Compared to the controls, women with asthma were more often non-smokers and primiparous, were less often immigrants, and had more often attended prenatal screening (Table 1).

Based on the current level of therapy, the majority of cases had mild asthma (71%, $n = 666$), whereas 29% ($n = 272$) were classified as having moderate to severe asthma (Table 2). At the first visit, 58%

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