Psychosocial variables are related to future exacerbation risk and perinatal outcomes in pregnant women with asthma

Running Head: Psychosocial variables in pregnancy and asthma

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Key words: asthma control, pregnancy, perception, exacerbation risk, perinatal outcomes

ABSTRACT

Objective: To determine the relationship between psychosocial variables, future exacerbation risk during pregnancy and perinatal outcomes. *Methods*: A secondary analysis of a randomised controlled trial of exhaled nitric oxide vs guideline based treatment adjustment in pregnant women with asthma. Women were recruited between 12 and 20 weeks gestation and monitored for the remainder of the pregnancy. Psychosocial questionnaires including the Perceived Control of Asthma Questionnaire, the Brief Illness Perception Questionnaire, and the Six-Item Short-Form State Trait Anxiety Inventory were assessed at randomisation. Exacerbations were defined as hospitalisation, emergency visit, unscheduled doctor visit or oral corticosteroid use for worsening asthma. Perinatal outcomes included preterm birth, small for gestational age, and caesarean section. Multiple logistic regressions were performed with predictor variables including demographics, psychosocial and clinical variables. *Results*: The 175 participants had a mean (SD) age=28.5(5.4) years, FEV1% predicted=95.9(13.4), and asthma control score=0.88(0.70). Greater perceived control of asthma reduced the odds of subsequent exacerbation (OR[95%CI] 0.92[0.85, 0.98], p=0.016), caesarean without labour (0.84[0.75, 0.94], p=0.003), and preterm birth (0.84[0.72, 0.97], p=0.019) while increased anxiety increased the odds of subsequent exacerbation (1.05[1.01, 1.08], p=0.008). *Conclusion*: Women's perceptions of asthma control and their psychosocial state (anxiety) are related to future exacerbation risk, caesarean section and preterm birth.

INTRODUCTION

Globally, asthma is a common chronic disease and one of the most prevalent conditions to complicate pregnancy, occurring in 8-12% of pregnancies.[1-4] Pregnant women with asthma are at a significantly increased risk of adverse perinatal outcomes including low birth weight, small for gestational age (SGA), preterm birth and pre-eclampsia.[5] Exacerbations can complicate a third of asthmatic pregnancies and are key events which may contribute to poor perinatal outcomes.[6, 7] Prevention of asthma exacerbations and active management of asthma during pregnancy is recommended by international guidelines to optimise the health of both the mother and fetus.[8] Psychosocial variables such as quality of life, illness perception and anxiety are known to influence asthma control and future risk of asthma exacerbation in non-pregnant people with asthma.[9-12] In pregnancy, one study has reported a relationship between asthma specific quality of life and future asthma morbidity.[13] We have previously demonstrated that illness beliefs and anxiety are related to quality of life (QoL) and asthma control in pregnant women.[14] However no prior studies have reported a relationship between illness beliefs, perceived self-efficacy and anxiety on future exacerbation risk during pregnancy or with perinatal outcomes. The aim of this paper was to assess psychosocial variables in pregnant women with asthma and relate these to perinatal outcomes and future risk of exacerbation.

METHODS

Participants

Women were participants in the Managing Asthma in Pregnancy (MAP) Study, a randomised controlled trial (RCT) of exhaled nitric oxide (FENO) vs guideline based treatment adjustment in pregnant women with asthma.[15] Pregnant women with asthma were recruited from the John Hunter Hospital antenatal clinic between 12 and 20 weeks gestation. Informed written consent was given by all participants and the study was approved by the Hunter New England Health and

University of Newcastle Human Research Ethics Committees. The MAP study is registered with the Australian and New Zealand Clinical Trials Registry, number 12607000561482.

Design

At randomisation socio-demographic variables were collected, asthma control was assessed using the asthma control questionnaire which includes assessment of FEV_1% predicted (ACQ7),[16] spirometry and fractional exhaled nitric oxide (FENO) measurements were performed. Women were non-smokers confirmed by urinary cotinine measurement <5 (Nicalert: NYMOX Corp. St-Laurent, Quebec, Canada) and exhaled carbon monoxide <10ppm which were measured in all participants.

Psychosocial questionnaires including the Perceived Control of Asthma Questionnaire (PCAQ),[17] the Brief Illness Perception Questionnaire (IPQ), [18] and the Six-Item Short-Form State Trait Anxiety Inventory (STAI-6)[19] were administered.

Previously published data from this study include the primary efficacy data from non-smoking pregnant participants of the MAP RCT[15] and baseline maternal psychosocial outcomes for a subset of study participants.[14] This analysis represents prespecified secondary analysis.

Exacerbations during pregnancy

Asthma exacerbations during pregnancy, defined as uncontrolled asthma requiring oral corticosteroid or unscheduled health care utilisation (hospitalisation, emergency department visit, or general practitioner visit) were prospectively assessed at monthly antenatal clinic visits and by fortnightly telephone follow up.

Perinatal Outcomes

Perinatal outcomes including preterm birth, SGA and caesarean section, were extracted from the women's medical records after delivery. Preterm birth was defined as delivery prior to 37 weeks gestation; Caesarean section was defined as either without labour (planned or unplanned) or with labour, for maternal or fetal indications and SGA as birth weight<10^{th} centile.

Asthma Control Questionnaire

Asthma control was assessed using the ACQ7. The ACQ7 [16] assesses 7 items over the previous week on a 7-point scale including: 5 asthma symptom items (night time waking, symptoms on waking, activity limitation, shortness of breath and wheezing), an item on short-acting bronchodilator use and a score for pre-bronchodilator FEV1% predicted. The ACQ7 score is the mean of all 7 items and ranges from 0 (well controlled) to 6 (severely uncontrolled).

Psychosocial Questionnaires (Table I)

Perceived self-efficacy to deal with asthma symptoms and exacerbations was measured using the PCAQ[17] and the IPQ.[18] The PCAQ, an 11-item questionnaire, measures individuals' perceptions of their asthma. A 1-5 point likert scale (strongly disagree to strongly agree) is used to grade responses with a possible total score ranging from 11-55. Better perceived control of asthma is indicated by a higher score. The IPQ is a nine-item scale designed to assess illness perceptions (consequence, timeline, personal control, treatment control, identity, concern, understanding, emotional response and cause) and has been validated in several medical conditions, including asthma. The first eight items are assessed independently on a continuous linear scale from zero to10 with an open ended causal question (Appendix 1). The word 'illness' was replaced with 'asthma' for this study. The Six-Item Short-Form State Trait Anxiety Inventory (STAI-6)[19] was used to assess anxiety. A 1-4 point Likert scale (not at all to very much) is used and the total is prorated to give a score range of 20-80 (low-high anxiety).

Statistical Analysis

Analysis was performed using STATA 11 (StataCorp, College Station, Texas, USA). Data is presented by mean (SD) or median (1,3Q) for nonparametric data. Logistic regression was performed for the psychosocial questionnaires against future exacerbation risk and perinatal outcomes (preterm delivery, SGA and caesarean section). Predictor variables included psychosocial questionnaire scores, age and clinical characteristics: ACQ7 score, maintenance inhaled

corticosteroid (ICS) beclomethasone (BDP) equivalent dose (no ICS; low-moderate dose ICS (<800mcg BDP equivalent); high dose ICS (>=800 BDPmcg equivalent)) and management group. Any predictor variable with $p \leq 0.2$ on simple regression was included in a multiple regression and stepwise removal performed. A p value of <0.05 was considered statistically significant. Predictor variables were tested for colinearity using STATA's variance inflation factors (VIF) post estimation.

RESULTS

Exacerbation data were available for 175 women and perinatal outcomes data for 166, all of whom completed the psychosocial questionnaires at randomisation and completed the study. The women had a mean (SD) age = 28.5 (5.4) years and gestational age at study entry of 19.7(2.0) weeks. The majority of the women had mild asthma with a mean FEV1% predicted = 95.9 (13.5), and asthma control score = 0.88 (0.70), (Table 2).

The results of the psychosocial questionnaires at study entry (randomisation) are reported in table 3. The perceived ability to deal with asthma symptoms and exacerbations was moderate to good, with a mean PCAQ score of 43.8. They had low anxiety (median STAI-6 = 26.7). The women's illness perception scores are shown in table 3. The women believed the consequences of their asthma were not too serious but understood it was a long term illness. They found treatment helpful and believed they had good control over their asthma. Their asthma symptoms (IPQ: Identity) were perceived as mild and causing some concern, however they perceived asthma to have a minimal emotional affect and felt they had a good understanding of asthma.

The women's perinatal outcomes are shown in figure 1.

Predictors of Future Risk of Asthma Exacerbation

Asthma exacerbations post randomisation occurred in 61 (34.9%) women with asthma during pregnancy. The future risk of asthma exacerbation was related to perceived control of asthma,

anxiety and management group after adjustment for maintenance ICS dose. Logistic regression identified that future exacerbation risk was associated with perceived control (OR [95%CI] 0.92 [0.85, 0.98], p= 0.016) and anxiety (OR [95%CI] 1.05 [1.01, 1.08], p=0.008, Table 4). This indicates that for each 5 unit increase in PCAQ score, women were 40% less likely to exacerbate during the remainder of pregnancy while a 5 unit increase in STAI-6 score would lead to a 25% increase in the odds of exacerbation. Women in the FENO management group were significantly less likely to exacerbate as has been previously reported [15].

Predictors of Perinatal Outcomes

Preterm Birth

Greater perceived control of asthma reduced the odds of preterm birth (OR [95%CI] 0.84 [0.72, 0.97], p=0.019) (table 5). For each 5 unit increase in PCAQ score women were 80% less likely to have a preterm delivery. Increased perception that asthma is a long term illness (IPQ timeline) also reduced the odds of preterm birth (OR [95%CI] 0.75[0.59, 0.96], p=0.022).

SGA

There were no significant psychosocial predictors of SGA, (table 6).

Caesarean Section

Greater perceived control of asthma reduced the odds of caesarean section without labour (OR [95%CI] 0.84 [0.75, 0.94], p=0.003), (table 7) after adjustment for age. There were no associations between psychosocial variables and caesarean section during labour, (table 8).

DISCUSSION

The women's perceived control of asthma was related to their future exacerbation risk during pregnancy, and to preterm birth and caesarean section (without labour). Their illness perceptions were related to preterm birth and anxiety was related to future exacerbation risk. These psychosocial variables, measured earlier in pregnancy, were associated with future exacerbation and

perinatal outcomes while clinical measures, asthma control including FEV_1% and maintenance ICS dose, were not.

Psychosocial variables including anxiety have previously been associated with future exacerbation risk in non-pregnant men and women with asthma or COPD. Wang et al reported that psychological symptoms such as anxiety and depression independently predicted the future risk of unplanned physician visits and emergency department visits for asthma.[12] Anxiety and depression has also been associated with hospital readmission following exacerbation in men and women with COPD.[9] Similarly, we have confirmed these findings that increased anxiety is associated with future exacerbation risk in pregnant women. The only previous work reporting a relationship between psychosocial variables and future exacerbation risk during pregnancy was in a study of asthma specific QoL which found that increased QoL reduced the odds of a subsequent asthma exacerbation by more than 25%.[13]

We report for the first time that a woman's perception of her asthma control and her efficacy to deal with symptoms in the first half of her pregnancy is associated with her future exacerbation risk during the pregnancy. Calfee et al.[20] conducted a prospective study of hospitalised non- pregnant asthma patients and reported greater perceived control, as measured by the PCAQ, reduced the risk of subsequent emergency department visits (HR=0.92) and hospitalisations for asthma (HR=0.84) which is similar to our odds ratio of 0.92. To our knowledge there have been no published reports examining the relationship between perceived control of asthma and future exacerbation risk during pregnancy. Interestingly the women's perceptions of asthma control were more sensitive than clinical measures such as their ACQ7 score and maintenance ICS dose which did not predict future exacerbation.

Maternal asthma has been shown to increase the risk of preterm birth[5] which may be related to oral steroid use[21, 22] and asthma severity[23] while other studies have found a relationship between lower maternal lung function and premature birth.[24] A recent meta-analysis of perinatal

outcomes in women with asthma has demonstrated that the risk of preterm delivery is reduced in women who receive active asthma management.[5] The women in our study all received active asthma management throughout their pregnancies which may explain why asthma severity, as measured by ACQ7 score and maintenance ICS dose, was not significantly associated with preterm delivery. However the women's perceptions of their asthma control was significantly associated with preterm delivery.

Women with asthma have an increased risk of caesarean section which is mediated by a doubling of caesarean sections performed without labour, compared to women without asthma.[25] The women in our study who had greater perceived control of their asthma were less likely to have a caesarean section performed before the onset of labour. Interestingly we found no significant relationships between psychosocial variables and caesarean section with labour. There are differences between caesarean section with or without labour. Those without labour are planned for maternal or fetal indications and occasionally on request, while a caesarean section with labour is conducted as an emergency procedure once labour is in progress [26].

In our group of non-smoking pregnant women with asthma, indicators of asthma severity, ACQ7 score and maintenance ICS dose, were not associated with future exacerbation risk or perinatal outcomes. The PCAQ was more sensitive than these clinical measures. There is a known association between anxiety and exacerbations but the PCAQ is not a measure of anxiety but explores a person's ability to deal with asthma and its exacerbations. The PCAQ has been shown to improve significantly after behaviour modification-based asthma education in non-pregnant adults with severe asthma.[27] The PCAQ is a quick and easy tool to use and could be measured early in antenatal care. Utilising this questionnaire could provide an opportunity to intervene during pregnancy to improve the women's perceptions of asthma control and potentially reduce the risks of asthma exacerbation and adverse perinatal outcomes. However, intervention studies to improve

perceptions of asthma control during pregnancy would need to be conducted to address this hypothesis.

CONCLUSION

Women's perceptions of asthma control and their psychosocial state (anxiety) during pregnancy are related to future exacerbation risk, caesarean section and preterm birth. Further intervention studies are needed to test whether reducing the psychological morbidity identified in this study will help to improve these outcomes for pregnant women.

ACKNOWLEDGEMENTS

We would like to thank Kelly Steel, Karen McLaughlin, Linda Howell and Sandra Dowley for their assistance, the midwives of the antenatal unit and the women who participated in this study.

FUNDING

National Health and Medical Research Council, Australia

DECLARATION OF INTEREST

PGG has received payment for reimbursement of meeting/travel expenses from GlaxoSmithKline, AstraZeneca, Novartis and BoerhingerIngelheim. MJH, KMcC, WG, HP, VLC and VEM declare no conflict of interest.

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Table 1. Psychosocial Questionnaires

Questionnaire [Citation]	**Questionnaire Title**	**Score Range**	**Score Range Interpretation**	**Questionnaire Domains**
Perceived self-efficacy				
PCAQ[17]	Perceived Control of Asthma Questionnaire	11-55	Poor - Good	Total score
IPQ[18]	Brief Illness Perception Questionnaire	0-10	None/not at all – extreme/very clearly	Consequences Timeline Personal control Treatment control Identity Concern Understanding Emotional response Total score
Anxiety				
STAI-6[19]	Six-Item Short-Form State Trait Anxiety Inventory	20-80	Low -High	Total score

Table 2. Baseline characteristics

n	175
Age[γ]	28.5 (5.4)
Gestational age[γ]	19.7 (2.0)
FEV1%[γ]	95.9 (13.5)
FVC%[γ]	104.9 (14.7)
FEV1/FVC%[γ]	80.0 (7.0)
ACQ7 score[γ]	0.88 (0.70)
Maintenance ICS:* None	100 (57.1%)
Low-moderate dose	30 (17.1%)
High dose	45 (25.7%)
ICS BDP equivalent mcg/day[α], n=75	800 (400, 800)
FENO management group*	85 (48.6%)
Exacerbation*	61 (34.9%)

[γ]Mean (SD);* n(%);[α] Median (1, 3Q); FEV1: forced expiratory volume in 1 second; FVC: forced vital capacity; ACQ7: asthma control score; ICS: inhaled corticosteroid; BDP: beclomethasone equivalent.

Table 3. Psychosocial Questionnaires

IPQ1: Consequences [α]	2 (1, 3)
IPQ2: Timeline [α]	8 (5, 10)
IPQ3: Personal control [α]	8 (6, 9)
IPQ4: Treatment control [α]	9 (8, 10)
IPQ5: Identity [α]	3 (2, 5)
IPQ6: Concern [α]	2 (1, 4)
IPQ7: Understanding [α]	8 (5, 9)
IPQ8: Emotional response [α]	1 (0, 2)
PCAQ total score[γ]	43.8 (4.9)
STAI-6 total score [α]	26.7 (20, 36.7)

[γ] Mean (SD); [α] Median (1, 3Q); IPQ: Brief illness perception questionnaire; PCAQ: Perceived control of asthma questionnaire; STAI-6: Six-Item Short-Form State Trait Anxiety Inventory.

Table 4. Predictors of future exacerbation risk.

	Simple regression		Multiple regression	
N=175	**OR(95%CI)**	**P value**	**OR(95%CI)**	**P value**
IPQ: Consequences	1.28 (1.08, 1.51)	0.005		
IPQ: Timeline	1.02 (0.92, 1.13)	0.756		
IPQ: Personal Control	0.93 (0.82, 1.06)	0.289		
IPQ: Treatment Control	1.13 (0.93, 1.37)	0.227		
IPQ: Identity	1.23 (1.05, 1.45)	0.011		
IPQ: Concern	1.14 (0.99, 1.31)	0.050		
IPQ: Understanding	1.01 (0.88, 1.17)	0.854		
IPQ: Emotional response	1.20 (1.03, 1.41)	0.022		
PCAQ Total score	0.90 (0.84, 0.96)	0.002	0.92 (0.85, 0.98)	**0.016**
STAI Total score	1.06 (1.02, 1.09)	0.001	1.05 (1.01, 1.08)	**0.008**
Age, yrs	1.02 (0.96, 1.08)	0.552		
ACQ7 score	1.45 (0.93, 2.26)	0.102		
Low-moderate dose ICS	1.97 (0.85, 4.57)	0.116	1.80 (0.72, 4.48)	0.205
High dose ICS	2.06 (0.99, 4.28)	0.054	1.80 (0.83, 3.94)	0.139
FENO group	0.51 (0.27, 0.96)	0.037	0.48 (0.24, 0.95)	**0.035**

ACQ7: asthma control score; IPQ: Brief illness perception questionnaire; PCAQ: Perceived control of asthma questionnaire; STAI-6: Six-Item Short-Form State Trait Anxiety Inventory; ICS: inhaled corticosteroid; FENO: fractional exhaled nitric oxide; OR: odds ratio; CI: confidence interval.

Table 5. Predictors of preterm birth (<37weeks).

	Simple regression		Multiple regression	
N=166	**OR(95%CI)**	**P value**	**OR(95%CI)**	**P value**
IPQ: Consequences	1.14 (0.82, 1.57)	0.436		
IPQ: Timeline	0.84 (0.69, 1.01)	0.069	0.75 (0.59, 0.96)	**0.022**
IPQ: Personal Control	0.86 (0.68, 1.09)	0.222		
IPQ: Treatment Control	0.91 (0.67, 1.26)	0.579		
IPQ: Identity	1.29 (0.95, 1.73)	0.098		
IPQ: Concern	1.12 (0.86, 1.45)	0.395		
IPQ: Understanding	0.85 (0.65, 1.10)	0.223		
IPQ: Emotional response	1.26 (0.97, 1.63)	0.086		
PCAQ Total score	0.87 (0.77, 0.99)	0.037	0.84 (0.72, 0.97)	**0.019**
STAI Total score	1.06 (1.001, 1.12)	0.046	1.05 (0.99, 1.12)	0.108
Age, yrs	0.99 (0.88, 1.12)	0.932		
ACQ7 score	1.19 (0.51, 2.75)	0.685		
Low-moderate dose ICS	0.48 (0.06, 4.09)	0.503		
High dose ICS	0.68 (0.14, 3.45)	0.645		
FENO group	1.11 (0.31, 3.98)	0.875		

ACQ7: asthma control score; IPQ: Brief illness perception questionnaire; PCAQ: Perceived control of asthma questionnaire; STAI-6: Six-Item Short-Form State Trait Anxiety Inventory; ICS: inhaled corticosteroid; FENO: fractional exhaled nitric oxide; OR: odds ratio; CI: confidence interval.

Table 6. Predictors of small for gestational age (<10th centile).

	Simple regression	
N=164	**OR(95%CI)**	**P value**
IPQ: Consequences	1.03 (0.80, 1.32)	0.817
IPQ: Timeline	1.09 (0.93, 1.28)	0.281
IPQ: Personal Control	1.08 (0.88, 1.33)	0.447
IPQ: Treatment Control	0.91 (0.72, 1.14)	0.405
IPQ: Identity	0.85 (0.65, 1.09)	0.201
IPQ: Concern	0.88 (0.70, 1.10)	0.254
IPQ: Understanding	1.02 (0.83, 1.25)	0.846
IPQ: Emotional response	1.04 (0.82, 1.30)	0.766
PCAQ Total score	0.95 (0.87, 1.04)	0.243
STAI Total score	0.99 (0.95, 1.04)	0.875
Age, yrs	0.95 (0.87, 1.04)	0.278
ACQ7 score	0.68 (0.33, 1.44)	0.318
Low-moderate dose ICS	1.56 (0.50, 4.87)	0.446
High dose ICS	1.09 (0.36, 3.32)	0.885
FENO group	0.91 (0.37, 2.23)	0.832

ACQ7: asthma control score; IPQ: Brief illness perception questionnaire; PCAQ: Perceived control of asthma questionnaire; STAI-6: Six-Item Short-Form State Trait Anxiety Inventory; ICS: inhaled corticosteroid; FENO: fractional exhaled nitric oxide; OR: odds ratio; CI: confidence interval.

Table 7. Predictors of caesarean section (without labour)

	Simple regression		Multiple regression	
N=166	**OR(95%CI)**	**P value**	**OR(95%CI)**	**P value**
IPQ: Consequences	1.26 (0.100, 1.58)	0.050		
IPQ: Timeline	1.08 (0.92, 1.28)	0.346		
IPQ: Personal Control	0.89 (0.75, 1.06)	0.186		
IPQ: Treatment Control	1.08 (0.82, 1.44)	0.584		
IPQ: Identity	1.23 (0.99, 1.54)	0.061		
IPQ: Concern	1.11 (0.91, 1.34)	0.302		
IPQ: Understanding	1.02 (0.83, 1.26)	0.850		
IPQ: Emotional response	1.25 (1.02, 1.53)	0.030	1.16 (0.91, 1.49)	0.233
PCAQ Total score	0.85 (0.77, 0.94)	0.001	0.84 (0.75, 0.94)	**0.003**
STAI Total score	1.03 (0.99, 1.08)	0.134		
Age, yrs	1.11 (1.02, 1.21)	0.021	1.16 (1.05, 1.28)	**0.004**
ACQ7 score	1.85 (1.05, 3.26)	0.034		
Low-moderate dose ICS	1.19 (0.35, 4.04)	0.775		
High dose ICS	1.02 (0.34, 3.12)	0.967		
FENO group	1.25 (0.50, 3.11)	0.639		

ACQ7: asthma control score; IPQ: Brief illness perception questionnaire; PCAQ: Perceived control of asthma questionnaire; STAI-6: Six-Item Short-Form State Trait Anxiety Inventory; ICS: inhaled corticosteroid; FENO: fractional exhaled nitric oxide; OR: odds ratio; CI: confidence interval.

Table 8. Predictors of caesarean section (with labour)

	Simple regression	
N=166	**OR(95%CI)**	**P value**
IPQ: Consequences	0.96 (0.73, 1.25)	0.753
IPQ: Timeline	1.02 (0.87, 1.19)	0.800
IPQ: Personal Control	0.90 (0.75, 1.07)	0.225
IPQ: Treatment Control	1.10 (0.82, 1.49)	0.514
IPQ: Identity	1.11 (0.88, 1.40)	0.379
IPQ: Concern	1.10 (0.90, 1.33)	0.352
IPQ: Understanding	0.97 (0.79, 1.19)	0.754
IPQ: Emotional response	1.06 (0.84, 1.33)	0.622
PCAQ Total score	0.99 (0.90, 1.09)	0.887
STAI Total score	1.00 (0.96, 1.05)	0.923
Age, yrs	1.06 (0.97, 1.16)	0.190
ACQ7 score	1.22 (0.66, 2.26)	0.523
Low-moderate dose ICS	0.50 (0.11, 2.37)	0.385
High dose ICS	0.93 (0.31, 2.81)	0.904
FENO group	0.89 (0.35, 2.27)	0.805

ACQ7: asthma control score; IPQ: Brief illness perception questionnaire; PCAQ: Perceived control of asthma questionnaire; STAI-6: Six-Item Short-Form State Trait Anxiety Inventory; ICS: inhaled corticosteroid; FENO: fractional exhaled nitric oxide; OR: odds ratio; CI: confidence interval.

Figure Legends

Figure 1. Perinatal Outcomes.
SGA: small for gestational age; C section: caesarean section.