

Association between maternal sleep practices and risk of late stillbirth: a case-control study

Tomasina Stacey, midwifery lecturer, PhD student,¹ John M D Thompson, senior research fellow,² Ed A Mitchell, professor of child health research,² Alec J Ekeroma, senior lecturer, obstetrics and gynaecology,¹ Jane M Zuccollo, senior lecturer, perinatal pathology,³ Lesley M E McCowan, professor of obstetrics and gynaecology¹

¹Department of Obstetrics and Gynaecology, University of Auckland, Private Bag 92019 Auckland 1142, New Zealand

²Department of Paediatrics, University of Auckland, Auckland

³Department of Obstetrics and Gynaecology, Wellington Medical School, Wellington 6021, New Zealand

Correspondence to: T Stacey
t.stacey@auckland.ac.nz

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ABSTRACT

Objectives To determine whether snoring, sleep position, and other sleep practices in pregnant women are associated with risk of late stillbirth.

Design Prospective population based case-control study.
Setting Auckland, New Zealand

Participants Cases: 155 women with a singleton late stillbirth (≥ 28 weeks' gestation) without congenital abnormality born between July 2006 and June 2009 and booked to deliver in Auckland. Controls: 310 women with single ongoing pregnancies and gestation matched to that at which the stillbirth occurred. Multivariable logistic regression adjusted for known confounding factors.

Main outcome measure Maternal snoring, daytime sleepiness (measured with the Epworth sleepiness scale), and sleep position at the time of going to sleep and on waking (left side, right side, back, and other).

Results The prevalence of late stillbirth in this study was 3.09/1000 births. **No relation was found between snoring or daytime sleepiness and risk of late stillbirth.** However, women who **slept on their back or on their right side on the previous night (before stillbirth or interview) were more likely to experience a late stillbirth** compared with women who slept on their left side (adjusted odds ratio for back sleeping 2.54 (95% CI 1.04 to 6.18), and for right side sleeping 1.74 (0.98 to 3.01)). The absolute risk of late stillbirth for women who went to sleep on their left was 1.96/1000 and was 3.93/1000 for women who did not go to sleep on their left. **Women who got up to go to the toilet once or less on the last night** were more likely to experience a late stillbirth compared with women who got up more frequently (adjusted odds ratio 2.28 (1.40 to 3.71)). Women who **regularly slept during the day in the previous month** were also more likely to experience a late stillbirth than those who did not (2.04 (1.26 to 3.27)).

Conclusions This is the first study to report maternal sleep related practices as risk factors for stillbirth, and these findings require urgent confirmation in further studies.

INTRODUCTION

The death of a baby before birth is a tragedy for the family and wider community. In high income countries more than one in 200 births result in a

stillbirth.^{1,2} Stillbirth therefore remains an important public health issue, with little change in its rate over the past two decades.^{2,3} Many studies have examined risk factors for stillbirth, but they have often been population based retrospective studies⁴⁻⁶ that have been unable to explore a broad range of potential risk factors, in particular those relating to maternal lifestyle and personal habits.

Around a third of a person's life is spent asleep, but there has been little research on the potential impact of sleep practices on the developing fetus. Previous studies have reported an association between sleep disordered breathing and pregnancy complications such as pre-eclampsia and preterm birth,⁷ but exploration of a potential association with stillbirth has been limited to a single case report.⁸ We and others have described a dose dependent relation between maternal obesity and stillbirth risk,⁹⁻¹¹ but the mechanisms underlying this association are not understood. Obesity is also associated with sleep disordered breathing.¹² It is therefore possible that sleep disordered breathing is one of the mechanisms underlying the association between obesity and stillbirth risk.

Supine sleeping position is associated with sleep disordered breathing¹³ and in late pregnancy has also been associated with reduced maternal cardiac output,¹⁴ but the impact of position during sleep and risk of stillbirth is not known. There have been no reports of other sleep related practices and risk of stillbirth.

The broad aim of the Auckland Stillbirth Study was to identify potentially modifiable risk factors for late stillbirth (≥ 28 weeks' gestation). We explored a range of factors relating to women's health and behaviour during pregnancy, including general health, socioeconomic factors, diet, exercise, and maternal sleep practices.¹⁵ We hypothesised that sleep disordered breathing and maternal supine sleep position would be associated with increased risk of late stillbirth. We also investigated the relation between risk of late stillbirth and other sleep related practices, specifically; regular daytime sleep, duration of sleep, and getting up during the night.

METHODS

Women who gave birth to a stillborn baby at or after 28 completed weeks of gestation in the Auckland region between July 2006 and June 2009 were invited to participate in the study.¹⁵ Stillbirth was defined as the birth of a baby that died in utero during the antenatal or intrapartum periods. Cases were ascertained weekly from key clinicians in the participating centres (all maternity units in Auckland region) and from hospital birth records checked on a regular basis (by TS). A national system for perinatal data collection started in New Zealand¹⁶ on the same date as recruitment began; cases were compared with this registry to ensure complete ascertainment.

Women were excluded if their baby had died from a congenital abnormality or was from a multiple pregnancy, or if they had not been booked to deliver their baby within the Auckland region (which consists of three district health boards). Two controls were randomly selected from the pregnancy registration list of the district health board in which the stillbirth occurred, with the same exclusion criteria as the cases. Controls were matched to cases by gestation, thus ensuring that the controls were representative of the antenatal population at the same gestation at which the stillbirth occurred.

Data were obtained through interviewer administered questionnaires in the first few weeks after stillbirth. For the controls, interviews occurred at the equivalent gestation of pregnancy as that of the matched case. Participants were not aware of any of the specific research questions related to risk factors for stillbirth. As there are no validated tools for screening for sleep disordered breathing in pregnancy, we used snoring and daytime sleepiness as proxy indicators for sleep disordered breathing.¹⁷ Participants were asked whether they regularly snored before their pregnancy or during pregnancy. The Epworth sleepiness scale was used to determine the general level of daytime sleepiness.¹⁸

Specific questions were asked about maternal sleep position both at the time of going to sleep and on waking. Sleep position was classified as left side, right side, back, and other ("other" included front, sitting up, both sides, and unsure or don't remember). The time periods for which data were collected were before the pregnancy and in the last month, week, and night of the pregnancy. The last night was the night before when the woman thought that her baby had died or, for the controls, the night before the interview.

Participants were also asked whether they regularly slept during the daytime in the last month. Further questions were asked about the usual duration of sleep at night during the last month and frequency of getting up to the toilet. The reference duration of sleep was defined as 6–8 hours at night,^{19,20} and sleep duration was therefore categorised as <6, 6–8, or >8 hours. Data were collected on frequency of waking in the night and of getting up to go to the toilet at night. A strong correlation was seen between these two

variables, and therefore only getting up to the toilet at night is presented here.

Demographic data and information on other potential confounding factors were collected during the interview, specifically maternal age, ethnicity, parity, smoking status, body mass index at booking (first antenatal visit), and social deprivation level. Ethnicity was self assigned, and a single ethnicity was applied based on a system of prioritisation as described by the New Zealand Ministry of Health.²¹ Smoking status was defined as having smoked at any time during the pregnancy. Maternal body mass index was calculated from the earliest known weight taken in pregnancy and from maternal height measured at interview. Social deprivation level was derived from the address at which the participant lived, based on the 2006 New Zealand census data, with category 1 being the least deprived and category 5 the most deprived.²² Detailed information about methodology has been reported previously.¹⁵

Analysis

All statistical analyses were performed with SAS version 9.1.²³ We used standard conditional regressions for matched case-control studies using the "proc logistic" procedure with the "strata" statement to control for matching. We compared continuous variables with Student's *t* test and used the Pearson correlation coefficient to assess the correlation between variables. There were

Table 1 | Characteristics of 155 women who experienced a late stillbirth between July 2006 and June 2009 and of the 310 controls. Values are numbers (percentages) of women unless stated otherwise

Characteristic	Cases (n=155)	Controls (n=310)	P value of difference
Age (years):			
<20	10 (6)	24 (8)	$\chi^2=0.56$, P=0.75
20–34	113 (73)	216 (70)	
≥35	32 (21)	70 (23)	
Ethnicity:			
Maori	19 (12)	46 (15)	$\chi^2=6.67$, P=0.08
Pacific	48 (31)	67 (22)	
European	55 (35)	139 (45)	
Other	33 (21)	58 (19)	
Parity:			
0	77 (50)	144 (46)	$\chi^2=11.88$, P=0.003
1–3	62 (40)	156 (51)	
≥4	16 (10)	10 (3)	
Social deprivation level:			
1–4	91 (59)	218 (70)	$\chi^2=6.25$, P=0.01
5 (most deprived)	64 (41)	92 (30)	
Body mass index at booking:			
<25	55 (35)	156 (50)	$\chi^2=9.72$, P=0.008
25–29.9	39 (25)	67 (22)	
≥30	61 (39)	87 (28)	
Smoked in pregnancy:			
Yes	46 (30)	66 (21)	$\chi^2=3.98$, P=0.05
No	109 (70)	244 (79)	

no missing data for the variables included in this paper. A multivariable regression model was developed to include maternal variables reported to be associated with increased risk of stillbirth, based on previous literature (age, body mass index, ethnicity, parity, smoking, and socioeconomic status). The study was powered to

detect an odds ratio of 2 with 80% power and significance level of 5%, with a prevalence of the risk factor of $\geq 20\%$ in the control population. Statistical significance in multivariable analysis was defined at the 5% level. Global χ^2 statistics were used to assess the significance of variables in the models, and individual level odds ratios were estimated for each category in comparison to a reference category, defined as the category hypothesised to have the lowest risk.

Table 2 | Relation between sleeping position and risk of late stillbirth among 155 women who experienced a late stillbirth and 310 controls. Values are numbers (percentages) of women unless stated otherwise

Sleeping position	Cases (n=155)	Controls (n=310)	Univariable odds ratio (95% CI)	P value of difference
Position on going to sleep				
Before pregnancy:				
Left side	28 (18)	50 (16)	1.00	$\chi^2=0.45, P=0.93$
Right side	24 (15)	45 (15)	0.97 (0.49 to 1.91)	
Back	16 (10)	35 (11)	0.82 (0.38 to 1.75)	
Other	87 (56)	180 (58)	0.88 (0.53 to 1.46)	
Last month of pregnancy:				
Left side	49 (32)	109 (35)	1.00	$\chi^2=7.70, P=0.05$
Right side	49 (32)	72 (23)	1.51 (0.92 to 2.47)	
Back	12 (8)	13 (4)	2.01 (0.87 to 4.65)	
Other	45 (29)	116 (37)	0.88 (0.55 to 1.42)	
Last week of pregnancy:				
Left side	49 (32)	111 (36)	1.00	$\chi^2=7.19, P=0.07$
Right side	51 (33)	73 (24)	1.56 (0.95 to 2.55)	
Back	10 (6)	12 (4)	1.83 (0.76 to 4.45)	
Other	45 (29)	114 (37)	0.93 (0.57 to 1.50)	
Last night of pregnancy:				
Left side	42 (27)	132 (43)	1.00	$\chi^2=12.52, P=0.006$
Right side	49 (32)	84 (27)	1.88 (1.14 to 3.10)	
Back	15 (10)	15 (5)	3.28 (1.46 to 7.34)	
Other	49 (32)	79 (25)	2.00 (1.20 to 3.33)	
Position on waking up				
Before pregnancy:				
Left side	27 (17)	44 (14)	1.00	$\chi^2=1.86, P=0.60$
Right side	24 (15)	42 (14)	0.92 (0.47 to 1.84)	
Back	21 (14)	38 (12)	0.92 (0.45 to 1.88)	
Other	83 (54)	186 (60)	0.73 (0.42 to 1.25)	
Last month of pregnancy:				
Left side	41 (26)	86 (28)	1.00	$\chi^2=4.78, P=0.19$
Right side	43 (28)	65 (21)	1.40 (0.82 to 2.40)	
Back	21 (14)	33 (11)	1.36 (0.70 to 2.67)	
Other	50 (32)	126 (41)	0.84 (0.51 to 1.37)	
Last week of pregnancy:				
Left side	39 (25)	88 (28)	1.00	$\chi^2=4.77, P=0.19$
Right side	44 (28)	64 (21)	1.56 (0.90 to 2.69)	
Back	22 (14)	37 (12)	1.36 (0.70 to 2.64)	
Other	50 (32)	121 (39)	0.95 (0.57 to 1.58)	
Last night of pregnancy:				
Left side	31 (20)	106 (34)	1.00	$\chi^2=10.08, P=0.018$
Right side	45 (29)	72 (23)	2.26 (1.28 to 3.97)	
Back	23 (15)	37 (12)	2.32 (1.18 to 4.56)	
Other	56 (36)	95 (31)	2.11 (1.24 to 3.57)	

RESULTS

During the study period 215 eligible women experienced a late stillbirth, giving a prevalence of late stillbirth of 3.09/1000 births. Of these 215 women, 155 (72%) consented to participate, as did 72% (310/429) of the eligible controls, and there were no significant differences in ethnicity, age, or parity between those who consented and those who declined.¹⁵ The overall autopsy rate for the stillborn babies was 47% (73/155). The most common classification for late stillbirth (based on the Perinatal Society of Australia and New Zealand Perinatal Death Classification System²⁴) was “unexplained antepartum death.”¹⁵ Women with late stillbirth were more likely to be obese, socioeconomically deprived, to smoke, and be of high parity compared with controls (table 1). Detailed analysis of these factors has been published previously.¹¹

No association was seen between risk of late stillbirth and self reported snoring, either before or during pregnancy: 69/155 (45%) of women who experienced stillbirth and 130/310 (42%) of controls reported snoring during pregnancy (adjusted odds ratio 1.12 (95% confidence interval 0.75 to 1.67)). There was also no difference between levels of daytime sleepiness, with a mean (SD) Epworth sleepiness score of 5.9 (4.1) for cases and 5.6 (3.8) for controls ($P=0.51$).

In univariable analysis, a significant association was found between risk of late stillbirth and maternal sleep position (both on going to sleep and waking up) on the last night of pregnancy (table 2). Maternal position on going to sleep in the last month was also associated with late stillbirth risk ($P=0.05$), although none of the individual odds ratios reached statistical significance in comparison with the reference category. No relation was seen between maternal sleep position before pregnancy and late stillbirth risk.

The study was not able to ascertain changes in sleep position during the night, so two data points were collected, position on going to sleep and position on waking up. These two positions were found to be highly correlated (Pearson correlation coefficient $r=0.72$ $P<0.001$). The association between risk of late stillbirth and non-left sleeping position was only evident in those who neither went to sleep on the left nor woke on the left (table 3). As maternal position on going to sleep is more modifiable than position on waking, we used the position on going to sleep in our multivariable analysis.

In univariable analysis, a significant relation was seen between sleeping regularly in the daytime and late stillbirth risk (table 4), as was longer than average night time

Table 3 | Changes in sleeping position on the last night of pregnancy and risk of late stillbirth among 155 women who experienced a late stillbirth and 310 controls. Values are numbers (percentages) of women unless stated otherwise

Maternal position		Cases (n=155)	Controls (n=310)	Univariable odds ratio (95% CI)
On going to sleep	On waking up			
Left	Left	29 (19)	95 (31)	1.00
Left	Other	13 (8)	37 (12)	1.15 (0.54 to 2.45)
Other	Left	2 (1)	11 (4)	0.60 (0.13 to 2.84)
Other	Other	111 (72)	167 (54)	2.28 (1.35 to 3.52)

sleeping duration. Getting up to the toilet infrequently (once or less) during the night was also significantly associated with late stillbirth risk in the last month, week, and night of pregnancy; there was no association between frequency of getting up to the toilet during the night before pregnancy and late stillbirth risk.

After adjustment was made for a range of potential confounders, not going to sleep on the left side on the last night of pregnancy remained independently associated with risk of late stillbirth (table 5), with sleeping on the back having the greatest risk. Compared with women who went to sleep on the left side, women who went to sleep in any other position had a doubled risk of late stillbirth (adjusted odds ratio 2.03 (95% confidence interval 1.24 to 3.29)). The absolute risk of late stillbirth in the population we studied was 3.09/1000 (95% confidence interval 2.70 to 3.53/1000); extrapolating our results to this population would give a risk of late stillbirth for women who went to sleep on the left of 1.96/1000 (1.50 to 2.51/1000) and a risk of

Table 4 | Sleep related practices and risk of late stillbirth among 155 women who experienced a late stillbirth and 310 controls. Values are numbers (percentages) of women unless stated otherwise

Practice	Cases (n=155)	Controls (n=310)	Univariable odds ratio (95% CI)	P value of difference
Regular sleep in daytime (last month of pregnancy):				
No	77 (50)	194 (63)	1.00	$\chi^2=7.08$, P=0.006
Yes	78 (50)	116 (37)	1.78 (1.18 to 2.68)	
Hours of night time sleep (last month of pregnancy):				
<6	30 (19)	46 (15)	1.72 (0.98 to 3.01)	$\chi^2=7.79$, P=0.02
6–8	82 (53)	205 (66)	1.00	
>8	43 (28)	59 (19)	1.83 (1.14 to 2.94)	
No of times getting up to toilet during night:				
Before pregnancy:				
>1	6 (4)	12 (4)	1.00	$\chi^2=0$, P=1.00
≤1	149 (96)	298 (96)	1.00 (0.37 to 2.74)	
Last month of pregnancy:				
>1	89 (57)	205 (66)	1.00	$\chi^2=3.37$, P=0.07
≤1	66 (43)	105 (34)	1.44 (0.97 to 2.14)	
Last week of pregnancy:				
>1	90 (58)	215 (69)	1.00	$\chi^2=5.84$, P=0.02
≤1	65 (42)	95 (31)	1.62 (1.09 to 2.41)	
Last night of pregnancy:				
>1	86 (55)	207 (67)	1.00	$\chi^2=4.80$, P=0.03
≤1	69 (45)	103 (33)	1.55 (1.04 to 2.30)	

3.93/1000 (3.35 to 4.59/1000) for women who did not go to sleep on their left.

The relation between regular daytime sleeping and getting up to the toilet infrequently during the last night and risk of late stillbirth persisted in the multivariable analysis (table 5). After adjustment for potential confounders, the length of night time sleep was also significantly associated with risk of late stillbirth (P=0.05).

DISCUSSION

In this case-control study we did not find an association between snoring or daytime sleepiness and late stillbirth risk. However we report a novel association between late stillbirth risk and non-left sided maternal sleep position and with other sleep related practices.

There is no validated questionnaire for sleep disordered breathing in pregnancy. Indeed, the Berlin questionnaire, which is one of the best validated questionnaires for obstructive sleep apnoea, has been shown to perform poorly in pregnancy.²⁵ We therefore used self reported snoring and daytime sleepiness as markers for sleep disordered breathing.^{17,26} However, snoring is common in pregnancy and is mostly not associated with sleep apnoea.²⁷ Tiredness and reduced daytime functioning are frequently experienced by pregnant women, not just among those with sleep disordered breathing, and this may make it harder to assess the true prevalence of sleep disordered breathing within the population.^{26,27} Further studies are warranted to more clearly distinguish between common symptoms of pregnancy and true sleep disordered breathing.

We report that women who slept on their left side on the last night of pregnancy had a reduced risk of late stillbirth compared with women who slept in any other position. The risk associated with non-left sided sleep position was independent of other known risk factors for late stillbirth, such as obesity. The association between maternal sleep position and late stillbirth risk was strongest on the last night, but a trend towards significance was also seen in the earlier time periods in pregnancy.

As the absolute risk of late stillbirth for an individual pregnant woman in a high income country is low (3.09/1000 in our study population), for women who did not sleep on the left side the increased risk would still be small in absolute terms (about 3.93/100), although this finding could be important at a population level if confirmed in other studies.

As far as we are aware, no other studies have described such an association. However, some studies have explored the impact of maternal position in late pregnancy on cardiac output and fetal oxygen saturation.^{28–31} Because of the anatomical position of the inferior vena cava and the aorta, the enlarged uterus can exert greater pressure on these vessels when the mother lies in a supine or right lateral position compared with the left lateral position, thus inhibiting venous return and decreasing uterine blood flow.³¹ Milsom and Forssman found that there was a

Table 5 | Multivariable analysis of relation between maternal sleeping practices and risk of late stillbirth among 155 women who experienced a late stillbirth and 310 controls

Practice	Adjusted odds ratio (95% CI)*	P value of difference
Maternal sleeping position in last night of pregnancy:		
Left side	1.00	$\chi^2=7.77$, P=0.005
Right side	1.74 (0.98 to 3.01)	
Back	2.54 (1.04 to 6.18)	
Other	2.32 (1.28 to 4.19)	
Regular sleep in daytime in last month of pregnancy:		
No	1.00	$\chi^2=9.23$, P=0.002
Yes	2.04 (1.26 to 3.30)	
Hours of night time sleep in last month of pregnancy:		
<6	1.89 (0.98 to 3.65)	$\chi^2=6.13$, P=0.05
6–8	1.00	
>8	1.71 (0.99 to 2.95)	
No of times getting up to toilet during last night of pregnancy:		
>1	1.00	$\chi^2=9.99$, P=0.002
≤1	2.42 (1.46 to 4.00)	

*Adjusted for age, ethnicity, overweight or obesity, parity, social deprivation level, smoking, and the other variables in the table.

gradient of effect of maternal body position on cardiac output, with the greatest reduction in cardiac output in the supine position followed by the right lateral position when compared with the left lateral position.³¹ Another study investigated the effect of supine and right and left lateral maternal positions in labour and found a similar gradient of effect between these positions and fetal oxygen saturation.²⁹ Further studies have compared maternal and physiological parameters in supine and left sided positions and have also shown adverse effects in the supine position compared with the left-sided position, such as decreased uterine blood flow²⁸ and reduced pulsatility index in the fetal middle cerebral artery (a surrogate for fetal hypoxia).³²

Although daytime sleepiness was not found to be associated with late stillbirth risk, sleeping regularly in the daytime was associated with increased risk. This may seem contradictory, but there is not a direct correlation between the two variables. Women who are able to go to sleep in the day may feel less sleepy overall. These findings may also reflect what happens during daytime sleep; for example, women who sleep during the day may spend additional time in a non-optimal position. Data were not collected on daytime sleep position, and so this speculation could not be tested.

An association between length of sleep and risk of late stillbirth has not previously been described. However, quantity of sleep, both too little³³ and too much,¹⁹ is associated with poor health outcomes unrelated to pregnancy.

Getting up to the toilet frequently at night was also found to be associated with an independent reduction

in risk of late stillbirth. Again, no previous studies have explored this association.

Strengths and limitations of study

This is the first case-control study of risk factors for stillbirth that selected controls from the pregnant population matched by gestation. This method of control selection allowed for a comparison of maternal lifestyle practices between cases and controls at a similar gestation in pregnancy. This is also the first study that has explored the potential relation between a range of maternal sleep habits in pregnancy and risk of late stillbirth.

We were not able to validate maternal sleep position in the current study, but participants often had reference points to remember their sleep position, such as, “I always faced away from the door,” “I slept facing my husband,” and similar comments. Case-control studies are potentially subject to differential misclassification or recall bias. Misclassification reduces the ability to detect a difference between the cases and controls. Recall bias was reduced as far as possible in this study by using a structured interview and by ensuring that participants were not aware of the study hypotheses being tested. Sleep position and getting up in the night have not previously been related to stillbirth, so it is unlikely that recall bias had a significant impact on our findings. There is also the possibility of bias due to the length of time between stillbirth and interview, which was 25 days on average, compared with controls, who were asked about sleep practices on the previous night. However, findings from studies about risk factors for sudden infant death syndrome have shown that women could remember in great detail the events leading up to and around the time of their baby’s death.^{34,35}

It was not always possible to be certain as to the exact timing of fetal death, and therefore there is potential that in some cases the “last night” was not the final night before fetal death or during which the baby died. However, we also saw a relation between position on going to sleep in the last month and late stillbirth risk that is consistent with the association seen on the last night.

The recruitment rate for this study was 72% for both cases and controls. Although this is a reasonable rate of recruitment for such a study³⁶ and there were no significant differences in age, parity, or ethnicity between those who did and those who did not consent,¹⁵ there is still a possibility of selection bias in the current study population. It is also possible that there is some other, as yet unidentified, confounding factor(s) that is associated with both the position that women choose to sleep in at night and late stillbirth risk.

This is the first time that an association has been described between maternal sleep practices and late stillbirth risk, and the findings need to be treated with caution. Further studies, ideally with prospectively collected sleep data, are urgently needed to confirm or refute our findings.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Maternal body position in pregnancy has been shown to influence maternal cardiac output and fetal oxygen saturation

No published studies have investigated maternal sleep position and other sleep related factors and the risk of late stillbirth

WHAT THIS PAPER ADDS

Women who did not go to sleep on their left side on the last night before fetal death had a doubled risk of late stillbirth compared with women who went to sleep on their left side

The absolute risk of late stillbirth for women who went to sleep on their left side was 1.96/1000 and was 3.93/1000 for women who did not go to sleep on their left

Women who got up to the toilet once or less on the last night and those who regularly slept during the day in the last month were also at higher risk of late stillbirth

Conclusions

Our study has identified a potentially modifiable risk factor for late stillbirth; women who did not sleep on their left side on the last night had a doubled risk of late stillbirth compared with those who slept on their left side. This is a new observation, and confirmatory studies are needed before public health recommendations can be made. However, if our findings are confirmed, promoting optimal sleep position in late pregnancy may have the potential to reduce the incidence of late stillbirth.

Contribution: TS participated in the design and coordination of the study, carried out the data collection, and drafted the manuscript. JMDT participated in the study design and assisted with statistical analysis and drafting the manuscript. EAM participated in the conception and design of the study, advised on the statistical analysis, and helped draft the manuscript. AJE participated in the design of the study and helped edit the manuscript. JMZ participated in the design of the study and helped to edit the manuscript. LMEM participated in the conception and design of the study and helped to draft the manuscript.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: TS, JMDT, and EAM received support from Cure Kids for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The Northern X Regional Ethical Committee approved the study in June 2006 (NTX/06/05/054).

Data sharing: No additional data available.

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