

# Fetal surveillance from 39 weeks' gestation: an alternative to earlier induction of labour to reduce stillbirth in South Asian born women? A Retrospective Cohort Study

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## Abstract

**Objectives:** In July 2017, Victoria's largest maternity service implemented a new clinical guideline aimed to reduce the rates of stillbirth at term for South Asian-born women. Here we present the evaluation of the change in care on rates of stillbirth, neonatal and obstetric interventions. **Design:** Cohort Study **Setting:** Victoria's largest metropolitan university-affiliated teaching hospital. **Population:** All women receiving antenatal care who gave birth in the term period between January 2016 and December 2020. **Methods:** Differences in rates of stillbirths, neonatal deaths, perinatal morbidities, and interventions after July 2017 were determined. Multigroup interrupted time-series analysis was used to assess changes in rates of induction of labour. **Main Outcome Measures:** Rates of stillbirths, neonatal deaths, perinatal morbidities, and obstetric interventions. **Results:** 3506 south Asian-born women gave birth prior to, and 8532 after the change. There was a 64% reduction in term stillbirth (95%CI 87% to 2%;  $p=0.047$ ) for south Asian-born women after the change in practice from 2.3 per 1000 births to 0.8 per 1000 births. The rates of early neonatal death (3.1 per 1000 vs 1.3 per 1000;  $p=0.03$ ) and SCN admission (16.5% vs 11.1%;  $p<0.001$ ) also decreased. There were no significant differences in admission to NICU, Apgar<7 at 5 minutes, birthweight or differences in the trends of induction of labour per month. **Conclusions:** Fetal monitoring from 39 weeks' may offer an alternative to routine earlier induction of labour to reduce the rates of stillbirth without causing an increase in neonatal morbidity or obstetric interventions.

## Introduction

It is widely acknowledged that the rates of stillbirth are higher among women of South Asian background (e.g. India, Sri Lanka, Pakistan and Bangladesh) compared to other women in high income countries around the world<sup>1-10</sup>. The drivers of this are likely multifactorial, but one potential contributing mechanism is earlier fetoplacental maturation. Evidence in support of this hypothesis includes south Asian women having a shorter duration of pregnancy<sup>8, 9</sup>, higher rates of fetal compromise in late pregnancy<sup>11</sup> and during labour<sup>12</sup>, more functionally mature babies at preterm gestations<sup>13</sup> and an earlier and more rapid increase in the risk of stillbirth at the end of pregnancy than in other women<sup>8</sup>. We have previously shown that south Asian women at 39 weeks' gestation have similar rate of stillbirth to Australian born women at 41 weeks<sup>8</sup>.

Leading maternity guidelines (NICE guidelines, Royal Australia and New Zealand College of Obstetricians and Gynaecologists Guidelines (RANZCOG)) recommend routine ultrasound assessment and/or induction of labour at 41 weeks to reduce the rates of stillbirth. However, by the time south Asian born women are offered these tests to assess fetal wellbeing they are already at between 2 and up to five times the risk of stillbirth compared to the Australian-born population<sup>1, 14, 15</sup>. The most recent NICE guidelines have recommended earlier induction of labour from 39 weeks for all women of South Asian background. However,

widespread criticism and concern around this recommendation<sup>16</sup> have been highlighted and there is currently no evidence to suggest that earlier induction for south Asian women would reduce their rates of stillbirth.

In July 2017, informed by our observations of biological variation in gestation length and gestation specific stillbirth rates in South Asian women, Monash Health, Victoria's largest maternity service implemented a new clinical guideline. The new guideline recommended twice weekly "post-term" monitoring to assess fetal wellbeing (cardiotocography (CTG) and measurement of amniotic fluid) from 39 weeks for south Asian women rather than the 41 weeks it had previously been and remains for all other women. Here we present the evaluation of the impact of the change in clinical care for south Asian women on rates of stillbirth, neonatal and obstetric interventions.

## Methods

### *Study Design*

A cohort study of all women receiving antenatal care and planning to give birth at Monash Health, Victoria's largest metropolitan university-affiliated teaching hospital caring for about 10,000 women per year across three separate hospital sites of different acuity levels (Clayton, Dandenong and Casey) between January 1st, 2016 and Dec 31st, 2020 was undertaken. Women who gave birth at term or beyond ([?] 37 completed weeks gestation) to a singleton baby and who were booked and received antenatal care at the health service were included.

Maternal self-reported country of birth was classified into regional groups, as defined by the United Nations<sup>17</sup>. As the change in clinical practice was specific only to women from south Asia, we then classified women as either as being born in South Asia (SA) if they were born in Afghanistan, Bangladesh, Bhutan, India, Iran, the Maldives, Nepal, Pakistan, or Sri Lanka or not ("Other women").

Data was extracted from the Monash Health Birthing Outcomes System (BOS). BOS is an electronic database recording all births [?]20 weeks' gestation. For each birth the attending midwife, supported by routine data validation, enters 46 data items into BOS. This data is included in formal state and national perinatal statistics.

### *Exposure Definition*

All births that occurred between January 2016 and June 30<sup>th</sup> 2017 were classified as "unexposed" and those occurring between July 1<sup>st</sup> 2017 and December 2020 were classified as "exposed" to the clinical practice change.

### *Description of the Clinical Practice Change*

In collaboration with Monash Health, we amended the Monash Health Prolonged pregnancy guideline to include a specific pathway for women who were of South Asian background (based on women self-identifying their background regardless of where they were born). The original clinical guideline recommended twice weekly fetal surveillance with cardiotocography (CTG) and measurement of amniotic fluid at 41 weeks gestation. Our change to the guideline recommended that takes place from 39 weeks' gestation for women born in South Asia. The fetal surveillance monitoring remained unchanged for all other women. For all women, including south Asian women, an induction of labour is recommended from 41 weeks and close to 42 weeks unless sooner as clinically indicated. The clinical guideline is provided as Appendix 1.

### *Primary Outcome Measure*

The primary outcome was stillbirth occurring either before the onset of labour (antepartum death) or during labour (intrapartum death).

### *Secondary Outcome Measures*

Secondary outcomes included neonatal death <7 days, admission to special care nursery, admission to neonatal intensive care, Apgar score < 7 at 5 minutes, baby birth weight (grams), gestation of birth, induction of

labour, and mode of birth.

### *Maternal Demographics*

The following maternal demographics were also extracted: Maternal age (years), maternal body mass index, parity, maternal medical conditions (pre-existing hypertension, pre-existing type 2 diabetes, pre-existing thyroid disease, gestational hypertension, pre-eclampsia and gestational diabetes).

### *Statistical Analysis*

All continuous data were assessed for normality and summary statistics were reported as mean (standard deviation), median (interquartile range) or number(percent) as appropriate. Demographics of the women before and after the guideline was implemented were tabulated compared using either a *t*-test, a Kruskal Wallis or  $\chi^2$  test as appropriate. The rate of stillbirth per 1000 births before and after the guideline for south Asian born women and all other women were determined. The association between the change in clinical practice and rates of stillbirth was then determined using log linked generalised linear regression. Adjustment with maternal age, BMI, parity, and presence of pre-existing medical conditions (pre-existing hypertension, type 2 diabetes or thyroid disease) or obstetric conditions (gestational hypertension, pre-eclampsia and gestational diabetes) was also performed. The rate of stillbirth per ongoing week for south Asian born and all other women before and after the change in practice was determined and plotted. Differences in secondary outcomes stratified by maternal exposure group before and after the change in practice were also tabulated and compared using standard approaches. When evaluating the impact of interventions to reduce stillbirth, understanding potential harms or changes to intervention rates need to be balanced. The rates of induction of labour are widely acknowledged to be increasing therefore pooling and comparing rates before and after the change is not appropriate. Therefore we performed a two-group, interrupted time-series analysis using Newey-West standard errors and a lag of 1 to determine the change in rates of induction of labour over time following the implementation of the guideline, taking into account the trends in induction over time prior to the guideline between south Asian and all other women<sup>18</sup>. We did not correct for seasonality. All statistics were performed using StataCorp 12.

### *Patient and Public Involvement.*

Patients and the public were not involved in this research however the experiences of clinical staff have been formally captured<sup>19</sup> and the experiences of South Asian born women themselves will be reported elsewhere.

### *Funding*

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## **Results**

Between January 2016 and December 2020, a total of 12 095 women with a singleton pregnancy gave birth at term prior to the change in clinical practice and 28 162 gave birth after it was implemented. One third of women giving birth at Monash Health in both time periods were themselves born in South Asia. The characteristics of the women who gave birth in the two time periods are presented in Table 1. There was a total of 3506 south Asian born women in the period prior to and 8532 in the period after the change in practice.

The rates of stillbirth at term before and after the change in practice are presented in Table 2. Prior to the change in practice the rate of stillbirth at term for south Asian born women was 2.3 per 1000 births.

This was 2.6-fold higher than the overall rate for all other women (0.9 per 1000 births) at the health service ( $p=0.06$ ). After the change in practice there was a 64% reduction in rate of stillbirth (95%CI 87% to 2%;  $p=0.047$ ) for south Asian born women after adjustment for potential confounders. The rate of stillbirth for south Asian born women after the change in practice reduced to a rate that was equivalent all other women giving birth at Monash Health.

The rates of stillbirth per on going week before and after the change in practice are presented in Figure 1. For south Asian born women prior to the change in practice the rates of stillbirth increased earlier and at a steeper rate for each advancing week of gestation when compared to all other women. After the change in practice, we observed a 45% reduction in the rate of stillbirth at 38 weeks, a 60% reduction at 39 weeks and there were no stillbirths that occurred at 40 weeks or beyond. The rates of stillbirth per on going week for all other women are also presented. Overall, the rates of stillbirth from 37-39 weeks remained the same across the whole study period and there was an observed 25% reduction in the rate of stillbirths at 40 and 41 weeks in the post period.

The rates of secondary outcomes before and after the change in practice and the impact of the practice change on the rates of induction of labour are presented in Table 3 and Figure 2. For south Asian born women, the rates of early neonatal death (3.1 per 1000 vs 1.3 per 1000;  $p=0.03$ ) and SCN admission (16.5% vs 11.1%;  $p<0.001$ ) decreased after the change in practice and there were no significant differences in admission to NICU, Apgar<7 at 5 minutes or baby birthweight. Similar to what was observed with stillbirth rates, the rate of NND for south born women following the change in practice became equivalent to all other women. Review of the timing of NNDs revealed that prior to the guideline NNDs were experienced following birth between 38- and 41-weeks' gestation and following the change in practice the NNDs that occurred were all born below 40 weeks' gestation. Prior to the change in practice the median gestation of birth for south Asian born women was  $39^{+3}$  (IQR  $38^{+4}$  to  $40^{+1}$ ) weeks and this reduced by 1 day in the period after the change in practice  $39^{+2}$  ( $38^{+3}$  to 40) weeks ( $p<0.001$ ). There were no differences in the mode of birth following the change in practice. For comparison the rates for all other women who were not undergoing earlier monitoring are also presented.

The overall rates of induction of labour were significantly higher following the change in practice for both south Asian and all other women. The impact of the change in practice on trends in rates of induction of labour for South Asian born women compared to all other women are presented in Figure 2. South Asian born women initially (January 2016) had an absolute 3% higher rate of induction of labour (95% CI 0.3% to 4.8%;  $p=0.03$ ) compared to all other women at the maternity service. For both south Asian and all other women, the rates of induction of labour increased in the period prior to the change in practice, however there was no difference in the slope of this increase between south Asian and all other women (-0.05%, 95% CI -0.3% to 0.2%;  $p=0.67$ ). Immediately following the change in practice, the rates of induction in south Asian born women were 4.9% higher (95% CI 1.3% to 8.5%;  $p=0.008$ ) than in all other women however there was no significant difference in the rate of change of induction rates per month after the change in practice in south Asian born women when compared to all other women (-0.1%, 95%CI-0.3% to 0.1%;  $p=0.41$ ). Finally, in the period after the change in practice the rates of induction did not significantly change per month in south Asian born women (0.02%, 95% CI -0.08% to 0.1%) however all other women experienced a 0.17% increased rate of induction per month (95% CI 0.10% to 0.20%;  $p<0.001$ ).

## Discussion

### *Main Findings*

We found that a change in clinical care to offer fetal wellbeing surveillance from 39 rather than 41 weeks in gestation for south Asian born was associated with a significant reduction in the rates of both stillbirth and neonatal death at term without increasing rates of perinatal morbidity, early term birth or interventions such as induction of labour or caesarean birth. Following the change in clinical care the rates of stillbirth for south Asian born women were equivalent to all other women at the maternity service and we did not observe any stillbirths or neonatal deaths after 39 weeks' gestation. To our knowledge this is the first stillbirth

prevention intervention for migrant women globally.

### *Strengths and Limitations*

Strengths of our study include the uniformity of the implementation of the change in practice across the 3 three separate hospital sites, the large number of south Asian born women (Monash Health cares for one third of all south Asian born women giving birth in Victoria), a longer follow up post implementation of 3.5 years thus determining whether any benefits or harms were sustained over time, and we studied all women who received antenatal care and gave birth at Monash health using routinely reported mandatory validated health data to minimise bias. Limitations of our study were that it was an observational study at one Health Service. However, Monash Health is the largest maternity service in Victoria, caring for women of all acuity level. While it is also possible that other stillbirth prevention approaches may have influenced the rates of stillbirth in south Asian women this is unlikely as rates did not change for all other women. This analysis included 2020. The COVID 19 pandemic and extended lockdowns in Victoria may have influenced our results, however cases of COVID 19 were low in Victoria and there were no impacts on the rates of stillbirth either at Monash Health<sup>20</sup> or more broadly in Victoria<sup>21</sup>. Finally, we have analysed the data by maternal region of birth not identified maternal background. The clinical guideline offered earlier monitoring to any woman of south Asian background, regardless of where she gave birth. Any associations we report are therefore likely underestimated.

### *Interpretation*

While there is good evidence that induction of labour from 41 weeks' gestation reduces the rates of perinatal mortality<sup>22</sup>, what to do prior to 41 weeks is less clear. The increasing rates of induction of labour and early term birth are a growing global concern due to their association with adverse neonatal<sup>23</sup>, childhood<sup>24</sup>, neurodevelopmental and educational outcomes<sup>25, 26</sup>. Induction of labour from 39 weeks' gestation has been suggested as a solution to balancing these risks, however this has yet to be demonstrated as effective<sup>27</sup>. Evidence suggests that many women would also prefer to wait for labour to start naturally<sup>28</sup> or regret their decision to accept an induction of labour<sup>29</sup>. Observational data from the Netherlands has suggested that over 3500 inductions at 39 weeks would be needed to prevent adverse neonatal outcomes in African women, another group at higher risk of stillbirth<sup>30</sup>. To our knowledge there have been no studies examining the impact of earlier induction labour for south Asian women. It is therefore not surprising that the new NICE guidelines, recommending that Asian and Black women should undergo induction of labour from 39 weeks have received widespread criticism due to their lack of evidence, for being racist, discriminatory and for not placing the desires and expectations of the woman at the centre<sup>16, 31-33</sup>.

Our approach to offer earlier fetal monitoring for south Asian women provides an alternative solution, using established clinical tools that are already embedded in clinical care. The implications to maternity care providers are that this change in practice can be readily implemented. While a randomised controlled trial of earlier monitoring would offer the best evidence, this may no longer be possible as equipoise is lost. Future studies should therefore focus on improving the sensitivity and predictive ability of fetal monitoring through the addition of other ultrasound or serum biomarkers, determining the economic cost to services associated with offering earlier monitoring compared to earlier induction of labour and capturing the views and experiences of south Asian born women on stillbirth prevention strategies.

### *Conclusion*

In conclusion, earlier fetal monitoring from 39 weeks gestations offers an alternative to routine earlier induction of labour to not only reduce the rates of stillbirth, but also neonatal death at term in south Asian born women without causing an increase in neonatal morbidity or obstetric interventions.

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We would like to acknowledge the staff at Monash Health for their hard work caring for women following the implementation of the new guideline.

## Disclosure of Interests

All authors have completed the *Unified Competing Interest form* (available on request from the corresponding author) and declare financial support from the Red Nose Foundation, the National Health and Medical Research Council (NHMRC) Centre for Research Excellence(CRE) and a NHMRC programme grant (APP1113902); 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.

## Contribution to Authorship

MDT and EW conceived the study. All authors designed the study. MDT acquired the data and performed the data analysis. All authors were involved in the review of the data analysis and interpretation. MDT drafted the manuscript and all authors contributed to revisions and approved the final version for publication.

## Details of Ethics Approval

This low risk research was approved by The Human Research Ethics Committee of Monash Health (HREC/18/MonH/171)

## Transparency Statement

MDT affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

## Data Sharing

The datasets analysed for the current study are not publicly available as they are a clinical dataset of patient outcomes

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