

Classification system for IOL

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Methods of classification for women undergoing induction of labour: a systematic review and novel classification system.

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Methods of classification for women undergoing induction of labour: A systematic review.

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TITLE:

Induction of labour: the development and application of a novel classification system.

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Running title: Classification system for IOL

ABSTRACT

OBJECTIVE

To develop and demonstrate the applicability of a classification system for induction of labour (IOL) that fulfils recognised classification system attributes for clinical, surveillance and research purposes.

DESIGN

Proof of concept.

SETTING, POPULATION

Applicability demonstrated in a population cohort of 909,702 maternities in New South Wales, Australia, 2002-2011.

METHODS

A multidisciplinary collaboration developed a classification system through a systematic literature review, development of a clinically logical model, and presentation to stakeholders for feedback and refinement. Classification factors included parity (nulliparous, parous), previous caesarean section (CS), gestational age (≤ 36 , 37-38, 39-40, ≥ 41 weeks gestation), number (singleton, multiple) and presentation of the fetus (cephalic, non-cephalic). We determined: the size of each classification group, the contribution each group made to overall IOL rates, and within-group IOL rates (calculated as proportions of all maternities, all maternities excluding prelabour CS and of all continuing maternities).

MAIN OUTCOME MEASURES

Applicability of IOL classification using routinely collected obstetric data.

RESULTS

A 10 group classification system was developed. Of all maternities, 25.4% were induced. Nulliparous and parous women without a prior CS at 39-40 weeks gestation with a singleton cephalic-presenting fetus were the largest groups (21.2% and 24.5% respectively) and accounted for the highest proportion of all IOL (20.7% and 21.5% respectively). The highest within group IOL rates were for nullipara (53.8%) and multipara (45.5%) ≥ 41 weeks gestation.

CONCLUSION

We propose a classification system for IOL that has the attributes of simplicity and clarity, utilises information that is readily and reliably collected and reported, and enables standard characterisation of populations of women having an IOL.

KEYWORDS

Labour induction; classification; categorisation; pregnancy.

INTRODUCTION

Induction of labour (IOL), which involves the selective early delivery of the fetus by artificially commencing labour, is commonly practised in modern maternity care. It is performed when the perinatal and/or maternal risks of continuing the pregnancy are thought to be higher than the risks of IOL.¹

The effect of IOL on pregnancy outcomes when compared to expectant management (i.e. continuing pregnancy) are contested. Traditionally, IOL has been thought to increase the risk of a caesarean section (CS) outcome compared to awaiting spontaneous labour,^{2,3} but recently this has been questioned with two systematic reviews^{4,5} suggesting that IOL is associated with a lower risk of CS compared to expectant management. Another concern is that although IOL rates have increased in the developed world in the last decade, there has not been a commensurate decrease in neonatal mortality⁶ or morbidity.⁷ Women having IOL with different characteristics would be considered to be at variable risk for these outcomes and heterogeneous study populations may in part explain the disparate findings.⁸

In order to assess the effects of IOL, a classification system is required. Typically, IOL is classified on the basis of the indication for IOL [BJOG 2014-SR-14469; under review], which has major limitations due to the inconsistencies and subjectivity associated with indication-based classification systems. A robust method of classification would allow examination of IOL practice with resultant maternal and perinatal outcomes, among homogeneous groups of women having an IOL, thereby better informing clinical practice.

Rates of IOL also vary according to the denominator used (e.g. all maternities, all women who labour or population-at-risk). When a clinician decides delivery is required, the option is to offer an IOL or a CS. Hospitals with high prelabour CS rates may have low IOL rates among all maternities, but not necessarily among women who labour. Furthermore, high rates of IOL at 37 weeks gestation result in fewer women still pregnant beyond 37 weeks

gestation. Therefore, denominator selection potentially has a large impact on the interpretation and comparison for rates of IOL.⁹

Our aim was to develop a classification system for IOL that fulfils the attributes of a clinically useful classification system;¹⁰ that enables local, regional and international comparisons; and facilitates surveillance and research. We used population data to inform gestational age groupings and demonstrate applicability of the proposed classification system. Finally, we aimed to assess the impact of denominator selection on the interpretation of the findings.

METHODS

Development of a new classification system for IOL

A systematic review evaluating methods of classifying women having an IOL [BJOG 2014-SR-14469; under review] identified the Robson classification system for CS¹¹ as a potential base to develop a similar classification system for IOL. The Robson classification system is a recognised, internationally accepted and established method for classifying CS¹² and fulfils the attributes of a clinically useful classification system (namely the concepts of ease, clarity, mutually exclusive and totally inclusive, prospectively identifiable, available data, clinical utility and implementable¹⁰). It allows comparison of clinical practice across centres and investigation of differences in practice and outcomes.¹³⁻¹⁸

However, our multidisciplinary team consisting of obstetricians, epidemiologists, policy-makers and biostatisticians, found that directly applying the Robson classification was problematic for IOL. One of the categorising factors is the 'course of labour and delivery', with women at term having an IOL being grouped together with women having a prelabour CS (nulliparae in Robson Group 2, multiparae in Robson Group 4). A recent study of variation in CS rates among the subgroup of nulliparous women with IOL (Robson Group 2A) showed large unexplained variation in CS rates after adjusting for casemix, labour and delivery and hospital factors; this was not apparent in the prelabour CS rates [BJOG 2014-

OG-14132; under review]. Unexplained variation in CS rates after IOL at term was thought to be due to the heterogeneous nature of the population of women undergoing IOL ≥ 37 weeks gestation, a group that includes women having IOL for post term pregnancy, social IOL at 39 weeks as well as women with fetal or maternal complications requiring IOL at 37 weeks gestation. A system, such as the Robson CS classification but tailored to inductions, could be used for classification of IOL and would address these issues.

Therefore, we used the Robson classification system for CS¹¹ as the genesis for discussion and developed a clinically logical, hierarchical model to formulate a classification system for IOL (Figure 1). Proceeding from the Robson classification for CS, readily available and reliably collected variables were used as the basis of the classification system for women having IOL.¹¹ The variables were parity, gestational age, number of fetuses, presentation of the fetus, and previous CS. Our approach was to group women based on the likelihood of similar clinical decision-making and management around IOL. First, we separated singleton and multifetal pregnancies (Figure 1). Among singletons, we divided by presentation and then parity. For parous women, a prior CS had to be taken into account. Finally we created 4 gestational age categories. Consideration of all these issues eventuated in a hierarchical, mutually exclusive but totally inclusive 10 group classification system for women having an IOL.

The proposed system was presented and considered at multidisciplinary clinical, academic, research, and government-sponsored policy forums for feedback and refinement. We also examined population data to assess whether the groups identified *a priori* were homogeneous with respect to their IOL rates.

Groups 1-6

All women with a singleton, cephalic fetus at ≥ 37 weeks gestation without a prior CS were categorised according to parity (nulliparous vs. multiparous) and gestational week group (37-

38 weeks gestation, 39-40 weeks gestation and ≥ 41 weeks gestation), making 6 groups in total (Table 1). The decision to group women of ≥ 37 weeks gestation into 3 gestational age groups was based on several factors. Firstly, there is increasing recognition of a difference in perinatal outcomes between the early term births (37-38 weeks gestation), full term births (39-40 weeks gestation), and late term births (40-41 weeks gestation)¹⁹ such that the American College of Obstetricians and Gynaecologists have formally changed the definition of term births into the previously described categories. Furthermore, examination in population data by gestational week showed homogeneity in IOL rates conforming to the 3 distinct groups: 37-38 weeks gestation, 39-40 weeks gestation and ≥ 41 weeks gestation, especially among the multiparae (Figure S1). Finally, different clinical recommendations for IOL management for women would occur at different gestational ages within this group. For example, women at 41 weeks gestation would be induced because they have reached 41 weeks gestation, based on evidence recommending IOL due to perinatal risks of continuing beyond this gestation,²⁰ in contrast to IOL at 37 weeks gestation, where indication is based on evidence of fetal compromise (e.g. growth restriction) and/or maternal disease (e.g. preeclampsia).

Group 7

Nulliparous and multiparous women (no previous CS) at preterm gestations ($\leq 36+6$ weeks) with a singleton cephalic fetus were grouped together. Combined, they represent a small population subgroup 4.2% (Table 1). It is primarily the gestational age that makes this group unique and governs clinical decision making, and therefore this group was not subcategorised by parity. This group also includes those women who have an IOL due to fetal anomalies and preterm stillbirths.

Group 8

Group 8 comprises *parous women with a prior CS and a singleton cephalic pregnancy, regardless of gestation*, as the prior CS leads to different clinical decisions in offering and

conducting the IOL. Clinical decision-making for both nulliparous and multiparous women who have had a prior non-CS uterine scar (e.g. due to hysterotomy or prior myomectomy) may be similar to those parous women who have previously had a CS. However, the group of women who have had a prior non-CS uterine scar is thought to be small and information on prior non-CS uterine scars is not available in most routinely collected perinatal data collections.²¹ Hence, for pragmatic reasons, this group was restricted to parous women with a prior CS.

Group 9

All women with non-cephalic presentations (i.e. breech presentation, transverse lie, oblique lie, compound presentations) of a singleton pregnancy, regardless of gestation comprise the next group (Table 1; Figure 1). These women are categorised separately as it is the presentation that will determine the clinical decision to have an IOL. This group could be further divided as some presentations are clearly not suitable for IOL and generally make a small contribution to overall IOL rates.

Group 10

All women with multifetal pregnancies, including women with a prior CS were categorised together (Figure 1). The decision to separate this group is based on clinical management of these women; decisions for delivery and IOL will be primarily based on the risks unique to multifetal pregnancy. Group 10 already represents a small number of women (1.5% of all births; Table 1), but can be subdivided if necessary for further analysis by the presentation of the first fetus, parity and the presence of prior CS.

Finally, consideration was given to the women who cannot be categorised into any of the clinically relevant groups due to missing information; i.e. one or more of the classification variables were not available. An additional group has been previously suggested as an

amendment to the Robson classification for CS.^{17,22} The size of this group is also an indicator of data quality.

To assess the applicability of potential IOL classification groups, we applied them to population data for all maternities in New South Wales (NSW); the most populous state in Australia, accounting for one third of Australian births.

Study Population

The study population included all maternities from 2002 to 2011 recorded in the NSW Perinatal Data Collection (PDC), which is a legislated population-based surveillance system covering all live births and stillbirths of at least 20 weeks gestation or at least 400 grams birthweight. Maternal demographic, medical and obstetric information and infant outcomes were reported by the treating medical practitioner or midwife. Multifetal pregnancies were treated as one maternity. Records were linked to previous pregnancy records to maximise information on prior CS. Variables are reliably reported in the PDC, with IOL reporting having sensitivity 92.5% and positive predictive value 96.1%.²³ IOL information has been collected since inception on the PDC as an 'onset of labour' variable with checkboxes for 'spontaneous', 'induction' or 'no labour'. In NSW, further information is collected on the method of induction, but this is not widely available in routinely collected perinatal data.²¹

Data analysis

The relative size of each classification group as a proportion of all maternities was determined and then the contribution of IOL in each group as a percentage of all inductions. Finally, the IOL rate within each classification group was determined using different denominators: (i) all women in the classification group; (ii) women in the classification group who laboured: that is, excluding women who had prelabour CS; (iii) all women potentially at risk of being induced. For example women who are still pregnant at 39+0 weeks are "at risk"

of being induced during the 39th gestational week, and if they give birth at 39 weeks gestation they will not be “at risk” of being induced at 40 or more weeks.

Ethical approval was obtained from NSW Population and Health Services Research Ethics Committee (Reference No. 2012-12-430).

RESULTS

From 2002-2011, the population data included 909,702 maternities in NSW. Of these, 98.5% were singleton births, 95.4% had a cephalic presentation at birth, 25.4% had IOL and 16.6% had a pre-labour CS. Of all maternities, 42.1% were nulliparous, while overall 14.1% had a previous CS. The majority of women delivered at 39 or 40 weeks gestation (54.2%); with only 6.6% of maternities delivering before 37 weeks of gestation, 22.4% between 37-38 weeks, and 16.7% at 41 weeks or more gestation. The majority of maternities (76.8%) were the result of a single cephalic pregnancy at 37 or more weeks gestation to a woman who had not had a previous CS.

Application of the 10 Group classification system

The 10 groups of the IOL classification system are listed, described and applied to population data, in Table 1. In this population cohort, only 2407 maternities (0.26%) were unable to be classified because they were missing one or more of the necessary variables. There were no missing data on plurality, but there were records with missing information pertaining to presentation of the fetus (n= 895, 0.10%), gestational age (n= 143, 0.02%), parity (n= 293, 0.03%) and previous CS (n= 1,198, 0.13%) (Table 1). Furthermore, there were 168 (0.02%) records with no information on labour onset.

Nulliparous and parous women without a prior CS, 39-40 weeks gestation with a singleton fetus in cephalic presentation (Groups 2 and 5) were the largest groups, comprising 21.2% and 24.5% of all maternities respectively (Table 1). Not only were these the largest groups,

but they also accounted for the highest proportion of overall IOL, comprising 20.7% and 21.5% of total IOL respectively (Table 1). Parous women who have had a prior CS (Group 8) comprised the next largest group, accounting for 13.1% of all maternities. The smallest group was women with a multifetal pregnancy (Group 10), consisting of 1.5% of all maternities, while women who had a fetus in a non-cephalic presentation (Group 9) was the group that contributed least to overall IOL (1.0% of all IOL).

Like the relative size of the groups, there were differences in labour induction rates within each group. The highest within group IOL rates (using all women in the group as the denominator) were women at $\geq 41+$ weeks gestation (Group 3 and Group 6), with 53.8% of nulliparous women and 45.5% of multiparous women respectively being induced (Table 1). There was also a tendency (stronger for multiparous women but also present for nulliparous women) for inductions to make up a higher proportion of births at 37 and 38 weeks than at 39 or 40 weeks (within group IOL rate). Only a small proportion of women in group 8 (previous CS, single cephalic presentation) and group 9 (singleton pregnancy, non- cephalic presentaion) had an IOL with the induction rate of the group being 5.6% and 6.4% respectively (Table 1).

Assessing the impact of differing denominators

The impact of changing the denominator varied the IOL rate for some classification groups (Table 1, Figure 2). For two groups the choice of the denominator has only a slight impact on the rate of IOL: Groups 3 and 6 (those women at 41 weeks or more) (Table 1, Figure 2A). In these two groups, the rate of prelabour CS is low (prelabour CS would have been done at 39 weeks gestation) and all the women who are at risk of being induced are in this group only (Table 1).

For Groups 8, 9, and 10 (women with a previous CS, non-cephalic presentation or multifetal pregnancy) the rate of IOL differs when considering IOL as a proportion of all women who laboured compared to using the other 2 denominators (Figure 2B). These 3 groups have a higher proportion of women who have a clinical indication for prelabour CS, and so the denominator that includes only women who labour almost doubles the IOL rate among women in these 3 groups.

In the 5 remaining groups (Groups 1, 2, 4, 5, 7), the IOL rate is substantially lower when all women at risk of being induced are being considered, as the denominator is larger for earlier gestational age categories (Table 1) and more women are still pregnant and are 'at risk' of being induced. Additionally, the rate for IOL is higher when only those women who labour are considered (Figure 2C).

DISCUSSION

Main findings and interpretation

We present a new classification system for IOL, which results in 10 mutually exclusive but totally inclusive groups. The system overcomes the limitations and issues faced by current IOL classification systems that are based on indication. [BJOG 2014-SR-14469; under review]. Due to the use of 5 readily available and reliably collected variables as the basis of the classification system,²¹ these proposed groups are clinically-based, simple, clear and easy to implement consistently at the institutional, regional, national and international level. As with the Robson classification system for CS, this classification system can be used to monitor and compare rates for IOL within institutions and across populations, analyse trends over time, compare differences in maternal and perinatal outcomes, be used for clinical benchmarking and measures of clinical quality performance.¹²⁻¹⁸

Depending on the purpose of the study, substantial differences in rates of IOL will be found if different denominators are used. For some groups, the denominator used will not make a

substantial difference to the rate of IOL, and since the denominator of all women in the group is the simplest to determine, that denominator is preferable. However, in some groups, there will be substantial differences in rates of IOL. Which denominator is used will depend on the intention of the study and the population of interest. As suggested in the context of stillbirth research,⁹ investigators might choose an 'at risk' denominator when developing a 'causal' model for IOL. When undertaking research on IOL based on a 'prognostic' model, 'all maternities' or 'all maternities who laboured' denominators may be most appropriate.

The differences in denominator choice can be illustrated when examining rates for IOL for women in Group 1 (ie nulliparous women delivering a single cephalic presenting fetus at 37-38 weeks). If the outcome of interest is perinatal morbidity and mortality for pregnancies of women in Group 1 who have an IOL compared to women in Group 1 who do not have an IOL, ie a 'causal' model, it would be more appropriate to use the rate of IOL among the 'at risk' population, as the outcomes for women who are expectantly managed need to be considered. However, if the intention is to describe trends in IOL among nulliparae at 37-38 weeks, ie a 'prognostic' model, investigators have the choice of using the rate of IOL as a proportion of all women who laboured or as a proportion of all women in the induction group. The IOL rate as a proportion of all maternities who laboured factors in the prelabour CS rate in the population, and so is useful when comparing practice across hospitals. It is important to take into account the differences in rates of IOL as a result of different denominators being used, especially when using these rates to compare across hospitals and between studies.

Strengths and limitations

The utility of this classification is demonstrated by the practical application to all maternities in NSW over a 10 year period (2002-2011). A high proportion (99.7%) of the population of maternities in NSW were classified, indicating evidence of a good classification system.²⁴

The system allows easy sub-classification within the groups if more detail is required; for instance the group that includes pregnant women with the fetus in non-cephalic presentation (Group 9) may be subdivided by parity or the presentation (for example breech, compound, shoulder) who will have different probabilities of vaginal birth to examine differences in outcomes for IOL in these subgroups. This system will allow institutions, provinces and countries to compare homogeneous groups of women having an IOL and their birthing outcomes, contributing to improvement and guidance for current international quality measures or indicators²⁵⁻²⁷ designed to measure IOL process performance in obstetric care.²⁸ Furthermore, subject to the availability of data, analyses can be extended to an examination of indications for IOL within the homogeneous groups of the classification system.

A limitation in classifying IOL is differing definitions of IOL between countries, and even between different maternity units within the same country. Different definitions are related to uncertainty about whether IOL includes artificial rupture of membranes and whether augmentation of labour with oxytocics are misclassified as IOL.²⁹ It is recognised that the ability to compare rates of IOL across different jurisdictions requires consistency in the definition of IOL.^{10,29} Internationally, there are efforts to standardise obstetric definitions.³⁰ The lack of consensus on the definitions of core variables has also been recognised as a challenge for the Robson classification system for CS on which the IOL is based.¹⁰

The clinical applicability of this system will require testing by other researchers. We are confident that through the multidisciplinary consultation and feedback, that this classification system will be functional and practical. Additionally, like all classification systems, it may require modification over time, based on increasing medical knowledge and understanding of disease processes.

Conclusion

We suggest a novel classification system for IOL that has the attributes of simplicity and clarity, utilises information that is readily and reliably collected and reported, overcomes the problems associated with indication based classification and enables standard characterisation of populations of women having an IOL. This system should facilitate local, regional and international comparisons of rates of IOL and improve the ability to compare homogeneous populations of women having IOL to understand differences in health outcomes for women and their babies.

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DISCLOSURES OF INTEREST

We have no conflicts of interest to report.

CONTRIBUTION TO AUTHORSHIP

CR and JM conceived the study. All authors contributed to the concept and design of the study. JT undertook data preparation and provided statistical analysis, with JP providing statistical oversight. All the authors took part in drafting the manuscript, approve and take responsibility for the final manuscript.

ETHICAL APPROVAL

Ethical approval for the study was obtained from the NSW Population and Health Services Research Ethics Committee (Reference No. 2012-12-430).

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Table 1: Induction rates by 10 group classification for induction of labour

Induction Group	Maternities N (col%)	Inductions N (col%)	% induced /group	% induced	
				/laboured in group	% induced /at risk*
1) Nulliparous, 37-38 weeks, single cephalic presentation	64,749 (7.1)	18,552 (8.0)	28.7	33.3	5.5
2) Nulliparous, 39-40 weeks, single cephalic presentation	192,706 (21.2)	47,849 (20.7)	24.8	26.4	17.6
3) Nulliparous, 41+ weeks, single cephalic presentation	79,041 (8.7)	42,519 (18.4)	53.8	55.1	53.8
4) Multiparous, no previous CS, 37-38 weeks, single cephalic	76,312 (8.4)	23,335 (10.1)	30.6	33.2	6.4
5) Multiparous, no previous CS, 39-40 weeks, single cephalic	222,498 (24.5)	49,572 (21.5)	22.3	22.9	17.3
6) Multiparous, no previous CS, 41+ weeks single cephalic	63,382 (7.0)	28,833 (12.5)	45.5	45.8	45.5
7) No previous CS, <=36 weeks, single cephalic	37,867 (4.2)	7,722 (3.3)	20.4	24.8	1.0
8) Previous CS, single cephalic	119,082 (13.1)	6,645 (2.9)	5.6	16.0	5.6
9) Singleton, non-cephalic presentation	37,675 (4.1)	2,407 (1.0)	6.4	18.4	6.4
10) Multi-fetal pregnancy	13,983 (1.5)	2,952 (1.3)	21.1	36.9	21.1
Missing data	2,407 (0.3)	614 (0.3)	25.5	34.0	25.5
Total	909,702 (100)	231,000	25.4	30.4	-

* 'at risk': includes those maternities that are 'at risk' of induction. For example, all nulliparous women with a single cephalic pregnancy from 37 weeks gestation onwards are 'at risk' of being induced at 37-38 weeks gestation (Group 1), regardless of whether they then go on to give birth at 37-38 weeks gestation (Group 1), 39-40 weeks gestation (Group 2) or ≥41 weeks gestation (Group 3). Thus, the 'at risk' denominator for Group 1 includes all women in Groups 1, 2 and 3.

Figure 1: Hierarchical nature of the 10 group classification system for induction of labour

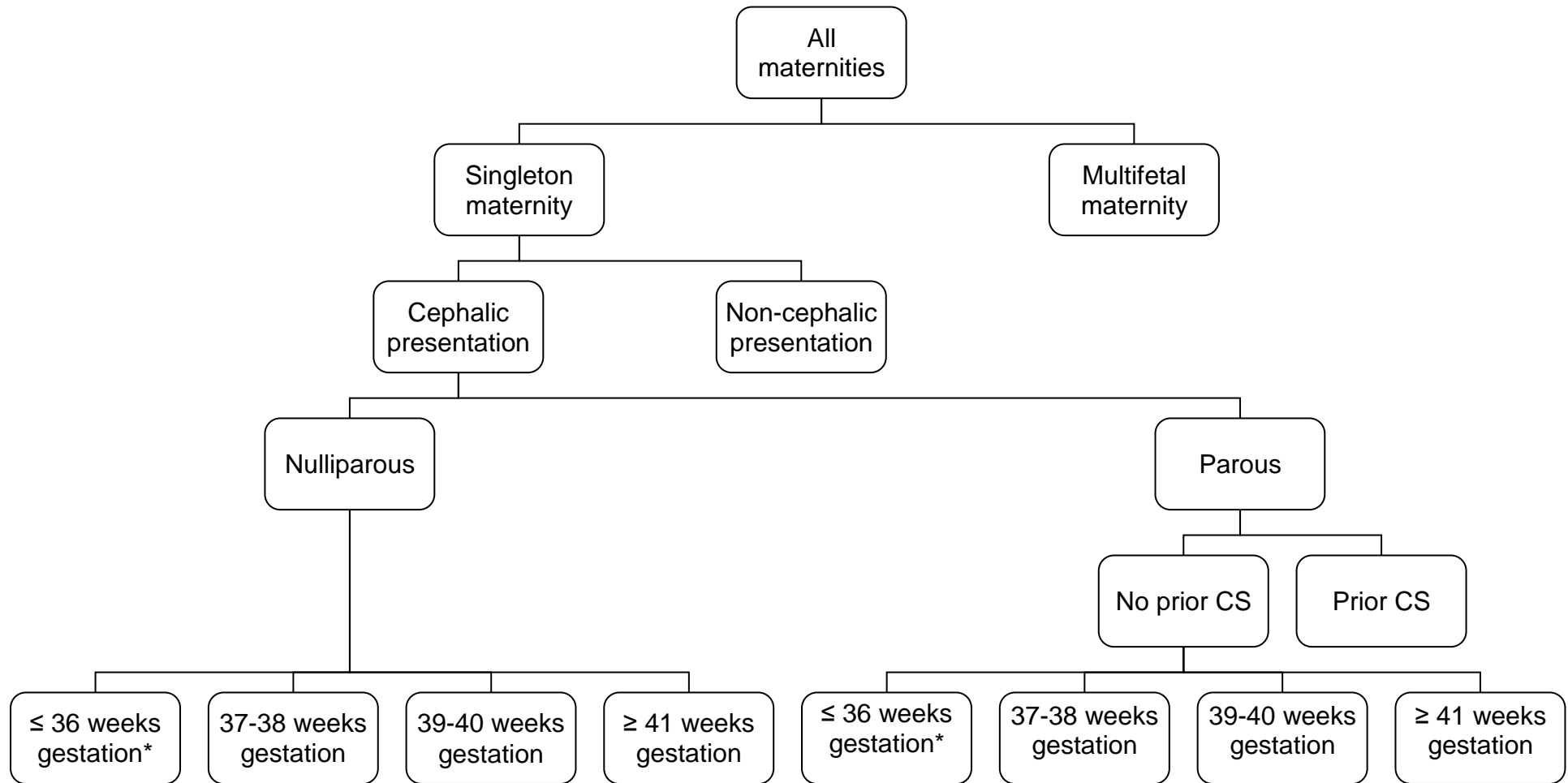


Figure 2: The induction rate in each of the 10 induction groups, calculated as a percentage of (i) all women in the induction group, (ii) women in the induction group who laboured or (iii) all women at risk of being induced.

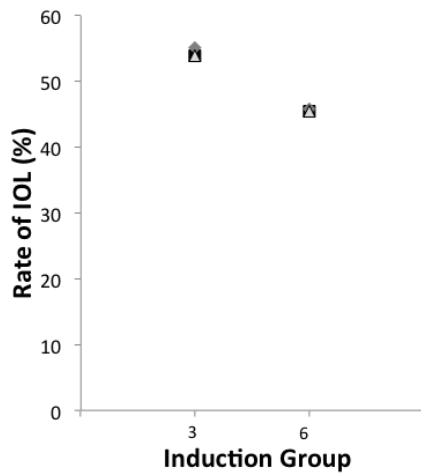


Figure 2A: Induction Groups 3 and 6 showing no difference in induction of labour (IOL) rate by denominator choice.

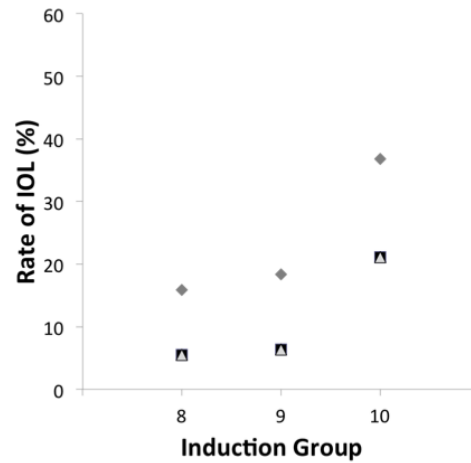


Figure 2B: Induction Groups 8, 9 and 10, showing a difference in IOL rates when using the denominator of all women who laboured compared to either all women in the induction group or all women at risk of being induced.

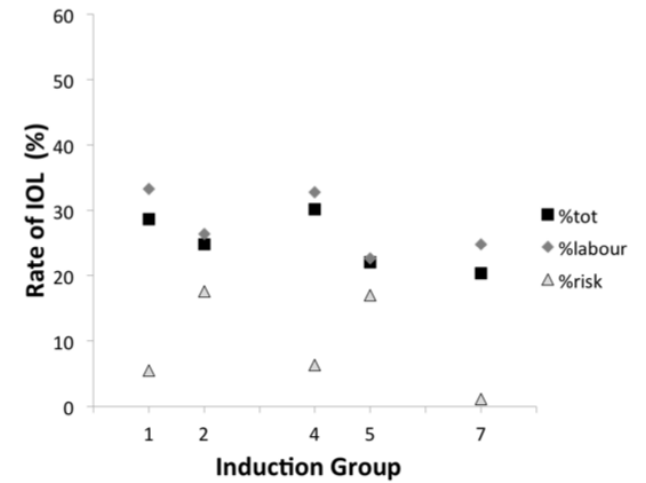
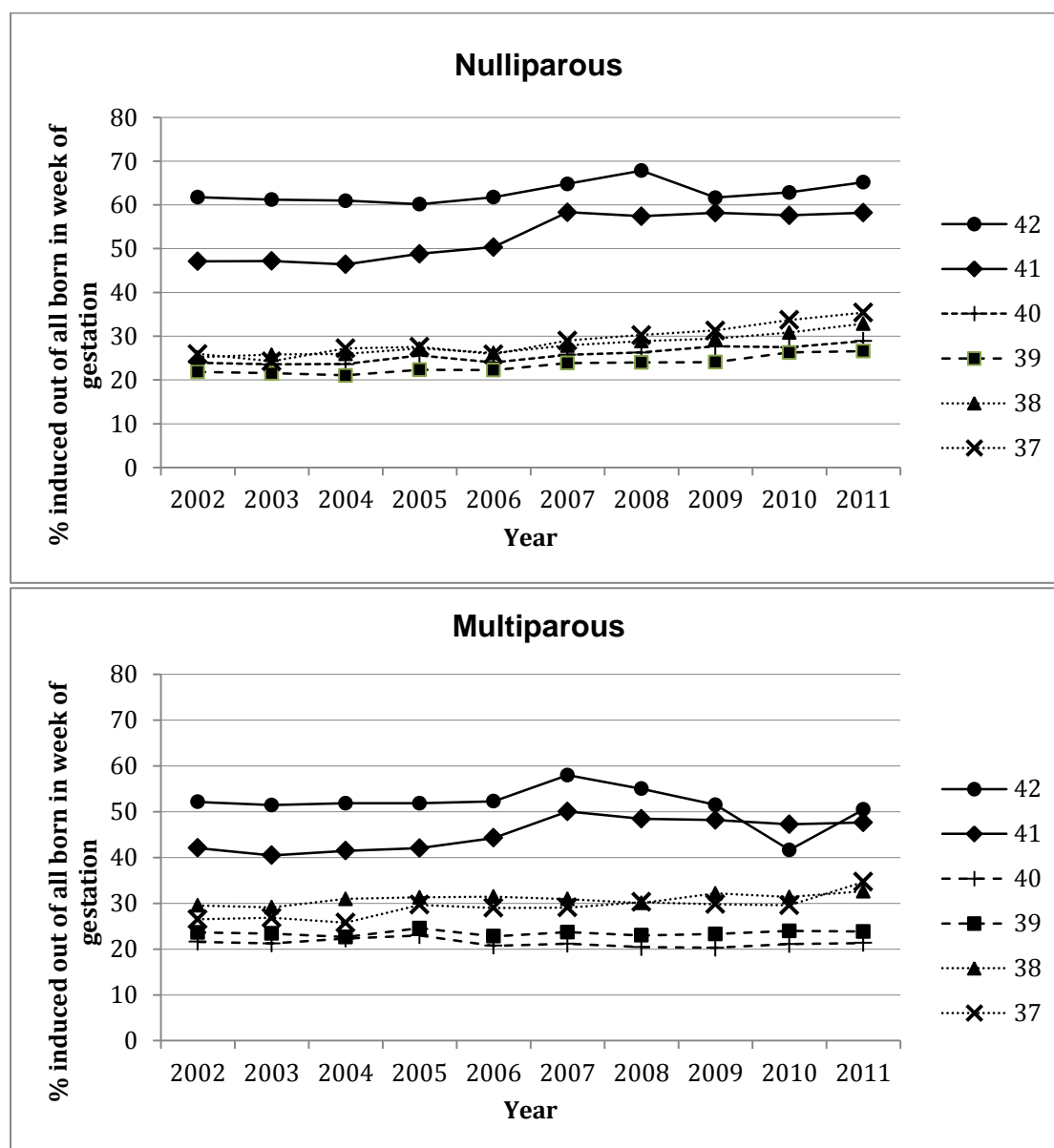


Figure 2C: Induction Groups 1, 2, 4, 5 and 7, showing the differences in IOL rates among the Groups when using any of the denominators.

Figure S1. The induction rate in each week of gestation (calculated as a proportion of the number of births in that week), separately for nulliparous women (top graph) and multiparous women (bottom graph).



(note that 'week 42' includes all births from 42 weeks onwards)

APPENDIX S1

IOL by gestational age among women with singleton, cephalic pregnancies at 37 weeks and beyond.

To inform the classification of women with singleton, cephalic pregnancies of ≥ 37 weeks gestation, IOL rates were calculated by each gestational week for nulliparae and multiparae (Figure S1). For both nulliparous and parous women, IOL rates were higher for women at 41 and 42 weeks gestation compared to 37 to 40 weeks gestation. Among multiparae, IOL rates were also higher at 37 and 38 weeks than at 39 and 40 weeks, although this pattern was less obvious among nulliparae. For both nulliparae and multiparae, the rates of IOL were similar at 37 and 38 weeks gestation, at 39 and 40 weeks gestation, and ≥ 41 weeks gestation, thus forming these three categories of gestational age.