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Commentary

Elective induction of labour: The problem of interpretation and communication of risks

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ARTICLE INFO

Article history:

Received 8 June 2012

Accepted 9 June 2012

Keywords:

Induction of labour

Prolonged pregnancy

Risk

Decision making

Induction of labour is one of the most commonly performed procedures in maternity care in developed countries, experienced by over 20% of pregnant women (approximately 160,000 women annually in the UK (UK National Statistics)). Current guidelines suggest that it should be used in situations where the risks to mother or baby of continuing pregnancy outweigh the risks of artificially bringing the pregnancy to an end (NICE, 2008). Where medical complications (for example, pregnancy hypertension, renal or liver disease or diabetes) are present the dangers are relatively clear and thus the balancing of risks is reasonably straightforward. However, around 50% of labour inductions are performed in the absence of recognised medical complications (Grivell et al., 2011; Stock et al., 2012). In these situations uncertainty persists about the appropriate timing, risks and benefits of induction, leaving significant room for both professional debate and maternal concern.

The majority of labour inductions conducted in the absence of medical complications are performed because pregnancy is considered to be prolonged. Prolonged pregnancy, defined as pregnancy continued beyond 294 days (42 completed weeks), is consistently associated with an increase in risk of perinatal death although the absolute risk remains low (NICE, 2008). A recent Cochrane review (Gulmezoglu et al., 2006) reported that a policy of preventing prolonged labour by induction at 41 completed weeks gestation or beyond led to fewer (all-cause) perinatal deaths (1/2,986 vs. 9/2,953; relative risk (RR) 0.30;

95% confidence interval (CI) 0.09–0.99). Prolonged pregnancy is also associated with risk of complications such as macrosomia, birth trauma and meconium aspiration (Olesen et al., 2003).

Despite these well accepted risks there can remain professional uncertainty in operationalizing any policy regarding labour induction. Firstly, although low, the risk clearly exists, leaving midwives and obstetricians knowing that perinatal death will occur at some point, but not knowing which woman will be affected. Secondly, induction of labour itself has been associated with increased risk of caesarean section and haemorrhage (Joseph et al., 2007; Grivell et al., 2011; Rossen et al., 2011; Burgos et al., 2012), and there is evidence that it is associated with longer, more painful labours and reduced satisfaction for women compared to spontaneous labour (Shetty et al., 2005). Thirdly, evidence remains unclear about the optimum timing of induction (Gulmezoglu et al., 2006; Hussain et al., 2011). All of these uncertainties, risks and benefits can lead to confusion and more conservative practices as staff attempt to interpret and weigh the evidence and manage their own willingness to tolerate risk.

Debate concerning the benefits, risks and resultant policy guidance surrounding induction in this climate of uncertainty is nothing new, and stems back to the introduction of oxytocin around the middle of last century (Kortenoever, 1950; Wrigley 1958). Changing recommendations for timing of induction of labour have reflected this ongoing uncertainty (Gulmezoglu et al., 2006). Present UK guidance (NICE, 2008) recommends that women with uncomplicated pregnancies should be offered induction of labour between 41+0 and 42+0 weeks gestation, and that all women should be offered information about the risks associated with prolonged

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pregnancies as well as the risks and benefits of induction of labour and their care options (NICE, 2008).

It is apparent however, that there is a spectrum of risk and benefit facing pregnant women and their clinicians; in deciding whether to perform induction of labour they have to weigh up the value they place on the consequences of each possible outcome and their belief about how likely it is to occur (probability), this creates a personal decision threshold for taking action. Research in other contexts suggests that the individual decision threshold may be influenced by past experiences (Dagleish et al., 2010) and will be strongly affected by the desire to act to avoid very negative consequences, in this case perinatal death, even if this means accepting large numbers of (if hindsight were possible) unnecessary inductions. This weighting towards *'erring on the safe side'* is characterised by the Blackstone Ratio, described in judicial decision making as follows: *better that ten guilty persons go free than one innocent person suffer* (Dagleish et al., 2010). Translated to decision making for induction of labour this could mean: better 1,000 labour inductions than one perinatal death.

Where medical complications are present the severity and probability of risks are high and known, thus the benefit of induction is relatively clear. Where otherwise uncomplicated pregnancy continues beyond 41 weeks the probability of risk increases, the baseline risk remains low *but* the risk level is severe and again evidence is reliable. In this situation current NICE guidance (2008) provides a decision threshold for clinicians. The dilemma facing practitioners is what decision to make when risks of induction are more common but are both less severe *and* evidence is less reliable. This is the contemporary problem facing prolonged pregnancy in the 40–41 weeks period. For these women there is conflicting evidence about the risks of more frequently occurring but less severe, complications of induction which yet may impact on the well-being of mothers and babies.

The complexity of these judgements may explain the widely variable rates of induction of labour between and within developed countries. For example, in 2004 the induction of labour rates for Sweden, France and Malta were 10.8%; 19.8% and 37.9% respectively (Euro-Peristat Project, 2008) while rates across consultant units within Scotland in 2010, varied between 17% and 32% (ISD Scotland, 2010), it seems unlikely that these variations can be explained by clinical factors alone. Indeed, it has been reported that between one quarter and half of cases induction cannot be explained by accepted clinical reasons (Humphrey and Tucker, 2009; Grivell et al., 2011); these variations are likely to be due to clinician or women's personal decision thresholds.

Against this background a new study published in the British Medical Journal (Stock et al., 2012) re-ignites the debate about appropriate timing of elective induction of labour, particularly in the 40–41 weeks period. The study makes a clear and valuable contribution to the empirical evidence to support decision making; however, it also poses real and significant challenges and dangers, not least in the increasingly complex demands that it potentially places on midwives and obstetricians in the communication of newly acquired risk knowledge and appropriate choices regarding this commonly used intervention.

The study (Stock et al., 2012) is a population based, retrospective cohort of all singleton births at 37 weeks gestation or greater in Scotland between 1981 and 2007. Using validated routinely collected data and record linkage, data was collected for 1,271,549 births. Outcomes were compared at each week of gestation between 37 and 41, comparing women who received elective induction of labour, defined as induction of labour in women who had no recognised medical indication for induction, and women who were expectantly managed. The study found that at each gestation studied elective induction of labour was associated with *decreased* odds of extended perinatal mortality

(stillbirth and death within the first month of life excluding death associated with congenital abnormalities), compared with expectant management. At 40 weeks gestation the odds ratio was 0.39 (99% confidence interval 0.24 to 0.63, 0.08% (37/44,764) v 0.18% (627/350,643)), without a reduction in the odds of spontaneous vertex delivery or increase in maternal morbidity. However, for all gestations, elective induction of labour was associated with significantly increased admission to neonatal units, at 40 weeks the odds ratio was 1.14 (99% confidence interval 1.09–1.20), 8.0% (3605/44,778) vs. 7.3% (25,572/350,791)). These findings indicate that at 40 weeks gestation 1,040 women would require elective induction (CI 792–1,513) to prevent one case of extended perinatal mortality, however an additional seven babies would be admitted to the neonatal unit. The authors conclude that elective induction of labour at 40 weeks gestation can reduce perinatal mortality.

This study has the potential to substantially influence maternity services across developed countries; although, clinicians first need to ask the question—are the findings trustworthy? To answer questions about the effectiveness of induction a randomised controlled trial (RCT) would clearly be preferential. However, such studies face significant ethical and practical barriers; not least of which would be the enormous numbers of women required to take part in order to detect a single adverse outcome. In the absence of an experimental design an observational based study in the form of a cohort study, as used by Stock et al., (2012) is optimal. Not only is this study to be recommended but the use of population based record linkage avoids many of the typical pitfalls of this design, namely atypical sample selection and loss to follow-up. Routinely collected health data in Scotland is acknowledged to be among the best in the world in relation to completeness and validity, more recently introduced data linkage has permitted high quality epidemiological data analysis to be conducted with a high level of confidence.

The major weakness of the retrospective cohort design is that while it enables a comparison between outcomes for women who have and who have not been induced, these women were non-randomly allocated to elective induction or expectant management and therefore may be different in some way. The important question this raises is whether the findings that elective induction reduces perinatal mortality is due to the induction itself or to some other difference between the groups. Typically this is the case for all cohort studies and simply means that unlike an RCT there is real potential for confounding in the findings. In this study there is some potential evidence to suggest that the women in the induction and expectant management groups might have been different. Firstly, a clinical decision was made to induce labour therefore, the possibility does exist that it is not the induction of labour that is the key factor but rather some other unknown factor associated with it, which explains why the decision to induce was made. Secondly, the babies in the elective induction of labour group had a higher rate of admission to the neonatal unit, while this might be seen as a cost of the extra induction; it may also be taken as evidence that there could have been some prior, underlying and unrecorded reason why induction was undertaken in this group. Thus, the intervention that is being evaluated is not elective induction of labour alone but also the decision to induce labour, and unfortunately and we do not know what informed that decision. These factors were not included in routine records available for data linkage, and therefore could not be accounted for in any analysis. Therefore, strictly speaking the benefits of one less perinatal death in 1,040 elective inductions may only be obtained if the whole intervention is replicated (same clinical decision making process + elective induction).

In a retrospective study design we are completely dependent on prior records and cannot record novel information prospectively.

In this case we are left with an absence of information on precisely why each labour was induced, and importantly why the baby was later admitted to a neonatal unit. In relation to induction real risk factors may have existed, this means that we cannot compare the groups. If we take these findings at face value and induce labour in 1,040 women who reach 40 weeks gestation then we may not get the benefit of the extra life saved.

In this study known risk factors such as maternal age, parity and socio-demographic factors were accounted for in the analysis. However, this only accounts for the dichotomous variable (present or absent) leaving a number of important aspects which are unknown. For example, we do not know if the clinical response to these and other unknown risk factors was too high or too low in general. Both would impact on our interpretation of the study findings. If a real risk factor existed but was not detected or appropriately acted on then some women may have continued to, or beyond term and had increased mortality in the expectant management group. This would mean that the current 1/1,040 is an underestimate of the potential benefit of elective induction. However, the converse is also possible, if the risk response of clinicians was overly cautious that would mean that some women were being unnecessarily induced then the 1/1,040 benefit is an over estimate as clinicians were already generously assessing and triaging women.

As discussed above, the decision about timing of induction, in the absence of medical complications, is one that is made under the conditions of uncertainty; i.e. there are risks and benefits associated with each of the options and their probabilities are often unknown. Current decision making in relation to induction of labour is highly risk averse, our decision thresholds for the outcome of perinatal death is understandably low and we act to avoid negative consequences. It is feasible that the findings of [Stock et al. \(2012\)](#) could further reduce thresholds resulting in a shift in clinical practice toward a policy of elective induction at 40 weeks gestation. The consequences of this potential change can be considered in relation to the likelihood that the study findings are trustworthy.

If the findings are trustworthy then lives of babies could be saved by offering elective induction at 40 weeks gestation. If this policy was implemented across England alone it could result in approximately 79,000 additional labour inductions annually (www.hesonline.nhs.uk). The study suggests that for every 1,040 inductions one perinatal death would be avoided at the cost of seven additional neonatal unit admissions therefore 76 babies lives would be saved each year and there would be an additional 532 neonatal unit admissions. There would be increased NHS costs for care of women in labour who may require more intensive monitoring, additional pain relief and possibly more caesarean sections and there would be reduced satisfaction with care. More particularly, there would be additional neonatal unit costs associated with increased numbers of admissions as well as unknown levels of longer term health problems for these babies.

If the findings are not trustworthy then the reported benefits stem not only from induction but also potentially from unknown characteristics of the women and/or the decision making process that was already happening in practice. If these aspects are implicated then rolling out induction to all women at 40 weeks gestation would incur at least the opportunity costs while producing a much lower level of benefit i.e. many more inductions would be required to achieve one less perinatal death. In conclusion *if* the findings are true then we have benefits but at the same time a massive operational problem for maternity service providers and if they are not true then we have dubious benefit and a massive operational problem for maternity service providers.

How then can we respond to the findings of this paper? There is evidence within the decision making literature to suggest that our decision thresholds are formed from the value we place on the consequences of possible outcomes (how much we want to achieve or avoid them) and our beliefs about their probability (how likely they are to occur). It seems both unlikely and undesirable that our aversion for perinatal death as an outcome will change. Therefore the only way to improve decision making about induction of labour is to improve our knowledge and understanding (belief) about how likely it is to occur. This can be achieved in two ways. Firstly, we need to obtain more evidence about the risk factors for perinatal death at 40 weeks gestation. Not all of the 1,040 women will have equal chance of stillbirth. This is too blunt—it would be more important to identify what the risk factors are for those who die as the spread of risk within these 1,040 is likely to be very varied. Some may actually have a 1 in 100,000 risk and others a 1 in 100—BUT we do not have that information at the moment. If we identify those of the 1,040 at higher risk then it all becomes more practical, cheaper and risk communication clearer.

Secondly, we need to improve our understanding and communication of the probability or likelihood of perinatal death in uncomplicated pregnancies at term and the risks and benefits of elective induction. It is widely recognised that in situations where there is no right or wrong answer from a clinical perspective and the choice involves a trade-off between risks and benefits of options, patients' personal values about the possible outcomes are likely to be central to the decision-making process ([Gafni et al., 1998](#)). Current guidance recommends that decisions about induction should be based on a discussion of risks, benefits and women's preferences ([NICE, 2008](#)). There is evidence that this is not currently happening very effectively ([Shetty et al., 2005](#)) and several issues need to be considered and addressed before this can be undertaken more effectively in routine practice. Firstly, we need to identify and test effective ways of communicating these risks to clinicians as well as women. Research in risk communication suggests that most people, including health professionals, have considerable difficulty in understanding and interpreting information on probability and risk ([Gigerenzer, 2003](#); [Bramwell et al., 2006](#)). Additionally, how information about risk is framed and presented (e.g. positive vs. negative frame, frequencies vs. odds,) affects people's judgements and subsequent decisions ([Wills and Holmes-Rovner, 2003](#); [Abhyankar et al., 2008](#)). Health professionals must be provided with effective ways of communicating risk information if they are to ensure that women are appropriately informed. However, provision of information alone is unlikely to help women take part in decisions about induction of labour ([Bekker et al., 2009](#)). There is evidence that people do not routinely make decisions systematically; they often use 'rules of thumb' in evaluating the information ([Baron, 2000](#); [Payne et al., 1993](#)) and integrating it with their personal values ([Fischhoff, 1991](#)). It would be naive to assume that merely providing professionals and women with more data will in itself improve communication and choice (<http://www.bbc.co.uk/news/health-18018067>). Maternal health policy has high ideals about quality of decision making and involvement of women, if these are to be realised further interventions will be required to facilitate a decision making process that is truly shared by women and maternity care professionals.

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