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Impacts of the ARRIVE TRIAL

Ontario Midwives respond to routine induction at 39 weeks

In August 2018, the New England Journal of Medicine published Labour Induction versus Expectant Management in Low-Risk Nulliparous Women. (1) This large (n = 6106) multicentre study in the US randomly allocated nulliparous participants to undergo elective induction at 39 weeks; or to be expectantly managed, which meant they could have a spontaneous labour, could electively induce between 40 weeks five days and 42 weeks two days, or could be induced at any point if there was a medical indication. The trial findings suggest that elective induction at 39 weeks results in significantly lower rates of caesarean section (18.6%) than expectant management (22.2%), but elective induction makes no significant difference in the risk of adverse perinatal outcomes. As this was the first randomized controlled trial on elective induction at 39 weeks, further studies are necessary to validate these findings.

A 2019 survey of members of the Association of Ontario Midwives documents growing use and acceptance of routine induction at 39 weeks in many Ontario communities. While the direct applicability of the trial's results to midwifery care in Ontario cannot be made without further investigation, midwives report an impact on client care. This document aims to support midwives in understanding and contextualizing the results of the ARRIVE trial within their communities. Key points to consider when discussing the possibility of elective induction at 39 weeks with clients and hospitals are highlighted.

RESPONDING TO CLIENTS' QUESTIONS ABOUT ELECTIVE INDUCTION AT 39 WEEKS

For clients who ask about early induction of labour, an informed choice discussion presents a key opportunity to critically appraise the ARRIVE trial and put risk into perspective. Explaining the trial results will help clients understand whether the ARRIVE trial applies to them.

Low-intervention approaches to reduce caesarean section rates:
MIDWIFERY MODELS OF CARE

The ARRIVE trial reports that nulliparous clients undergoing induction at 39 weeks have lower rates of caesarean section (CS). There are many other, low-intervention approaches associated with lower rates of CS, many of which are unique to the midwifery model of care. Two major elements of Ontario midwifery care – continuous support in labour and continuity of care – have been shown to reduce the risk of CS by 25% and increase the rate of spontaneous vaginal birth by 5%. (2,3) Planned home birth, also unique to the midwifery model of care, has been associated with lower rates of such interventions as CS, operative vaginal birth and epidural analgesia. (4) During labour, midwives use intermittent auscultation, which is also associated with lower CS rates when compared with electronic fetal monitoring typically used in obstetric care. (5) Midwives are well positioned to support clients in reducing the odds of CS without the use of induction. Nulliparous clients who are seeking a low-intervention approach may prefer these methods to induction of labour at 39 weeks.

Trial population in relation to your client:
CLIENT'S PERSPECTIVE ON INDUCTION

It is important to note that 73% of eligible birthing parents (n = 16 427) declined to participate in the ARRIVE study. Those who consented to participate (n = 6106) were open to having their labour induced at 39 weeks (intervention group); or to wait for spontaneous labour or elective induction between 40 weeks five days and 42 weeks two days, unless an earlier induction was medically indicated (expectant management group). Since induction of labour starting at 39 weeks may not be an acceptable intervention for all birthing parents, the trial results may not apply to clients who prefer to await spontaneous labour and avoid induction.

Trial population in relation to your client:
CLIENT DEMOGRAPHICS

Participants in the ARRIVE trial were defined as low risk, with "the absence of any condition considered to be a maternal or fetal indication for delivery before 40 weeks five days (e.g., hypertensive disorders of pregnancy or suspected fetal growth restriction)." (1) Participants were nulliparous, had a median age of 23 or 24 years, and had a median BMI of approximately 30 kg/m2; and 63% had an unfavourable Bishop score. Consider these demographics in relation to your client: if your client's demographics do not match the participants (i.e. nulliparous, younger, etc.) the results of the trial may not be applicable to them. If your client is interested in induction and their demographics match those in the trial, the results may be applicable. However, practice setting must also be considered.

Trial setting in relation to your practice setting:
CAESAREAN SECTION RATES AT YOUR HOSPITAL

The setting and conditions of this trial may not reflect the actual conditions in which Ontario midwives practice. The CS rates in this trial were 18% for those undergoing induction of labour and 22% for those expectantly managed. In Ontario, from 2016-2017, CS rates for in-hospital births were 31.4% for nulliparous people who were induced and 16.9% for nulliparous people who had spontaneous labour. (6) Consider the CS rates at your hospital. Hospitals in the study were encouraged to allow trial participants at least 12 hours in the latent phase after completion of any ripening, rupture of membranes, and use of oxytocin before considering the induction failed and proceeding to caesarean delivery, absent any acute maternal or fetal indication. (1) If your hospital does not currently have a similar protocol for induction of labour (IOL), results of this trial may not be applicable. Decisions outside of trial settings regarding

CS delivery are often made within the contexts of hospital protocols and labour and delivery floor cultures, which determine the management of patient flow, resource availability and staffing constraints. (7)

Trial setting in relation to your practice setting:

HAWTHORNE EFFECT

The Hawthorne (or Observer) effect is a well-studied effect that occurs in randomized controlled trials, in which the participants (in this instance the trial clinicians) alter their behaviour to perform better than they would in non-trial situations, due simply to the fact that they are being observed. Lack of blinding in this study may not have affected the measurement of the outcome, but may have contributed to the number of clients who had CS. Because we do not have access to the pre-trial CS rates for the participating hospital, it is unclear if the Hawthorne effect may be another contributing factor to the lower CS rate among participants. The low-risk CS rate in the US in 2018 was reported as 25.9%, which is higher than the rates reported in this trial. (8)

KEY POINTS TO REVIEW WITH YOUR CLIENT

- Review the aspects of midwifery care associated with a reduced CS rate, such as continuity of care, choice of birthplace, continuous labour support and use of intermittent auscultation when appropriate.
- Discuss routine interventions associated with IOL at any gestation:
  - » Oxytocin is a high-alert medication that requires electronic fetal monitoring, potentially impacting the birthing parent's ability to move freely in labour;
  - » Use of intravenous access to administer oxytocin, which may impact client comfort during labour;
  - » IOL may be a multi-day process and involve several trips to the hospital.
- Discuss your client's preferences and values regarding induction and physiologic birth.
- Discuss the demographics of the trial participants and how this may affect the applicability of the results.
- Consider your hospital's criteria for failed induction (does your hospital follow strict criteria for failed induction similar to the ARRIVE trial protocol?)
- Consider the CS rates at your hospital. Consider the CS rates at your hospital following routine induction of labour.
- Discuss Canadian guidance: in response to the ARRIVE trial, the Society of Obstetricians and Gynecologists stated "it is not appropriate to recommend elective induction solely to reduce the risk of caesarean section in an otherwise low risk nulliparous patient at this time."(9)

DISCUSSING ROUTINE INDUCTION OF LABOUR AT 39 WEEKS WITH YOUR HOSPITAL

Discussing the ARRIVE trial with other health-care providers or health administrators requires an understanding of the impact beyond the client. The uptake of routine induction at 39 weeks could impact hospital resource availability and health-care costs.

HOSPITAL RESOURCES

As mentioned above, hospitals in the study were encouraged to allow trial participants "at least 12 hours in the latent phase after completion of any ripening, rupture of membranes and use of oxytocin before considering the induction 'failed' and proceeding to caesarean delivery." (1) Furthermore, the study recommends that clients be admitted to hospital during cervical ripening. If induction at 39 weeks were to become routine, adoption of these protocols would require additional hospital staffing and resources.

COST ANALYSIS

A recent Australian cost analysis compared different methods of reducing the CS rate, including a model of care similar to the Ontario midwifery model (caseload midwifery), routine IOL at 39 weeks, chart audit and standard obstetric care. The cost analysis showed that caseload midwifery is the most cost-effective method for reducing CS rates. (10) Government support of midwifery reflects an initiative toward community-based client care and the cost savings associated with care with fewer interventions. Increasing elective inductions in a client base with an already-low CS rate could lead to increased government expenditures for midwifery clients.

KEY POINTS TO DISCUSS WITH YOUR HOSPITAL

- Does the hospital have a similar definition used in the ARRIVE trial or have plans to adopt the ARRIVE definition of a failed induction before moving to a CS?
- Does the hospital have the staffing resources and facility space available to support a substantial increase in elective inductions of labour and the conditions/protocols outlined in the ARRIVE trial?
- Will the hospital support midwifery clients through increased staffing resources or transfer of care during cervical ripening admissions and early labour?
- Does the hospital support physiologic birth, as described in the Provincial Council for Maternal and Child Health's (PCMCH) Quality Based Procedure for Low Risk Birth (membrane sweeping, one-to-one support, intermittent auscultation)? (11)
- What are the costs? Cost analysis shows that caseload midwifery may be more cost effective in reducing CS rates than elective induction at 39 weeks.

CONCLUSION

An informed choice discussion to contextualize the results of the ARRIVE trial will support client decision-making about routine induction of labour at 39 weeks. This informed choice discussion would ideally include how the trial results may or may not apply to individual clients, as well as how a midwifery approach can reduce CS rates. For birthing parents who strongly wish to have their labour induced at 39 weeks, the ARRIVE trial may provide some reassurance that IOL at 39 weeks, in select individuals where a similar IOL protocol is applied, is unlikely to result in a higher risk of CS.

However, significant questions remain regarding the applicability of the ARRIVE trial results for midwifery in Ontario. Taking these into account, use of routine induction at 39 weeks is unjustified for several reasons: the Ontario midwifery model already results in low CS rates and is more cost effective than routine elective induction; hospitals are not yet resourced to support routine elective induction at 39 weeks; and there is a lack of Canadian research to support the applicability of the trial results to midwifery practice.

Nonetheless, the ARRIVE trial provides a good opportunity to initiate rigorous informed choice discussions with clients, and to further consider these issues with hospitals from a midwifery perspective.

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