



Research Critical Analysis of Obstetric Interventions: Perspectives from the ARRIVE Trial and Subsequent Findings in Slovenia

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Abstract:

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Copyright: © 2024 by the authors. Submitted for possible open access publication under the terms and conditions of the Creative Commons Attribution (CC BY) license (https://creativecommons.org/license s/by/4.0/). The quest for optimal maternal and neonatal outcomes in midwifery and obstetrics revolves around the timing of labor induction, a subject of ongoing debate. The ARRIVE trial (A Randomized Trial of Induction Versus Expectant Management) furthered this discourse by comparing labor induction with expectant management, revealing reduced cesarean section rates and improved perinatal outcomes with induction. Concerns arose regarding the generalizability and potential biases of the ARRIVE trial's findings. European studies questioned the applicability of its findings to their populations, given demographic disparities. Despite varied results on cesarean section rates, Cochrane reviews affirmed induction's positive impact on perinatal outcomes. However, recent studies indicated increased risk for cesarean delivery for low-risk nulliparous women undergoing induction. Following the publication of the ARRIVE trial, obstetric practices worldwide experienced a notable shift towards earlier inductions. However, our own study, conducted across all 14 Slovenian hospitals, indicates a rise in labor induction rates that does not correspond with the timeline of the ARRIVE trial's publication. Specifically, the trend of inducing labor in women whose labor started spontaneously in Slovenia is concerning, suggesting a trend towards medicalization of labor. Considering the complexities surrounding the ARRIVE trial, recommendations suggest a balanced approach. Healthcare providers should offer comprehensive information, including trial findings and limitations, empowering women to make personalized decisions. This patient-centered approach ensures optimal outcomes while acknowledging the nuances of individual circumstances.

Keywords: Labor induction, Low-risk pregnancy, Gynecology and obstetrics, ARRIVE trial, Healthcare, Slovenia







1. Introduction

1.1. Navigating timing of labor induction

The practice of midwifery and obstetrics is marked by continual quest for optimal maternal and neonatal outcomes, driven by evolving clinical guidelines, seminal research endeavors and shifting paradigms. Central to this discourse is the appropriate timing of labor induction. Over the past decades, significant efforts have been directed towards elucidating the ideal gestational age for labor induction, with a particular focus on mitigating risks associated with elective inductions and promoting optimal fetal development and maternal health.

In 2009, the American College of Obstetricians and Gynecologists (ACOG) issued a statement advocating against labor induction before 39 weeks of gestation in the absence of medical indications. This guideline aimed to minimize the risks associated with elective inductions and promote optimal fetal development and maternal health (ACOG practice). Furthermore, in 2007, the March of Dimes launched the "Healthy Babies are Worth the Wait" campaign. This initiative sought to educate both women and healthcare professionals about the neurological benefits of childbirth occurring after 39 weeks of gestation for the fetus (Healthy Babies are Worth the Wait). By disseminating information on the importance of allowing pregnancies to reach full term, the campaign aimed to reduce the incidence of elective inductions and promote better health outcomes for newborns (James-Conterelli & Kennedy, 2023).

1.2. A Randomized Trial of Induction Versus Expectant Management (ARRIVE trial)

In the year 2018, a seminal study was published, which continues to be cited by scholars engaged in discourse pertaining to the induction of labour beyond the 39th week of gestation (Grobman et al., 2018). This study, now known worldwide as the ARRIVE trial (A Randomized Trial of Induction Versus Expectant Management), marked a departure from conventional inquiries by eschewing the comparison of induced labour against spontaneous labour, opting instead to contrast labour induction with expectant management – a decision-making process commonplace in obstetric practice (Grobman et al., 2018; Walker et al., 2016).

2. Methods

This retrospective cohort study utilized data extracted from the National Informational Perinatal System (NIPS), encompassing comprehensive records from all 14 hospitals across Slovenia. The study population comprised all women admitted for labor between 2002 and 2022, ensuring a representative sample across various clinical presentations. The original data is included in the appendices (**Appendix A**, **Appendix B**).

The study aimed to classify labor cases according to a modified Robson classification system based on a set of specific criteria (Rossen et al., 2017). The Robson classification system is a widely accepted method for categorizing women into groups based on characteristics that affect the likelihood of cesarean section. The criteria and classification methods applied in this study are as follows:

Group 1: Women were assigned to Robson group 1 if they were carrying a singleton fetus in cephalic presentation, at term, had spontaneous labor, and were primiparous.

Group 2: Women were assigned to Robson group 2 if they were carrying a singleton fetus in cephalic presentation, at term, had labor induced, and were primiparous. This group also includes elective cesarean sections; if these are excluded, it is referred to as group 2A. *Group* 3: Women were assigned to Robson group 3 if they were carrying a singleton fetus in cephalic presentation, at term, had spontaneous labor, and were multiparous without a previous cesarean section.

Group 4: Women were assigned to Robson group 4 if they were carrying a singleton fetus in cephalic presentation, at term, had labor induced, and were multiparous without a previous cesarean section. This group also includes elective cesarean sections; if these are excluded, it is referred to as group 4A.







Group 5: Women were assigned to Robson group 5 if they were carrying a singleton fetus in cephalic presentation, at term, were multiparous with a previous cesarean section, regardless of whether labor was spontaneous or induced.

Group 6: Women were assigned to Robson group 6 if they were carrying a singleton fetus in breech presentation and were primiparous, regardless of gestational age or whether labor was spontaneous or induced.

Group 7: Women were assigned to Robson group 7 if they were carrying a singleton fetus in breech presentation and were multiparous, regardless of gestational age or whether labor was spontaneous or induced.

Group 8: Women were assigned to Robson group 8 if they were carrying multiple fetuses. *Group 9*: Women were assigned to Robson group 9 if they had a fetus in transverse lie.

Group 10: Women were assigned to Robson group 10 if they did not fit into the previous categories and had a preterm birth.

Each woman's data was evaluated according to these criteria, and they were assigned to the appropriate Robson group accordingly. This classification allowed for the standardized comparison of labor induction outcomes across different subgroups.

3. The ARRIVE trial and its generalisability

The study cohort in the ARRIVE trial comprised 6096 eligible women, randomly allocated into two distinct groups: those subjected to labour induction and those assigned to expectant management. Analysis revealed a significant reduction in cesarean deliveries among the labor induction group compared to expectant management, alongside improved perinatal outcomes, with adverse events occurring less frequently, specifically 4.3%, as opposed to the higher incidence of 5.4% recorded within the expectant management cohort (Grobman et al., 2018).

The findings of this investigation portend implications for clinical practice and policy formulation. Specifically, they suggest that discouraging elective labor induction among low-risk nulliparous women at 39 weeks may not effectively reduce population-level cesarean section rates (Grobman et al., 2018). On a different note, James-Conterelli and Kennedy highlighted alternative strategies to reduce cesarean deliveries beyond labor induction. They emphasized the importance of considering other factors and interventions that may impact birth outcomes (James-Conterelli and Kennedy, 2023).

James-Conterelli and Kennedy (2023) provided insightful critiques in their article, highlighting several notable counterpoints regarding the ARRIVE trial. Firstly, they underscored the absence of data regarding differences in cesarean section rates among the 41 hospitals involved in the study. This omission is particularly relevant as it is known that a woman's likelihood of experiencing a spontaneous vaginal birth may be diminished in hospitals with high cesarean section rates. Additionally, the authors raised concerns about the relatively low enrollment in the study, suggesting that women who chose to participate may have held more favorable attitudes towards induction, potentially biasing the results. They also noted the absence of mention regarding the use of continuous electronic fetal monitoring, which has been associated with higher cesarean delivery rates among low-risk women (James-Conterelli and Kennedy, 2023).

An important argument put forth by the authors is the observation that the cesarean rate for the expectant management cohort in the ARRIVE trial was 22%, notably lower than the average national rates in the United States (James-Conterelli and Kennedy, 2023). This raises questions about the generalisability of the trial's findings to broader population contexts and underscores the need for further investigation into the factors influencing cesarean delivery rates (Carmichael and Snowden, 2019).

It is crucial to acknowledge that the ARRIVE trial was conducted exclusively on the American population. Consequently, there arises a pertinent question regarding the generalizability of the trial's findings and the applicability of suggested policies to countries outside the United States. European nations, in particular, exhibit distinct population characteristics and socio-cultural environments compared to the United States. Factors such as the percentage of obese women, average childbearing age, and overall sociodemographic landscape vary significantly between European countries and the United States. Notably, European women tend to be older on average compared to their







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American counterparts, yet they exhibit lower rates of obesity (Facchinetti et al., 2022). Additionally, neonatal outcomes in European countries are often superior to those observed in the United States (Facchinetti et al., 2022). Given these disparities, the authors of the study assert that the potential benefits of elective labor induction at 39 weeks, as indicated by the ARRIVE trial, may not be readily applicable to low-risk women in most European countries (Facchinetti et al., 2022).

Stock et al. (2012) conducted a population-based cohort study, reporting no significant difference in cesarean birth rates between labor induction and expectant management groups. Nevertheless, they also reported that women in the labor induction cohort exhibited a decreased likelihood of perinatal death in comparison to those who underwent expectant management. However, akin to the ARRIVE trial, the generalizability of the data is limited. Additionally, the study did not differentiate between nulliparous and parous women, despite evidence indicating distinct cesarean section rates among these demographic categories (Stock et al., 2012).

In 2018, a Cochrane review was published, clearly affirming the positive effects of labor induction on both the baby and the rate of cesarean sections (Middleton et al., 2018). The review highlighted a reduction in perinatal deaths and a lower incidence of cesarean sections in the induction group, irrespective of the timing of induction or the state of the cervix (Middleton et al., 2018). Grobman et al. (2018) observed that labor induction at 39 weeks in low-risk nulliparous women was significantly associated with a lower caesarean delivery rate but not reduced frequency of adverse perinatal outcomes. Mishanina et al. (2014) confirmed the benefits of labor induction in reducing the risk of cesarean delivery in both term and post-term gestations. However, Butler et al. (2024) identified that low-risk, nulliparous women whose labor was induced between 38 and 41 completed weeks of gestation exhibited a higher likelihood of requiring an unplanned cesarean section compared to those who underwent expectant management.

4. Changes in obstetrical practice following the ARRIVE trial

Following the conclusion of the ARRIVE trial, numerous obstetric departments encountered challenges in adapting their clinical protocols. A study in May 2022, published in the American Journal of Obstetrics and Gynecology, evaluated the impact of the ARRIVE trial on obstetric practices and perinatal outcomes (Gilroy et al., 2022). The study endeavored to compare obstetric practices and adverse perinatal outcomes between pre-ARRIVE and post-ARRIVE cohorts. Notably, individuals in the post-ARRIVE group exhibited a higher propensity for labor induction and a reduced likelihood of delivering beyond 39+6 weeks of gestation. Echoing the findings of the ARRIVE trial, these individuals also demonstrated a diminished incidence of cesarean deliveries relative to their counterparts in the pre-ARRIVE cohorts (Gilroy et al., 2022).

Moreover, subsequent to the ARRIVE trial, a conspicuous increase in both labor inductions and deliveries preceding the 39 + 6 weeks gestational mark occurred, surpassing the incremental rates observed prior to the trial (Gilroy et al., 2022). However, in contrast to the findings of the ARRIVE trial, the aforementioned study revealed a heightened occurrence of immediate assisted ventilation and prolonged assisted ventilation (beyond 6 hours) among neonates in the post-ARRIVE cohort. Additionally, neonates within this cohort demonstrated an elevated probability of presenting with a 5-minute Apgar score below 3. Nonetheless, it is paramount to emphasize that significant pre-existing upward trends had been discerned prior to the dissemination of the ARRIVE trial findings, particularly evident in the utilization of immediate assisted ventilation and prolonged assisted ventilation exceeding 6 hours. Furthermore, there was a notable escalation in Intensive Care Unit (ICU) admissions in 2019, alongside an increased demand for blood transfusions. It is noteworthy that the latter exhibited a pre-existing upward trajectory, whereas ICU admissions did not display such a trend. Despite the unforeseen surpassing of projected values for immediate ventilation requirements in 2019, it is worth noting that both maternal blood transfusions and prolonged neonatal ventilation would have registered higher frequencies in the same year had the pre-ARRIVE trends persisted (Gilroy et al., 2022).







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It has been well-established that a significant portion of women express a preference for labor induction over expectant management once they reach post-term gestational stages (Heimstad et al., 2007). However, following the ARRIVE trial, a pertinent inquiry arose: do these preferences extend to labor induction prior to the due date? Gallagher et al. (2020) sought to address this query by investigating women's attitudes towards labor induction for maternal or fetal indications, and whether their stance shifts in the absence of such indications. The study revealed overwhelmingly positive responses from participants regarding labor induction for maternal or fetal reasons. Conversely, when there were no medical indications, slightly fewer than half of the surveyed women expressed interest in labor induction before their due date (Gallagher et al., 2020).

The study highlighted the pivotal role of women's knowledge concerning labor induction. Despite exhibiting good awareness of the techniques employed for labor induction, only 27% of participants were informed about one of the primary findings of the ARRIVE trial: that labor induction reduces the risk of cesarean delivery. Moreover, nearly half of the surveyed women harbored concerns that labor induction could potentially harm their baby, a misconception refuted by the ARRIVE trial, which found no significant disparities in adverse perinatal outcomes between the labor induction and expectant management cohorts (Gallagher et al., 2020).

5. Results

An examination of labor onsets in Slovenia over the period from 2002 to 2022 yielded notable findings. Analysis of the data reveals an upward trend in the percentage of labor inductions, including elective cesarean sections, accompanied by a corresponding decrease in spontaneous labor onset. As illustrated in **Napaka! Vira sklicevanja ni bilo mogoče najti.**, the increase in labor inductions commenced prior to the publication of the ARRIVE trial in 2018, suggesting that this trial alone cannot be attributed as a significant factor influencing the observed trend.





Figure 1. Proportion of different types of labor onsets in Slovenia during the years 2002–2022.

An examination of the distribution of labor inductions in Slovenia across different Robson groups over a 20-year period, as observed in **Napaka! Vira sklicevanja ni bilo mogoče najti.**, reveals a relatively stable overall pattern. There are no significant fluctuations in the percentage of inductions among the various Robson groups. Labor inductions are most commonly performed in women whose labor started spontaneously, specifically in Robson Group 1 (nulliparous, single cephalic, \geq 37 weeks, in spontaneous labor) and Robson Group 3 (multiparous, single cephalic, \geq 37 weeks, in spontaneous labor). Although the rate of inductions in these two groups has been gradually decreasing, they continue to constitute the largest proportion of labor inductions. The increase in inductions observed



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in Robson Group 5 (multiparous with a single cephalic pregnancy, \geq 37 weeks, with at least one previous cesarean section) can likely be attributed to the rising number of cesarean sections, resulting in a higher number of women falling into this category.



Figure 2. Distribution of Labor Inductions in Slovenia by Robson Groups between 2002 and 2022.

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The predominance of labor inductions in Robson Groups 1 and 3 is concerning, as it suggests a trend towards the medicalization of labor in Slovenia. This observation raises critical questions regarding the pre-induction protocols and whether there is sufficient consistency and persistence in employing non-pharmacological and non-invasive techniques to facilitate the continuation of labor. Before proceeding with labor induction, it is imperative to rigorously and systematically incorporate methods such as changing birth positions, which have been demonstrated to enhance the strength of contractions.

6. Conclusion

Considering the various critiques and complexities surrounding the ARRIVE trial, the recommendations put forth by reputable organizations such as the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and the American College of Nurse-Midwives (ACNM) appear to offer a prudent approach. It is advised that the results of the ARRIVE trial not be uncritically adopted as universal guidelines (Carmichael and Snowden, 2019; James-Conterelli and Kennedy, 2023). The significance of education and informed consent regarding both labor induction and expectant management cannot be overstated in enabling women to make informed decisions about their pregnancies.

Our study identifies a notable rise in labor induction rates over the period examined, although the timeline does not align with the publication of the ARRIVE trial. Therefore, any direct attribution of this increase to the ARRIVE trial cannot be made. Nonetheless, the observed trend of increasing labor induction rates raises significant questions regarding the implications and thresholds of such practices. The trend towards labor inductions in Robson Groups 1 and 3 in Slovenia raises concerns about the medicalization







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of labor, emphasizing the importance of ensuring vigorous pre-induction protocols that prioritize non-pharmacological and non-invasive approaches to support natural labor progression.

Healthcare providers should exercise discretion and present laboring women with comprehensive information, including the findings of the ARRIVE trial along with its limitations. By providing transparent and balanced discussions, midwives can empower women to make informed decisions tailored to their individual circumstances. This approach ensures that women are actively engaged in the decision-making process regarding their labor induction, thus promoting woman-centered care and optimal maternal and neonatal outcomes.

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Conflicts of Interest: The authors declare no conflict of interest.

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Appendix A: Types of labor onsets in Slovenia during the years 2002 – 2022

Table 1. Types of labor onsets in Slovenia during the years 2002 – 2022.

			Spontaneous	Induction	Elective s.c.	Total		
	2002	Count	13254	3334	759	17347		
Year	2002	%	76,40	19,20	4,40	100,00		
	2002	Count	12633	3441	831	16905		
	2003	%	74,70	20,40	4,90	100,00		
	2004	Count	13107	3618	904	17629		
	2004	%	74,30	20,50	5,10	100,00		
	2005	Count	12918	3841	1128	17887		
	2005	%	72,20	21,50	6,30	100,00		
	2000	Count	13663	3787	1211	18661		
	2006	%	73,20	20,30	6,50	100,00		
	2007	Count	14427	3816	1341	19584		
	2007	%	73,70	19,50	6,80	100,00		
	2008	Count	15997	4041	1507	21545		
	2008	%	74,20	18,80	7,00	100,00		
	2000	Count	15826	4127	1530	21483		
	2009	%	73,70	19,20	7,10	100,00		
	2010	Count	16199	4067	1735	22001		
	2010	%	73,60	18,50	7,90	100,00		
	2011	Count	15907	3876	1771	21554		
	2011	%	73,80	18,00	8,20	100,00		
	2012	Count	15821	3889	1776	21486		
	2012	%	73,60	18,10	8,30	100,00		
	2012	Count	15374	3489	1772	20635		
	2013	%	74,50	16,90	8,60	100,00		
	2014	Count	15221	3512	1878	20611		
	2014	%	73,80	17,00	9,10	100,00		
	2015	Count	14749	3397	1857	20003		
	2015	%	73,70	17,00	9,30	100,00		
	2016	Count	14357	3635	1814	19806		
	2016	%	72,50	18,40	9,20	100,00		
	2017	Count	13885	3928	1913	19726		
	2017	%	70,40	19,90	9,70	100,00		
	2018	Count	13236	3959	1941	19136		
		%	69,20	20,70	10,10	100,00		
	2019	Count	13051	4104	1810	18965		
		%	68,80	21,60	9,50	100,00		
	2020	Count	12481	4179	1829	18489		
	2020	%	67,50	22,60	9,90	100,00		
	2021	Count	12384	4523	1880	18787		
	2021	%	65,90	24,10	10,00	100,00		
	2022	Count	11394	4369	1734	17497		
		%	65,10	25,00	9,90	100,00		

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Appendix B: Labor inductions by Robson Groups in Slovenia between 2002 and 2022

Table 2. Labor inductions by Robson Groups in Slovenia between 2002 and 2022.

		Missing data	Robson 1	Robson 2A	Robson 3	Robson 4A	Robson 5	Robson 6	Robson 7	Robson 8	Robson 9	Robson 10	El. s.c. 2	El. s.c. 4	Total
Year	2002	1	5809	1600	6061	1446	446	359	239	303	28	804	105	146	17347
	2003	1	5681	1637	5646	1513	475	353	191	308	33	800	103	164	16905
	2004	1	5824	1733	5885	1566	488	439	213	314	46	835	129	156	17629
	2005	2	5867	1813	5683	1679	589	469	239	298	34	868	144	202	17887
	2006	14	6213	1878	6015	1588	612	477	270	286	40	864	182	222	18661
	2007	5	6454	1837	6418	1632	666	450	247	369	46	954	203	303	19584
	2008	3	7353	1908	6901	1770	957	511	292	387	37	1066	181	179	21545
	2009	3	7154	1978	6834	1746	1113	545	262	343	38	1074	217	176	21483
	2010	2	7320	2044	7020	1608	1146	581	304	411	53	1106	222	184	22001
	2011	4	7012	1935	7103	1554	1208	561	293	394	44	1035	210	201	21554
	2012	4	6979	1920	7047	1588	1264	582	264	381	50	991	212	204	21486
	2013	3	6966	1755	6515	1419	1226	612	254	363	32	1034	195	261	20635
	2014	0	6761	1787	6586	1407	1265	561	295	347	45	1082	190	285	20611
	2015	0	6575	1738	6466	1309	1281	508	279	391	28	982	186	260	20003
	2016	2	6272	1837	6355	1445	1270	500	292	387	37	966	195	248	19806
	2017	4	5820	1954	6423	1589	1326	471	282	355	41	1005	179	277	19726
	2018	0	5554	1958	6104	1636	1352	411	284	339	37	971	197	293	19136
	2019	1	5570	2049	5904	1716	1390	441	223	346	47	885	157	236	18965
	2020	1	5411	2113	5629	1708	1334	417	258	301	46	864	158	249	18489
	2021	1	5189	2219	5778	1928	1366	447	268	263	41	852	143	292	18787
	2022	1	4956	2222	5188	1800	1197	420	219	223	38	772	158	303	17497