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Cesarean delivery after non-medically indicated induction of labor: A population-based study using different definitions of expectant management

Christoph Zenzmaier[1] | Bernhard Pfeifer[2,3] | Hermann Leitner[2] | Martina König-Bachmann[1]

[1]University of Applied Sciences Tyrol, Innsbruck, Austria

[2]Department of Clinical Epidemiology, Tyrolean Federal Institute for Integrated Care, Tirol Kliniken, Innsbruck, Austria

[3]Austrian Institute of Technology Digital Health Information Systems, Hall in Tirol, Austria

Correspondence
Christoph Zenzmaier, University of Applied Sciences Tyrol, Innrain 98, A-6020 Innsbruck, Austria.
Email: christoph.zenzmaier@fhg-tirol.ac.at

Abstract

Introduction: Most observational studies found that non-medically indicated induction of labor (IOL) is not associated with an increased risk of cesarean delivery compared with expectant management, defined as all births at a later gestation. However, given the higher rate of cesarean delivery at late term, this definition of the expectant management group might bias the results of observational studies in favor of IOL at early or full term when estimating the risk of short-term (eg up to 1 week) expectant management.

Material and methods: We conducted a retrospective cohort study including 447 066 singleton term and post-term hospital births that occurred in Austria between 2008 and 2016. Multivariate logistic regression was used to test the association of IOL and cesarean delivery at each week of gestation from 37-41. Expectant management was either defined as all births at "next week or beyond" or "at next week".

Results: Non-medically indicated IOL was associated with increased odds for cesarean delivery at 37 and 38 weeks, and reduced odds at 40 and 41 weeks. At 39 weeks, IOL resulted in comparable cesarean rates compared with expectant management defined as "next week or beyond" (17.2% vs 16.2%; adjusted odds ratio [OR] 0.93; 95% confidence interval [CI] 0.86-1.00; $P = .059$). However, when defined as births "at the next week", expectant management was associated with significantly reduced odds for cesarean delivery (13.6%; adjusted OR 0.76; 95% CI 0.70-0.82; $P < .001$). Comparison of the cesarean delivery rates for the two definitions of expectant management showed that the "next week and beyond" model underestimates the benefit of short-term expectant management by up to 1 week, particularly for IOL at weeks 38 and 39.

Conclusions: Our findings demonstrate that the definition of the expectant management group has a significant impact when analyzing the outcome of IOL in retrospective cohort studies. Non-medically indicated IOL is not an all-or-none choice between "elective" induction and indefinite expectant management. Thus, to define

Abbreviations: CI, confidence interval; IOL, induction of labor; OR, odds ratio.

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the control group as all births at the next week could be useful for clinical decision-making, as it allows to estimate the risks of expectant management until the next appointment compared with immediate IOL.

KEYWORDS
cesarean, cohort study, expectant management, induction of labor

1 | INTRODUCTION

Induction of labor (IOL) is a common obstetric intervention in developed countries. In Austria, IOL rates significantly increased over the last decade from 16.2% in 2008 to 23.9% in 2018.[1] We and others demonstrated previously that compared with spontaneous labor, IOL at term is associated with increased odds for adverse birth outcomes, particularly cesarean delivery.[2-6] However, spontaneous labor should not be considered the only clinical alternative to IOL. In fact, the outcome of IOL without clear medical indications should be compared with expectant management, the outcome of all births at a later gestation irrespective of the mode of onset of labor. Applying this approach, several observational studies found decreased risks of cesarean delivery and other adverse outcomes after "elective" IOL compared with expectant management.[7-10] The definition of "elective" IOL in these studies is mainly based on the absence of clear medical indications documented in medical records.

There is evidence from randomized controlled trials that "elective" IOL at gestation week ≥41 is associated with fewer cesarean deliveries compared with expectant management.[11] The benefit of "elective" IOL before 41 weeks is currently under debate and randomized trials addressing IOL before gestational age 41^{+0} are scarce. In 2018, Grobman et al published the findings from the randomized ARRIVE trial that IOL at 39 weeks in low-risk nulliparous women resulted in a significantly lower frequency of cesarean delivery.[12] While the clinical effectiveness of this finding in non-research settings remains uncertain, a recent meta-analysis of observational studies supported the results of the ARRIVE study demonstrating that "elective" IOL at 39 weeks was associated with a significantly lower risk of cesarean delivery in nulliparous women.[13] However, in a meta-analysis based on the results of seven randomized trials, including data from the ARRIVE trial, IOL in singleton gestations at full term (39^{+0}-40^{+6}) did not significantly affect risk of cesarean delivery.[14]

In observational studies, the comparison group for "elective" or non-medically indicated IOL is usually defined as expectant management beyond gestational age of IOL and clinical trials typically include possible IOL at 41 or 42 weeks in the expectant management group. This setting allows estimation of the effect of a policy of non-medically indicated IOL at a certain week of gestation on the obstetric outcome in a healthcare system. However, at an individual level, similar to spontaneous onset of labor not being an actual alternative to IOL, expectant management up to 42 weeks is not the sole alternative to "elective" induction at early or full term. Counseling a women and considering non-medically indicated IOL typically means deciding between prompt IOL or expectant management for some time and then reconsidering IOL if the woman is still pregnant. Thus, it is relevant to consider the risks or benefits of IOL vs expectant management until the next appointment or week. However, the overall cesarean delivery rates have been shown to increase significantly at 41 weeks and above in various countries.[15] Therefore, we hypothesized that the higher rate of cesarean delivery at late term and beyond might bias the results of observational studies in favor of non-medically indicated IOL at early or full term when estimating the risk of short-term expectant management. We investigated the impact of an alternative definition of expectant management on the odds for cesarean delivery after non-medically indicated IOL. The widely used definition of expectant management as "all births at next week or beyond" was compared with "all births at next week".

Key message

Non-medically indicated induction of labor prior to 40 weeks increases the risk for cesarean births. Inclusion of late-term births in the control group might bias study results in favor of induction of labor at 38 and 39 weeks. Weekly outcome comparisons following induction of labor and expectant management should be considered when counseling pregnant women.

2 | MATERIAL AND METHODS

We conducted a retrospective cohort study using data from all hospital births that occurred in Austria between 2008 and 2016, retrieved from the Austrian Perinatal Registry. Obstetricians and midwives of all public and private hospitals in Austria provide structured data to this registry, according to the German Quality Assurance Program (Datensatz Geburtshilfe 16/1; specification 14.0 SR. AQUA Institute for Applied Quality Improvement and Research in Health Care, Göttingen, Germany).[16] Datasets comprise demographic information, basic data on the course of pregnancy and birth as well as the perinatal outcome.

In total, 717 135 hospital births were documented in the Austrian Perinatal Registry during the study period. Exclusion criteria included

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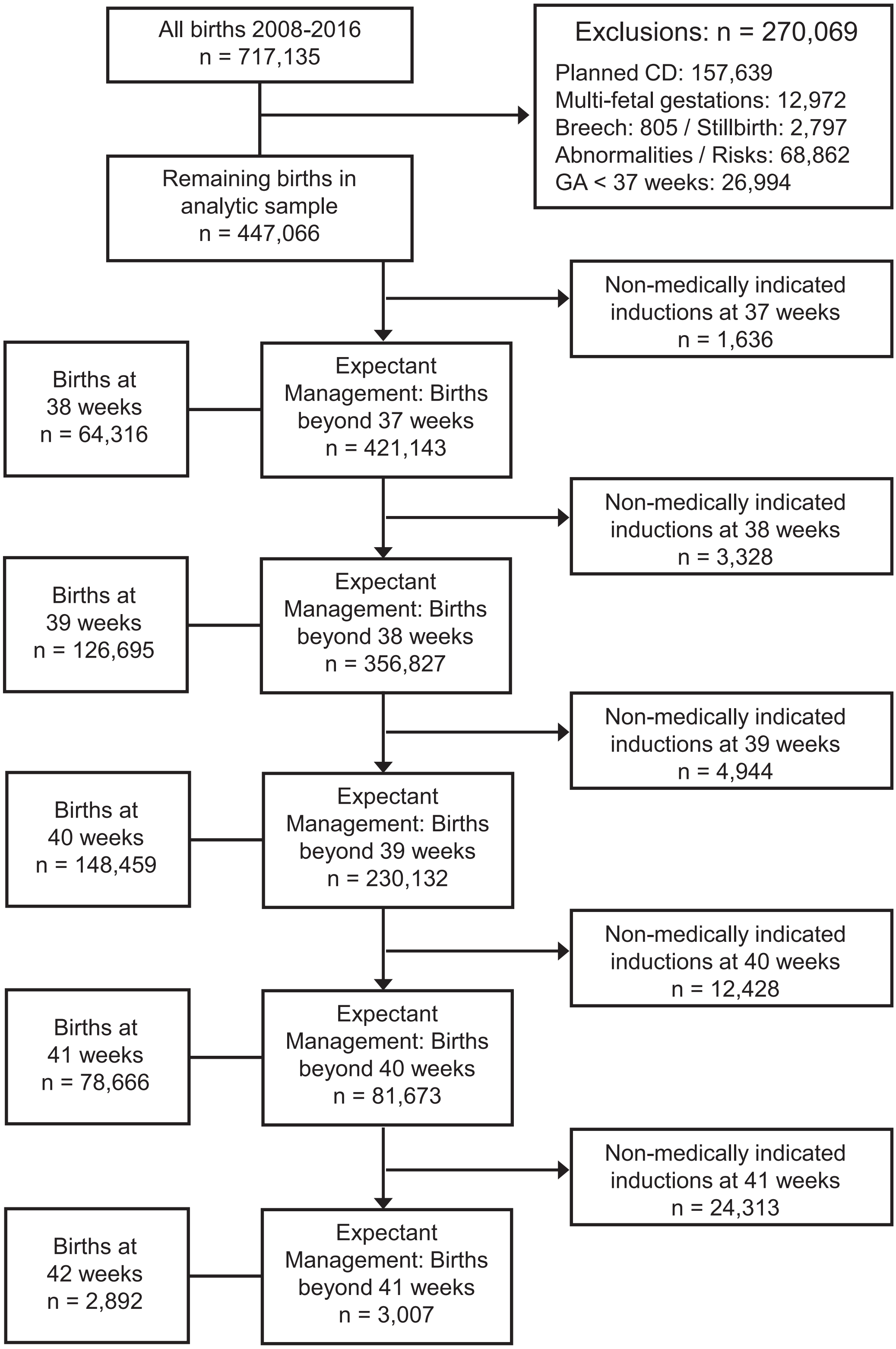

FIGURE 1 Sample flow and comparison groups for non-medically IOL compared with expectant management

planned cesarean deliveries, multi-fetal gestations, breech presentations and stillbirths. Additionally, the following antepartum conditions were excluded from the analytic sample: previous cesarean delivery or other uterine surgery, diabetes, hypertension, bleeding and thrombotic disorders, placenta previa and fetal abnormalities. After exclusion of preterm births, 447 066 singleton term and post-term births remained in the analytic sample.

To select non-medically indicated IOL the following medical indications were excluded from the induction group but were retained as part of the risk of expectant management in the comparator groups:

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prelabor rupture of membranes, placental insufficiency, premature separation of placenta, poly-/oligohydramnios, fetal distress, pre-eclampsia, eclampsia, HELLP, antepartum bleeding, amniotic infection and proteinuria.

To analyze the association of non-medically indicated IOL with cesarean delivery rates, non-medically indicated IOL study groups for each week of gestation from 37 (37^{+0}-37^{+6}) to 41 (41^{+0}-41^{+6}) were compared with expectant management. The comparator group either comprised all remaining births in the next week or beyond (eg all birth beyond week 37 starting from 38^{+0} as comparator for non-medically indicated IOLs at week 37) or all births that occurred at the next week (eg 38^{+0}-38^{+6}). Sample flow and comparison groups are depicted in Figure 1.

2.1 | Statistical analyses

Statistical analysis was performed using R 3.6.3 for Windows (https://cran.r-project.org/). Logistic regression models were applied to account for confounding. Different rates in sample characteristics and cesarean delivery were tested with the chi-square test and considered statistically significant when $P < .05$. Maternal age, pre-pregnancy body mass index, parity, duration of labor, birthweight, year of birth and hospital level were included as confounding factors. Data were additionally stratified by parity.

2.2 | Ethical approval

According to Sect. 7. (1) Federal Act Concerning the Protection of Personal Data (Datenschutzgesetz 2000) retrospective observational studies using medical records do not require approval by a research ethics committee.[17] The registry is operated and maintained by the Department of Clinical Epidemiology, Tyrolean Federal Institute for Integrated Care, Tirol Kliniken, Innsbruck, Austria, and the advisory board of the department approved the data analysis.

3 | RESULTS

The analytic sample included 447 066 singleton term and post-term births, with half of the women being nulliparous. A total of 81 609 (18.3%) of all women had IOL and 48 091 (10.8%) of these inductions were classified as non-medically indicated. Approximately half of the births after non-medically indicated IOLs were at gestational age 41^{+0}-41^{+6}. In all, 14.4% of women had cesarean deliveries with increasing rates at late term and post-term (20.4% at week 41^{+0}-41^{+6}; 34.3% at week 42^{+0}-42^{+6}).

Sample characteristics of the study groups, that is, non-medically indicated IOL and the expectant management comparison groups stratified by gestational age, are given in Table S1. All

TABLE 1 Cesarean delivery following non-medically indicated induction of labor compared with expectant management in general (births next week and beyond) or short-term expectant management (births next week)

	Non-medically indicated IOL		Births after IOL gestation week ($GA > GA_{IOL}$)				Births at subsequent gestation week ($GA = GA_{IOL} + 1$)			
Gestation week of IOL (GA_{IOL})	n	CD [%]	n	CD [%]	Adjusted OR (95% CI)	*P*	n	CD [%]	Adjusted OR (95% CI)	*P*
All deliveries										
37	1636	17.4	421 143	14.2	0.78 (0.69-0.89)	<.001	64 316	13.7	0.75 (0.66-0.86)	<.001
38	3328	16.0	356 827	14.3	0.88 (0.80-0.97)	.007	126 695	10.9	0.64 (0.58-0.71)	<.001
39	4944	17.2	230 132	16.2	0.93 (0.86-1.00)	.059	148 459	13.6	0.76 (0.70-0.82)	<.001
40	12 428	18.6	81 673	20.9	1.15 (1.10-1.21)	<.001	78 666	20.4	1.12 (1.06-1.17)	<.001
41	24 313	18.6	3007	34.3	2.28 (2.10-2.47)	<.001	2892	34.5	2.30 (2.12-2.50)	<.001
Nulliparous										
37	730	28.2	209 429	25.4	0.87 (0.74-1.02)	.088	31 689	20.2	0.65 (0.55-0.76)	<.001
38	1460	27.0	177 740	23.6	0.84 (0.75-0.94)	.003	60 382	18.1	0.60 (0.53-0.67)	<.001
39	2277	29.1	117 358	26.5	0.88 (0.80-0.96)	.005	72 286	22.7	0.72 (0.65-0.79)	<.001
40	5849	30.9	45 072	32.5	1.07 (1.01-1.14)	.018	43 127	31.9	1.04 (0.98-1.11)	.162
41	13 247	29.7	1945	46.4	2.05 (1.86-2.26)	<.001	1879	46.8	2.09 (1.89-2.30)	<.001
Prior vaginal										
37	880	8.2	210 591	5.4	0.64 (0.50-0.82)	<.001	32 446	7.3	0.88 (0.70-1.14)	.367
38	1823	6.7	178 145	5.0	0.74 (0.62-0.89)	.002	65 950	4.3	0.62 (0.52-0.75)	<.001
39	2547	6.1	112 195	5.5	0.89 (0.76-1.05)	.168	75 761	4.9	0.80 (0.68-0.94)	.008
40	6441	7.0	36 434	6.6	0.93 (0.84-1.04)	.213	35 376	6.4	0.91 (0.82-1.01)	.081
41	10 986	5.1	1058	12.1	2.58 (2.10-3.15)	<.001	1009	11.5	2.46 (1.98-3.02)	<.001

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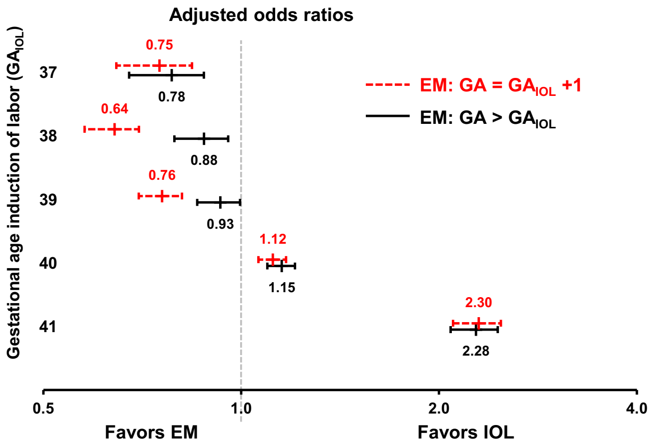

FIGURE 2 Adjusted odds ratios for cesarean delivery following non-medically indicated induction of labor compared with expectant management. For inductions at each gestation week from 37^{+0}-37^{+6} to 41^{+0}-41^{+6}, risk of expectant management until next week and beyond gestation week of induction (GA > GA_{IOL}) was compared with short-term expectant management, that is, births at next week (GA = GA_{IOL} + 1). Data are presented as odds ratios adjusted for maternal age, parity, pre-pregnancy body mass index, labor duration, birthweight, year of birth and hospital level with 95% confidence interval [Color figure can be viewed at wileyonlinelibrary.com]

variables (maternal age, parity, pre-pregnancy body mass index, labor duration, birthweight and hospital level) showed significant differences between the study groups and were thus included as confounders in all logistic regression models analyzing cesarean delivery rates. In general, in the non-medically indicated IOL groups for all gestational weeks, women were more likely to be above 35 years old, multiparous, have a pre-pregnancy body mass index >30, and have a newborn with low birthweight (1500-2499 g).

In our analytic sample, expectant management was associated with lower rates of cesarean deliveries compared with non-medically indicated IOL at early term (weeks 37 and 38). In contrast, at 40 and 41 weeks' gestation, IOL groups had reduced odds for cesarean delivery compared with expectant management. At 39 weeks, IOL resulted in similar cesarean section rates compared with expectant management when all births at a later gestation were included (17.2% vs 16.2%; adjusted odds ratio [OR] 0.93; 95% confidence interval [CI] 0.86-1.00; P = .059). However, when only births in the next week (gestational age 40^{+0}-40^{+6}) were considered, expectant management was associated with significantly reduced odds for cesarean delivery (13.6%; adjusted OR 0.76; 95% CI 0.70-0.82; P < .001; Table 1).

Comparison of the adjusted odds ratios for cesarean delivery for the two definitions of expectant management (next week and beyond vs next week) showed that the next week and beyond model underestimated the benefit of short-term expectant management by up to 1 week, particularly for IOL at weeks 38 and 39 (Figure 2).

Stratification by parity demonstrated that the associations observed in the total sample were similar in women with prior vaginal births (Table 1). Regarding IOL at week 39, the reduced odds for cesarean section associated with expectant management, defined as births at next week, did lose statistical significance when the expectant management was expanded to next week and beyond. Unlike the total sample, women with prior vaginal birth did not have reduced odds for cesarean section when undergoing non-medically indicated IOL at 40 weeks.

Nulliparous women had higher rates of cesarean delivery at all gestation weeks. Indeed, for nulliparous women in both models, adjusted odds ratios favored expectant management compared with IOL at week 39, and at week 40 IOL was slightly associated with reduced cesarean delivery rates only when expectant management was defined as next week and beyond. Thus, stratified by parity and based on cesarean delivery as outcome, women benefited from a non-medically indicated IOL only at week 41.

To estimate the difference between the two definitions of expectant management stratified by gestation week and parity, we calculated the adjusted odds ratios for cesarean delivery between the respective two study groups "births past IOL gestation week" (expectant management next week and above) and "births at subsequent gestation week" (expectant management next week). The next week and above group had higher odds for cesarean delivery for all gestation weeks except the comparators for IOL at 41 weeks (>41 weeks vs 42 weeks; Figure 3A). In agreement with the findings shown in Figure 2 and Table 1, the effect was strongest for IOL at 38 and 39 weeks. When analyzing nulliparous women, adjusted odds ratios were comparable to the total sample (Figure 3B). In women with prior vaginal birth, the impact of the definition of expectant management was less pronounced (Figure 3C).

Due to the retrospective manner of the analysis, in the model using "births at subsequent week" as control group for IOL, all women that were still pregnant beyond the subsequent week were excluded from the study population. In contrast, following a strict policy of expectant management for up to 1 week followed by non-medically indicated induction of the remaining pregnancies would lead to much higher numbers of inductions. To assess whether postponing non-medically indicated inductions would increase the risk of cesarean delivery, we calculated the adjusted odds ratios of cesarean delivery after IOL at each gestational week compared with the subsequent week. IOL at the subsequent week was not significantly associated with changes in cesarean rates for any gestational weeks except week 39 compared with week 40 (17.2% vs 18.6%; adjusted OR 1.11; 95% CI 1.02-1.20; P = .027; Table 2). However, when stratified by parity, increased gestation by 1 week did not significantly increase odds for cesarean delivery at any week tested. Nulliparous women and women with prior vaginal delivery both had the highest rates for cesarean delivery at week 40. In parous women, cesarean rate was significantly decreased at week 41, the week when the majority of non-medically indicated IOLs were performed.

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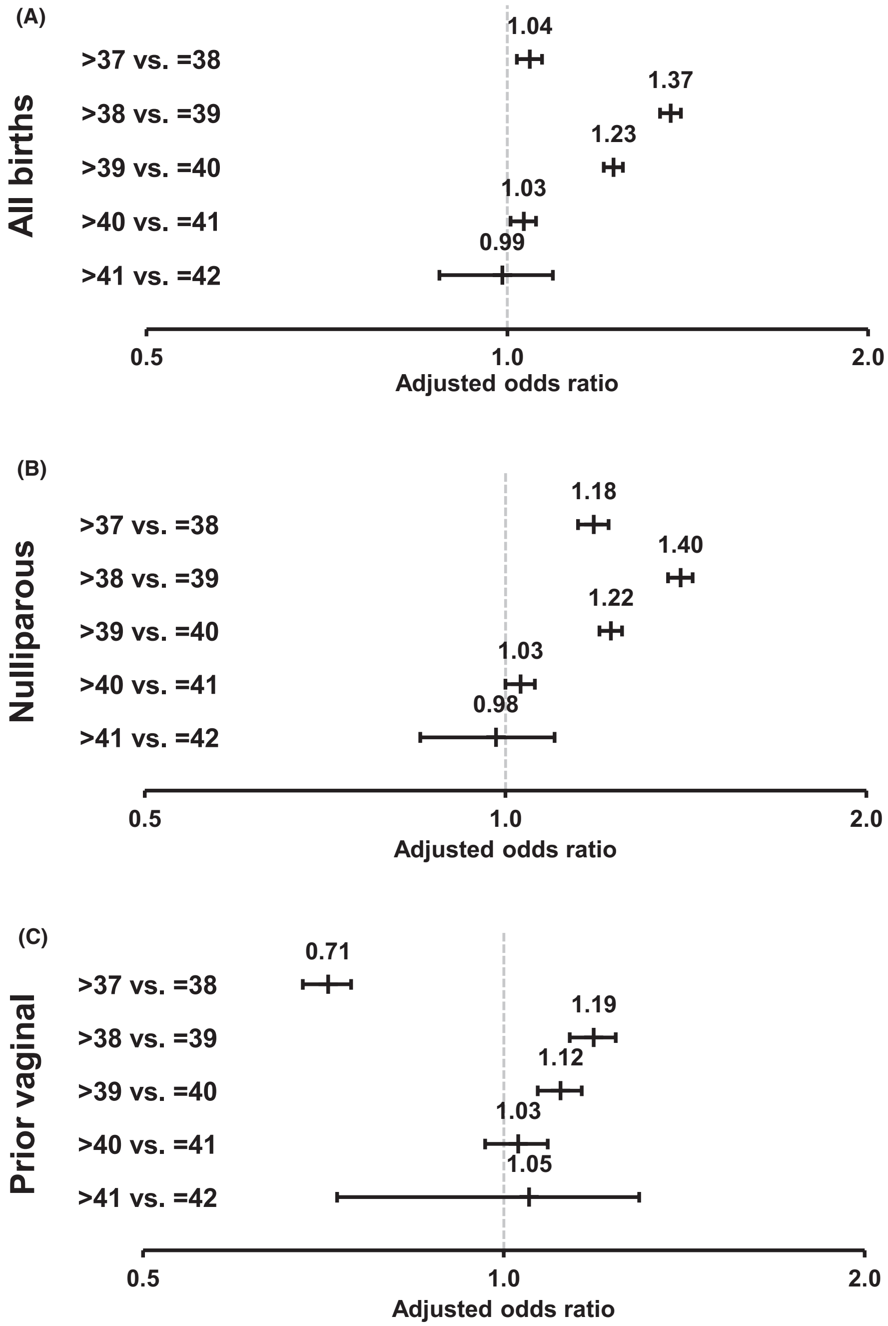

FIGURE 3 Comparison of cesarean delivery rate in expectant management study groups stratified by gestation week and parity. Adjusted odds ratios for cesarean delivery following expectant management until next week and beyond gestation week of induction (eg >37: GA ≥ 38^{+0}) vs expectant management comprising only all births at the subsequent gestation week of induction (eg =38: GA = 38^{+0}-38^{+6}). Data are presented as odds ratios adjusted for maternal age, parity, pre-pregnancy body mass index, labor duration, birthweight, year of birth and hospital level with 95% confidence interval. Data were stratified by parity in (A) all births irrespective of parity, (B) nulliparous women and (C) women with prior vaginal delivery

4 | DISCUSSION

We found that non-medically indicated IOL prior to gestation week 39 is associated with increased odds for cesarean delivery compared with expectant management. Moreover, for nulliparous women this association was observed for IOL prior to 40 weeks. This finding is conflicting with a recent meta-analysis of observational studies demonstrating that "elective" IOL at 39 weeks was associated with a significantly lower risk of cesarean delivery.[13] However, all studies included in this meta-analysis were performed in the USA and reported results only for nulliparous women. In 2019, Souter et al confirmed this finding in a retrospective cohort study but did not observe decreased cesarean birth rates in multiparous women.[18]

Observational studies comparing IOL with expectant management from outside the USA are scant. In a single-center retrospective cohort study from Australia, IOL was associated with increased risk of emergency cesarean for intrapartum fetal distress.[19] A Danish birth registry-based study indicated increased risk of cesarean delivery following IOL at 37 and 38 weeks, whereas there was no significant difference from gestation week 39 and after in either nulliparous or parous women.[20] In agreement with our findings, a large population-based study including all singleton pregnancies in Scotland between 1981 and 2007 found that "elective" IOL at week 39 was associated with increased risk of cesarean delivery, whereas IOL at higher gestational age had a lower risk on cesarean birth compared with expectant management.[21]

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TABLE 2 Cesarean delivery rate following non-medically indicated induction of labor stratified by gestation week

GA	IOL, n	CD, %	GA	IOL, n	CD, %	Adjusted OR (95% CI)	P
All births							
37	1636	17.4	38	3328	16.0	0.90 (0.77-1.06)	.192
38	3328	16.0	39	4944	17.2	1.10 (0.98-1.23)	.139
39	4944	17.2	40	12 428	18.6	1.11 (1.02-1.20)	.027
40	12 428	18.6	41	24 313	18.6	1.06 (1.00-1.12)	.063
Nulliparous							
37	730	28.2	38	1460	27.0	0.94 (0.78-1.15)	.576
38	1460	27.0	39	2277	29.1	1.12 (0.96-1.30)	.169
39	2277	29.1	40	5849	30.9	1.10 (0.99-1.22)	.114
40	5849	30.9	41	13 247	29.7	0.99 (0.93-1.06)	.737
Prior vaginal							
37	880	8.2	38	1823	6.7	0.81 (0.60-1.10)	.185
38	1823	6.7	39	2547	6.1	0.90 (0.71-1.16)	.432
39	2547	6.1	40	6441	7.0	1.18 (0.97-1.43)	.118
40	6441	7.0	41	10 986	5.1	0.74 (0.65-0.84)	<.001

Abbreviations: CD, cesarean delivery; CI, confidence interval; GA, gestation week; IOL, non-medically indicated induction of labor; OR, odds ratio.

These conflicting findings in observational studies reflect various factors including differences in sample size and characteristics, hospital culture, practice preferences, changes in clinical practice or differences in national guidelines.[22-26] In particular, observational studies apply different definitions for non-medically indicated IOL and there are differences in the available potential confounding factors. Of note, significant differences on the impact of IOL on cesarean birth rate were observed depending on the definition of the expectant management group, which included either spontaneous labor at the week of IOL or only births at later gestation weeks.[21,25-27] The majority of observational studies used births at next week and beyond as expectant management that biased the results in favor of IOL when compared with the inclusion of spontaneous labor at the week of IOL in the expectant management group.

Similarly, the majority of studies included in the expectant management group all births beyond the gestation week of IOL up to late term (42^{+6}) or even beyond, when the risk for cesarean delivery is higher. We suggest that this inclusion might also bias the results in favor of early IOL. Moreover, in randomized clinical trials that investigate the outcome of IOL, in the expectant management group, all births at late term were included.[14] Given the evidence that supports IOL at 41 weeks, the inclusion of later births in the expectant management group in randomized trials and observational studies has been criticized as potentially including substandard management. Therefore, it has been suggested that labor outcomes should be compared using both cumulative and weekly comparisons.[25,28-30] Using this approach, we herein demonstrated that compared with expectant management including births at the subsequent week, defining the control group as all births at next week and beyond, biases the results in favor of IOL, particularly for IOL at early term (38 and 39 weeks). Since non-medically indicated IOL is not an all-or-none choice between “elective” induction and indefinite expectant management,[25,30] this difference should be considered when counseling women.

Investigating the outcome of non-medically indicated IOL with a strategy of expectant management for 1 week and “elective” IOL for the remaining pregnancies using population-based studies retrospectively, in principle underestimates the numbers of “elective” IOL in the expectant management group. Thus, we additionally analyzed the risk of cesarean delivery after non-medically indicated IOL for each week compared with the subsequent week and found that postponing IOL for 1 week did not add significant risk.

We herein demonstrate that in Austria, non-medically indicated IOL at 41 weeks was associated with decreased odds for cesarean delivery. This finding is consistent with evidence from clinical trials indicating that “elective” IOL at gestation week ≥41 is associated with reduced cesarean birth rates.[11] However, in contrast to recent findings in the USA, we did not observe reduced odds for cesarean delivery at 39 weeks, irrespective of the definition of expectant management. These findings may reflect differences in clinical practice and may indicate that results from studies conducted in a certain setting or healthcare system should be interpreted cautiously, as they lack external validity.

The limitations of the present study include its retrospective nature, possible coding errors and missing information on applied induction method. Data were retrieved from the Austrian Perinatal Registry and thus were not collected for scientific purposes but primarily for benchmark and quality assurance. The study was designed as a population-based retrospective cohort study without randomization or matching of the groups. Thus, multivariate analysis was

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applied to adjust for differences in demographic parameters listed in Table S1. Furthermore, other potential confounding factors including Bishop score, anesthesia or interhospital variations may have influenced the results. Due to the retrospective and non-randomized study design of a population-based cohort study, the evidence level of our findings is limited. Thus, randomized controlled trials investigating weekly comparisons are needed to derive clear evidence-based recommendations for non-medically indicated IOL. The findings of this study are only applicable to singleton pregnancies and to countries with a comparable healthcare system and clinical practice. Cesarean delivery is only one of many obstetric outcome parameters. Thus, future research should address the impact of the different definitions of expectant management used in the present study on other relevant maternal and neonatal outcomes.

5 | CONCLUSION

Non-medically indicated IOL at 41 weeks significantly reduced the risk for cesarean birth compared with expectant management. In contrast, IOL prior to 40 weeks was associated with increased odds for cesarean delivery. Moreover, the definition of the expectant management group has a significant impact when analyzing the outcome of IOL in retrospective cohort studies. Thus, to define the control group as all births at the next week could be useful for clinical decision-making, as it allows estimation of the risks of expectant management to the next appointment compared with immediate IOL.

CONFLICT OF INTEREST

None.

ORCID

Christoph Zenzmaier https://orcid.org/0000-0002-1609-772X

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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