Induction of labour at term compared with expectant management in women over 40 years of age: a retrospective study.

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#### Abstract

Objective To compare maternal and neonatal outcomes of induction of labour at term to those of expectant management in women over 40 years of age. Design Retrospective cohort study. Setting Data were derived from the Hospital Álvaro Cunqueiro birth cohort (Vigo). Population Women at [?]40 years of age and [?]39 weeks of gestation that delivered from 1 January 2012 to 31 December 2017. Methods Women were classified into two groups: expectant management group (women who delivered from 1 January 2012 to 31 December 2014) and nonmedically indicated induction of labour group (women who delivered from 1 January 2015 to 31 December 2017). These two groups were described and compared. Main outcome measures The primary outcome was the route of delivery. Perinatal results were also studied. Results There was a total of 603 pregnant women in the expectant management group compared to 634 women in the induction group. The rate of cesarean section did not increase in the maternal age-based labour induction group compared to the expectant management group. Subgroup analysis did not demonstrate an increased risk by parity. Women in the expectant management group were more likely to require neonatal intensive care unit admission and need pediatric support. Conclusion Compared to expectant management, induction of labour at 39 weeks of gestation results in significantly better neonatal outcomes without increasing the cesarean section rates in older women. Tweetable abstract Induction of labour in women over 40 years of age associates better perinatal outcomes without increasing the rate of caesarean sections.

#### Title page

**TITLE:** Induction of labour at term compared with expectant management in women over 40 years of age: a retrospective study.

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## Running head:

Advanced maternal age and induction of labour.

#### Word count

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Data were derived from the Hospital Álvaro Cunqueiro birth cohort (Vigo).

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Women at [?]40 years of age and [?] 39 weeks of gestation that delivered from 1 January 2012 to 31 December 2017.

#### Methods

Women were classified into two groups: expectant management group (women who delivered from 1 January 2012 to 31 December 2014) and nonmedically indicated induction of labour group (women who delivered from 1 January 2015 to 31 December 2017). These two groups were described and compared.

#### Main outcome measures

The primary outcome was the route of delivery. Perinatal results were also studied.

## Results

There was a total of 603 pregnant women in the expectant management group compared to 634 women in the induction group. The rate of cesarean section did not increase in the maternal age-based labour induction group compared to the expectant management group. Subgroup analysis did not demonstrate an increased risk by parity. Women in the expectant management group were more likely to require neonatal intensive care unit admission and need pediatric support.

#### Conclusion

Compared to expectant management, induction of labour at 39 weeks of gestation results in significantly better neonatal outcomes without increasing the cesarean section rates in older women.

#### Tweetable abstract

Induction of labour in women over 40 years of age associates better perinatal outcomes without increasing the rate of caesarean sections.

## Keywords

Advanced maternal age, induction of labor, cesarean section, neonatal outcomes.

#### Main text

#### Introduction

The birth rate of women aged 40 years or older has been rising steadily. Delaying childbearing is an ongoing and universal phenomenon. In Spain, the average age of women at childbirth remained at 32.2 years in 2019.

In the last 10 years, the number of births to women aged 40 years and older has increased by 63.1%. In 2008, 4.2% of births were to women with maternal age? 40 years, while in 2019, this percentage increased to 9.7%.

Advanced maternal age has been historically defined as [?]35 years at the time of delivery and is widely associated with adverse obstetric outcomes. The risks of hypertensive disorders, gestational diabetes mellitus, placenta previa, placental abruption, and stillbirth are higher among women aged 35 years or older than among younger women.<sup>2-6</sup>

The incidence of stillbirth at 39–40 weeks of gestation is 2 in 1000 for women [?] 40 years of age compared with 1 in 1000 for women < 35 years old. Women [?] 40 years of age have a similar stillbirth risk at 39 weeks of gestation to younger women at 41 weeks of gestation.4 Induction of labour in older mothers is widely practiced as an intervention to reduce the risk of late stillbirth. <sup>5,6</sup> A survey showed that 37% of obstetricians offer induction of labour at term to women aged 40–44 years and 55% to those [?] 45 years. <sup>7</sup> Studies suggest that there is a low threshold to perform a caesarean section in older women. <sup>5,6</sup>

Nonmedically indicated induction of labour compared with spontaneous labour is associated with an increased risk of caesarean delivery, especially in nulliparous women. However, spontaneous labour may not be an ideal comparison. Detailed data regarding the outcomes of nonmedically indicated induction of labour are still limited. As of 1 January 2015, the Gynaecology and Obstetrics service of the Alvaro Cunqueiro Hospital offered induction of labour to women aged [?] 40 from the 39th week of gestation onwards. The objective of this study was to compare maternal and neonatal outcomes of nonmedically indicated induction of labour at term to those of expectant management in women over 40 years of age.

## Material and methods

#### Study design

This is a retrospective cohort study that included all women at [?] 40 years of age and [?] 39 weeks of gestation that delivered in the city of Vigo from 1 January 2012 to 31 December 2017. Data were derived from the Hospital Alvaro Cunqueiro birth cohort, an electronic database created from gestational, birth, and neonatal data from hospitalisations in the Vigo delivery room.

Women aged [?] 40 years with singleton pregnancies were included in the database. Women with < 39 weeks of gestation and those with multiple gestations were excluded. In January 2015, the gynaecology and obstetrics service of Vigo implemented the protocol for induction of labour due to advanced maternal age; therefore, patients were divided according to the management of labour at term. We compared expectant management (women who delivered from 1 January 2012 to 31 December 2014) to nonmedically indicated induction of labour (women who delivered from 1 January 2015 to 31 December 2017).

The primary outcome was the caesarean delivery rate. The secondary maternal outcomes were delivery methods other than caesarean section (that is, assisted vaginal delivery with the use of forceps or vacuum), the onset of labour (that is, spontaneous labour, elective caesarean section, or induction of labour), the indication for induction of labour, the method of labour induction, the indications for caesarean section, and intrapartum complications (that is, intrapartum fever or stained amniotic fluid).

The secondary neonatal outcomes were stillbirth, birth weight, the 5-minute Apgar score, the arterial cord pH value, paediatric birth support, degree of neonatal resuscitation, and admission to a neonatal intensive care unit (NICU). To analyse the type of paediatric support at birth, the participants were divided into 3 groups: group 1 included those new-borns who did not require paediatric assistance at birth; group 2 included new-borns who required suctioning; group 3 included those who required the three most advanced degrees of resuscitation, suctioning and oxygen administration, and use of ambu and intubation.

Basic demographic characteristics and obstetric and clinical outcomes were examined: parity, smoking status, assisted conception, gestational age at delivery, history of pregestational diabetes mellitus, gestational

diabetes mellitus, chronic hypertension, and any new hypertensive disorder during pregnancy (namely, preeclampsia or gestational hypertension), and pre-pregnancy medical pathology.

#### Statistical analyses

Data were analysed with SPSS 19.0. Qualitative variables were reported as absolute frequency and percentage, while quantitative variables were reported as the mean and standard deviation or the median and interquartile range if they did not fit a normal distribution. The Kolmogorov–Smirnov test was used for normality testing. A univariate analysis was performed to determine whether there were differences between the two study groups. For the relationship with qualitative variables, the Chi-square test was used, while for the comparison of quantitative variables, the parametric t-test or the non-parametric Mann-Whitney test was applied. Differences were considered statistically significant at p < 0.05. Ethics committee approval for this study was obtained from the Ethics and Clinical Research Committee of Galicia (approval number 2020/617).

#### Results

From 1 January 2012 to 31 December 2017, there were 1,776 women aged [?] 40 years who delivered at Alvaro Cunqueiro Hospital. Women who had multiple gestations and women delivering at < 39 weeks of gestation were excluded. There were a total of 603 pregnant women in the expectant management group compared to 634 women in the induction group. Baseline characteristics were similar between the two groups (Table 1). The delivery outcomes are shown in Table 2. There was no significant difference in the rate of caesarean section between the induction and expectant management groups (24% vs. 24.4%) (p=0,971). The risk of urgent intrapartum caesarean section was 44.1% in the induction group versus 33.1% in the expectant management group; these differences were not significant (p=0,127).

A secondary analysis showed that in the group of women without any previous surgical or vaginal delivery, the distribution according to the type of labour did not show statistically significant differences between groups (p= 0,109). The rate of successful trial of labour after caesarean (TOLAC) was 57.3% in the expectant management group and 51.2% in the induction group. These differences were not statistically significant (p=0,247). There were significant between-group differences in the frequency of stained amniotic fluid (147 of 603 in the expectant management group [24.4%] versus 89/634 in the induction of labour group [10.9%]).

The neonatal outcomes are presented in Table 3. No statistically significant differences were found for the Apgar value at 5 min and umbilical artery pH value. There were two cases of stillbirth in the expectant management group, and no intrauterine foetal deaths were registered in the induction group. These differences were not statistically significant (P = 0.147). The expectant management group needed more advanced paediatric support at birth than the labour induction group. (Table 4). The rate of admission to the NICU was lower in the labour induction group (p=0.000) than that in the expectant management group.

#### Discussion

#### Principal findings

This study analysed expectant management versus induction of labour at 39 weeks of gestation in women 40 years of age or older at the time of delivery. In older women, active labour management resulted in better perinatal outcomes without increasing the caesarean section rate and with similar vaginal delivery rates compared to expectant management.

Results in the context of what is known

The number of published studies on pregnant women of advanced maternal age is scarce. Most of the studies on induction of labour at term involved women with established complications, such as hypertensive disorders<sup>8</sup> rupture of membranes<sup>9</sup>, foetal growth restriction<sup>10,11</sup>, diabetes<sup>12</sup>, or foetal macrosomia<sup>13</sup>. The 35/39 study was a randomised clinical trial designed to test the hypothesis that induction of labour at 39 weeks of gestation would reduce the rate of caesarean delivery among nulliparous women of advanced

maternal age. Their data showed that induction of labour at 39 weeks of gestation, as compared with expectant management, did not increase caesarean delivery.<sup>14</sup>

The study by Knight et al included a total of 77,327 women aged 35 years. They found no statistically significant difference in the caesarean section rate between the 39-week labour induction groups and the expectant management group (Adjusted relative risk: 1.04, confidence interval [CI] 95%: 0.99–1.01). <sup>15</sup> In 2019, a retrospective cohort study including 35-year-old nulliparas with singleton gestations at term comparing elective induction at 37, 38, 39 and 40 weeks' gestation and those with expectant management at the same number of weeks found that induction at 39 weeks' gestation was associated with decreased odds of caesarean section delivery (Ora 0.69; CI95%, 0.53-0.91). Our data supported previous studies and found no statistically significant difference in the type of delivery between the expectant management group and the induction at 39 weeks group. In the secondary analysis of the type of delivery according to parity, we found no significant differences in the route of delivery among the groups studied. In the expectant management group, the subgroup of women aged 40 years at 39 weeks of gestation and without any previous type of delivery (vaginal or caesarean) included 227 patients, of whom 24.2% had vaginal deliveries and 41.4% had operative vaginal deliveries. This meant that 65.6% of deliveries were vaginal delivery versus 34.4% of deliveries by caesarean section. In the active management group, the group of patients with the same characteristics was made up of 252 women, of which 69% delivered vaginally (32.9% vaginal delivery and 36.1% operative vaginal delivery) as opposed to 31% of deliveries by caesarean section.

Our data showed a rate of successful TOLAC similar to the 62.3% reported in previous studies. 17

Another main finding was better neonatal outcomes in the labour induction group than in the expectant management group. The need for paediatric support at birth, the type of neonatal resuscitation measures, and the NICU admission rates were lower in the labour induction group than in the expectant management group. These data support the results of study lines in which perinatal outcomes improved with elective induction at 39 weeks of gestation. <sup>16,18</sup>

Finally, another result to highlight is the 0% stillbirth in the active management group versus the two intrauterine foetal deaths recorded in the expectant management group. These differences were not statistically significant because intrauterine foetal death is a rare adverse outcome, and a large sample size would be needed to find significant differences between the groups.

#### Research implications

There is a continuous risk for both the mother and baby with increasing maternal age, with numerous studies reporting multiple adverse foetal and maternal outcomes associated with advanced maternal age. Women [?] 40 years of age had a similar stillbirth risk at 39 weeks of gestation with younger women at 41 weeks of gestation. Induction of labour at 39 weeks of gestation reduced these adverse outcomes. However, at present, there are insufficient data available on the effect such a policy would have on caesarean rates and perinatal outcomes, specifically in older women. Our study analysed the effect of labour induction compared with expectant management in women over 40 years of age. Our results provided data on intrapartum complications, mode of delivery, neonatal morbidity, and late stillbirth.

#### Strengths and limitations

Our study has several limitations. The definition of advanced maternal age in the literature varies with publications using different criteria. The definition used in our study aligns with the hospital's definition of [?]40 years. The major limitation of our study was its retrospective nature. The retrospective dataset was subject to incomplete data entry and variation in practice. Despite our limitations, there are only a few studies in the literature that evaluated obstetric and perinatal outcomes according to active or expectant management in pregnant women of advanced maternal age and consider parity within their data.

## Conclusion

In conclusion, induction of labour at 39 weeks of gestation compared to expectant management in women

of advanced maternal age results in significantly better neonatal outcomes without increasing the caesarean section rate. Hence, it is important that advanced maternal age pregnant women be informed of the risks involved in delaying childbearing until the fourth decade of life. Further studies on this topic are necessary to develop new policies for clinical care in this group of pregnant women.

#### Disclosure of interest

The authors declare that we are free of any personal or commercial association that may constitute a conflict of interest. Ethical principles of research have also been respected.

## Contribution to authorship

All the authors contributed to the content and development of the article. All authors reviewed and agreed to the final version of this manuscript.

## Details of ethics approval

Ethics committee approval for this study was obtained from the Ethics and Clinical Research Committee of Galicia (approval number 2020/617, 20 May 2021).

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#### **Tables**

Table 1. Baseline Characteristics of the Participants

Variable	Expectant management group $(N = 603)$	Induction of labor group $(N = 634)$	P value
Maternal age at			
delivery (years)			
Mean Range	41 40-50	41 40-50	
Parity no. (%)			
Nulliparous	227 (37,65) 376 (62,35)	252 (39,75) 382 (60,25)	
Multiparous			
Current smoker no.	32 (5,3)	25 (3,9)	0,250
(%)	· · /		
Medical history no.			
(%)			
Yes No	99 (16,4) 504 (83,6)	118 (18,6) 516 (81,4)	
Assisted reproductive			0,181
technology no. (%)			,

Variable	Expectant management group $(N = 603)$	Induction of labor group $(N = 634)$	P value
Artificial insemination In vitro fertilization Ovodon	10 (1,65) 46 (7,62) 34 (35,63)	9 (1,42) 54 (8,51) 55 (8,67)	
Hypertension disorders no. (%)			0,601
Pregestational Gestational Preeclampsia	4 (0,7) 6 (1) 1 (0,1)	6 (0,9) 4 (0,6) 1 (0,1)	
Diabetes Mellitus no. (%)			0,070
Pregestational Gestational with diet Gestational with insulin	0 76 (12,6) 4 (0,7)	0 65 (10,3) 10 (1,6)	

## Table 2. Maternal outcomes

Variable	Expectant management group $N = 603$ )	Induction of labor group $(N = 634)$	P value
Gestational age at the	,	,	
time of delivery			
Mean Range	$40+2\ 39-42$	39+3 39-42+1	
Onset of the birth			0,000
process no. (%)			,
Spontaneous labor	357 (59) 211 (35,2) 35	100 (15,8) 509 (80,4)	
Induced labor Elective	(5,8)	25 (3,9)	
cesarean section			
Indication for induction			
of labor no. (%)			
>41 wk of gestation	72 (34.1) 61 (28.9) 26	10 (2) 26 (5.1) 13 (2.5)	
Term prelabor rupture	(12.3%) 14 $(6.6)$ 13	0 (0,0) 7 (1.4) 437	
of membranes Others	$(6.2)\ 0\ (0)$	(85.68)	
Posity amnioscopy			
Oligoamnios Advanced			
maternal age			
Amniotic fluid color			0,000
no. (%)			
Clear Stained	450 (74,6) 147 (24,4) 6	559 (88,2) 89(10,9) 6	
Hemorraghic	(1)	(0,9)	
Intrapartum fever no.	$21 \ (8,6)$	92 (14,6)	0,018
(%)		To ( /=0 0)	0.040
Epidural use no. (%)	$464\ (77,5)$	$504\ (79,9)$	$0,\!258$
Method of delivery no.			
(%)	200 (50 5) 150 (24.0)	207 (71.2) 177 (24.0)	
Vaginal delivery	306 (50,7) 150 (24,8)	325 (51,3) 157 (24,8)	
Assisted vaginal	147 (24,4)	152 (24)	
delivery Cesarean			
section			

Variable	Expectant management group $N = 603$ )	Induction of labor group $(N = 634)$	P value
No previous type of delivery. Method of delivery no (%)*	227	252	0,109
Vaginal delivery Assisted vaginal delivery Cesarean section	55 (24,2) 94 (41,4) 78 (34,4)	83 (32,9) 91 (36,1) 78 (31)	
Type of cesarean section no. (%)			0,127
Programmed Non-urgent intrapartum Urgent	33 (22,3) 66 (44,6) 49 (33.1)	25 (16,4) 60 (39,5) 67 (44.1)	
Indication for cesarean section no. (%)	N = 147	N = 152	
Suspected fetal distress Active phase arrest Cephalopelvic disproportion Breech presentation Failure of induction Elective	40 (27) 24 (16,2) 15 (10,1) 18 (12,2) 18 (8,1) 11 (7,4)	54 (34,9) 14 (9,2) 17 (11,2) 14 (9,2) 26 (17,1) 9 (5,9)	
Indication for assisted vaginal delivery no. (%)	N = 150	N = 157	
Suspected fetal distress Second Stage Protraction Maternal exhaustion	99 (66) 50 (33,3) 1 (0,7)	128 (81,5) 28 (17,9) 1 (0,6)	

# \* Patients without any previous surgical or vaginal delivery

Table 3. Neonatal outcomes

Variable	Expectant management group $(N = 603)$	Induction of labor group $(N = 634)$	P value
Sex no. (%)			
Male Female	285 (47,3) 318 (52,7)	324 (51,1) 310 (48,9)	
Birth weight (g)		, , , , , , , , , , , , , , , , , , , ,	0,001
Mean Range	3371,61g 2050g-4630g	3270,23g 2215g- 4600g	
Apgar score at 5 min			0,317
Mean Range	9,85 0-10	9,91 6-10	
Umbilical-cord- arterial			0,083
рН			
Mean Range	7,20 0-7,41	7,23 6,95-7,46	
Stillbirth no. (%)	2(0,3)	0 (0)	0,147
Required intervention no.	357 (59,3)	184 (29)	0,000
(%)	, ,	` '	
NICU adminission no.	143 (23,7)	65 (10,3)	0,000
(%)		•	

Table 4. Groups based on the degree of neonatal resuscitation

	Group 1*	Group 2**	Group 3***
2012-2014	245(40,7%)	279 (46,3%)	78 (13%)
2015-2017	450 (71%)	135 (21,3%)	49 (7,7%)

Group 1: No pediatric assistance at birth

<sup>\*\*</sup> Group 2: suctioning \*\*\* Group 3: suctioning and oxygen administration, use of ambu and intubation