Revista Colombiana de Obstetricia y Ginecología Vol. 70 No. 2 •Abril-Junio 2019 • (103-114)

ORIGINAL RESEARCH

DOI: https://doi.org/10.18597/rcog.3275

INADEQUATE ADHERENCE TO THE RECOMMENDATIONS REGARDING LABOR INDUCTION AS A TRIGGER OF CESAREAN SECTION IN WOMEN WITH SINGLETON TERM PREGNANCY. A DESCRIPTIVE STUDY

Cumplimiento inadecuado de las recomendaciones para el proceso de la inducción del trabajo de parto como desencadenante de la cesárea en mujeres con embarazo simple a término. Estudio descriptivo

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Received: noviembre 19/18 – Accepted: junio 18/19

ABSTRACT

Objective: To describe the characteristics of the labor induction process associated with the excess number of cesarean sections in women subjected to this intervention.

Materials and methods: Descriptive historical cohort that included pregnant women without a history of previous cesarean section, with singleton term pregnancy and cephalic presentation who were subjected to labor induction in a Level III complexity hospital in Medellín, Colombia, during the time period between May 2015 and October 2016. Consecutive sampling was used. Measured variables were maternal age, parity, gestational age, indication for labor induction, cervical favorability, time of induction, quality of uterine activity achieved, type of delivery, and time point during induction when the decision of cesarean section was made. The clinical practice guidelines of international organizations of the specialty and the new guidelines arising from the 2012 proposal of limiting the first cesarean section were used in order to define adherence to the recommendations for induction.

Results: Of the 2402 births, 289 which met the inclusion criteria were selected. Cesarean section was performed in 48% of the women subjected to induction, 60.8% nulliparous and 32.1% multiparous. Of those with unfavorable cervix, 72.2% received oxytocin for cervical maturation. Of the women subjected to delivery induction, 108 (37%) underwent cesarean section due to a diagnosis of failed induction. This was considered inadequate

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in all of them, given that the diagnosis was made before reaching a dilatation of 6 cm in 88 (81.5%), with intact membranes in 67 (62%), with no uterine activity in 42 (38.9%), with poor quality uterine activity in 23 (21.3%) and in 55 (61%) who did not have at least 24 hours of latent phase before undergoing cesarean section.

Conclusion: Failure to adhere to the recommendations for adequate induction was found, added to an incorrect diagnosis of failed induction.

Key words: Induced labor; cesarean section.

RESUMEN

Objetivo: describir las características del proceso de inducción del trabajo de parto relacionadas con el exceso de cesáreas en las mujeres a quienes se les realiza este procedimiento.

Materiales y métodos: cohorte histórica descriptiva en la que se incluyeron las gestantes sin antecedente de cesárea, con embarazo único, a término y presentación cefálica, sometidas a inducción del trabajo de parto en un hospital de tercer nivel de complejidad, en Medellín, Colombia, en el periodo de mayo de 2015 a octubre de 2016. Se excluyeron mujeres con feto muerto antes de la inducción. Muestreo consecutivo. Se midieron: edad materna, paridad, edad gestacional, indicación de la inducción del trabajo de parto, favorabilidad del cérvix, tiempo de la inducción, calidad de la actividad uterina lograda, tipo de parto, momento de la inducción en que se decide la cesárea. Para definir el cumplimiento de las recomendaciones de inducción se tuvieron como referencia las guías de práctica clínica de organizaciones internacionales de la especialidad y las nuevas directrices generadas en la propuesta de reducción de la primera cesárea del año 2012. Se utilizó estadística descriptiva.

Resultados: de 2402 nacimientos se seleccionaron 289 que cumplieron con los criterios de inclusión. Se realizó cesárea al 48 % de las gestantes, a 60,8 % de las nulíparas y a 32,1 % de las multíparas sometidas a inducción. El 72,2 % de las que tenían cérvix desfavorable recibieron oxitocina como método de maduración cervical. A 108 (37 %) de las mujeres llevadas a inducción de parto se les realizó cesárea por diagnóstico de inducción fallida que se consideró inadecuado en todas ellas, ya que el diagnóstico se realizó antes de alcanzar 6 cm de dilatación en 88 (81,5 %), con membranas íntegras en 67 (62 %), sin actividad uterina en 42 (38,9 %), con actividad uterina de mala calidad en 23 (21,3 %) y 55 (61 %), no tuvieron al menos 24 horas de fase latente antes de realizar la cesárea.

Conclusión: se encontró falta de cumplimiento de las recomendaciones para una adecuada inducción que lleva a un diagnóstico errado de inducción fallida.

Palabras clave: trabajo de parto inducido; cesárea.

INTRODUCTION

Cesarean section (c-section) is a life saving procedure for the fetus, the mother or both, when performed in accordance with clear clinical indications, and it has resulted in a reduction of maternal and perinatal morbidity and mortality. However, the rising number of cesarean sections over the past decades is a source of concern due to overuse of the procedure (1) and its association with an increased risk of complications as well as maternal and perinatal mortality (2-5).

At the present time, cesarean section rates are high throughout the world, in developed as well as developing countries (6). In Colombia, rates rose from 24.9% in 1998 to 45.7% in 2013 (7). The situation is no different at San Vicente Fundación University Hospital (HUSVF) in Medellín (Colombia), where the proportion of cesarean section was found to be of 43.1% according to a study that assessed deliveries between 2011 and 2012. Using the Robson model, the study identified excess frequency of cesarean sections among the subgroup of women with term pregnancy and cephalic fetal position who underwent induction of labor or were scheduled for c-section without labor, as compared to other institutions in the region and the world (8). Out of nine of the studies assessed

which include a break-down of the information for induction in these subgroups - Robson's group 2a corresponding to nulliparous women and group 4a corresponding to women with prior deliveries - the highest proportion of c-sections described was 41.5% (9) and 27.3%, respectively (10).

Induction consists of the artificial stimulation of labor before it manifests spontaneously, with the aim of achieving a vaginal delivery. It is indicated when the risks of continuing the pregnancy surpass the risk associated with induced labor and delivery (11). Modern techniques vary according to cervical status before induction and they include maturation agents for the unfavorable cervix, and childbirth induction in cases of favorable cervix. The former include local administration of drugs to soften and dilate the cervix such as prostaglandins, and mechanical methods such as catheter or dilator insertion directly into the endocervix. Oxytocin is not recommended as a method for cervical maturation due to its limited effect and the availability of more effective alternatives. In terms of childbirth inducers, these include systemic drugs that stimulate uterine contractions such as synthetic oxytocin and mechanical methods such as amniotomy (12). In the United States, a potential association between labor induction and the increased frequency of c-sections has been described, due to the simultaneous and parallel increase of the two procedures (13); however, the actual relationship between the two is contradictory, considering that several meta-analyses have actually described a reduction in the number of c-sections, even in subgroups of women apparently at a higher risk of being taken to that operation (14-17).

The World Health Organization (WHO) proposes that the events and outcomes in terms of c-sections in every delivery unit should be characterized and classified with the aim of collecting information about rates and analyzing the factors that influence the high percentages of procedures so that steps can be taken in order to reduce its frequency (18, 19). The objective of this study was to describe the characteristics of the labor induction process and establish the relationship between induction and the excess number of c-sections identified at the institution in women subjected to this procedure.

MATERIALS AND METHODS

Design and populatio. Descriptive historical cohort of women subjected to labor induction, with singleton pregnancy 37 weeks or more, fetus in cephalic position, with or without prior vaginal delivery and with no history of prior c-section, seen in a general Level III hospital of Medellín (Colombia), that serves a population under state-subsidized health coverage within the general social security system in health (GSSH). Women with fetal demise diagnosed before induction were excluded. To estimate the frequency of well conducted induction, assuming a 75% estimate based on unpublished institutional data, an average number of 1500 deliveries per year, with a confidence level of 95% and a 5% margin of error, 289 women were required. Sampling was strictly consecutive.

Procedure. The clinical records of the candidates to enter the study were identified in the Hospital's systematized prospective registry of deliveries. Three obstetrics and gynecology residents reviewed each of the clinical records in the list. Starting with the women seen in October 2016 and going back in a strictly consecutive fashion, they included in the study all the cases that met the inclusion criteria until the sample size was reached with the women who were delivered up until May 2015. A form which included the demographic and clinical variables was designed for direct transcription of the information documented in the clinical records by the treating team.

The Bishop score assigned before the start of induction was identified; for the cases in which it was not reported directly, the Bishop score was calculated by adding the various values, in the event all the characteristics required for the calculation had been included independently in the clinical

record. When an objective measure of any of the parameters was not found and only qualitative descriptions had been entered, the research team, based on consensus reached beforehand, assigned 3 points for cervical effacement, 2 for short cervix and 0 for a long cervix, and included those numbers in the calculation. A favorable cervix was defined as a score of 6 or more (20). Patients with Bishop scores documented in the clinical record as well as with scores calculated by the research team were all considered in the analysis.

The total induction time was quantified from the beginning of the administration of any induction method selected by the treating team, including cervical maturation period when required, until delivery or final discontinuation of the method. Cervical maturation was considered relevant when prostaglandins or mechanical methods were used. The use of oxytocin for cervical maturation was considered not relevant. The time during which the induction method was discontinued temporarily was discounted and continuous induction was considered to exist when there were no temporary discontinuations of the induction method.

Minimum and maximum times for the increase in oxytocin doses for each woman were calculated based on medical orders and nursing notes. Regularity in dose modification intervals was considered to exist when a periodic pattern for assessment and changes in oxytocin was identified. The time elapsed between spontaneous rupture of membranes and the diagnosis of failed induction was estimated from the moment of spontaneous or artificial membrane rupture until the diagnosis of failed induction by the physician. The active phase was considered started from the point of 6 cm of dilatation, in accordance with the most recent recommendations (21, 22). Good uterine activity was considered to exist when 3 to 5 regular uterine contractions of good intensity lasting 35 to 60 seconds in 10 minutes were described (23). The diagnosis of failed induction was based on the medical judgement documented in the clinical record. In these patients, the time elapsed without cervical changes before the diagnosis was quantified. A well performed induction was considered to exist when the following criteria were met concurrently: 24 hours or more of oxytocin administration, regular uterine activity at least every three minutes, rupture of membranes present for at least 12 hours, and favorable cervix (at least 6 cm) at the time of the diagnosis of failed induction.

A diagnosis of failed induction was defined as inadequate when there was no regular uterine activity at least every three minutes and no cervical changes after a minimum time of 24 hours after oxytocin administration, in the presence of spontaneous or artificial rupture of membranes lasting at least 12 hours and favorable cervix, i.e., at least 6 points on the Bishop score (21, 23).

Arrested or protracted labor was defined as failure to achieve minimum progression during 4 hours or more when the woman had at least 6 cm of dilatation and ruptured membranes, despite adequate uterine activity, or during more than 6 hours in the presence of inadequate contractions (21, 23).

In order to mitigate information bias and obtain standardized data, an easy tool was designed and the electronic and manual entries in the clinical records were assessed.

Measured variables. Age, parity, gestational age, indication for induction; the need or not to induce cervical maturation, the method used for cervical maturation, description of cervical characteristics and the status of the membranes at the start of the induction; induction method, induction time, membrane rupture time, well performed induction or inadequate use of the diagnosis of failed induction; use of epidural analgesia, route of delivery and instrumentation, indication for c-section, and newborn weight and APGAR score.

Statistical analysis. Qualitative variables are expressed as absolute numbers and percentages. The distribution of the quantitative variables was assessed using the Kolmogorov-Smirnov test and the different graphs for normal distribution were also

assessed; those which showed a normal distribution are expressed as means and standard deviations, or as medians and inter-quartile ranges (IQR) if they did not have that distribution. Data were analyzed using the SPSS 23 statistical software package.

Ethical considerations. This study was approved by the institutional committee for ethics in research.

RESULTS

Overall, 2402 records of births documented between May 2015 and October 2016 were identified, and 289 women who met the inclusion criteria during this period were included.

The median age of the women included was 24 years (IQR 20-31), 158 (54.6%) were nulliparous, 156 (53.9%) had between 37 and 38 weeks of gestation, 108 (37.3%) had between 39 and 40, 23 (7.95%) had 41 weeks and 2 (0.69%) had 42 or more. The indications for labor induction are shown in Table 1; 29 (10%) had indications that were not reported in the literature, including 40-week pregnancy, polyhydramnios, associated comorbidities such as HIV, epilepsy, recurrent urinary infection, gestational thrombocytopenia, ovarian mass, sickle-cell anemia, and fetal malformations such as mega cisterna magna and tetralogy of Fallot. Spontaneous vaginal delivery occurred in 149 (52%), 2 (0.7%) had instrumented delivery and 138 (48%) underwent cesarean section. On the other hand, 96 of the 158 nulliparous women (60.8%), Robson's group 2a, and 42 of the 131 multiparous women (32.1%), group 4a, were delivered through a c-section.

The Bishop score was found in the clinical record in 19 (6.6%) cases and, in 86 (29.8%), all the required parameters to estimate the score were present, despite the fact that the score was not directly documented in the clinical record. In 52 cases (18%), the treating team only assigned a qualitative rating, such as favorable or unfavorable cervix, and in 132 (45.7%) no data were found to enable an estimation. A total of 66 (22.8%) women had objective criteria to assign an unfavorable Bishop; of them, 54 (81.8%) received some method of cervical maturation, and the remaining 12 (18.2%) received oxytocin as part of an induction regimen from the very beginning (considered not relevant). Among the women with unfavorable cervix who underwent cervical maturation, 15 (27.8%) received dinoprostone and 39 (72.2%) received low-dose oxytocin with regular dose increases, not rated as incorrect even though it was not the ideal method. Finally, 32 of the 66 women (48.5%) with unfavorable cervix and 27 of the 39 (69.2%) with favorable cervix had a vaginal delivery. Table 2 shows the induction characteristics and some of the characteristics of the neonates.

In 108 of the 289 (37%) patients taken to induction, c-section was performed due to a failed induction diagnosis. One woman may have been a case of one or more incorrect actions simultaneously. Diagnosis was made before reaching the active phase of labor in 85 (78.7%). In 67, failed induction was diagnosed with intact membranes, and in 25 of the 38 with ruptured membranes at the time of diagnosis, the diagnosis was assigned before 12 hours had elapsed after the reupture, meaning that in 92 (87.6%) the recommendation to wait at least 12 hours after membrane rupture before confirming the diagnosis was not met. In 3 patients, membrane status was not documented in the clinical record at the time of making the diagnosis of a failed induction. At the time of the diagnosis, it was found in the clinical record that 42 (38.9%) did not have uterine activity, 23 (21.3%) were considered to have poor quality activity and no reference was made to the quality of uterine activity in 12 (11.1%). In 55 (61.0%), the criterion of at least 24 hours of induction before performing a c-section was not met.

The maximum dose of oxytocin was less than 8 mU/min in half of the women with a failed induction diagnosis. None reached the maximum dose of 30 mU/min despite the absence of good uterine activity, while some remained on the same does despite the absence of progression. In none of the cases of failed induction were all the recommendations

Table 1.
Indications for induction in term pregnancies in a referral institution in Medellín (Colombia), 2015-2016

Diagnosis	n (%)
Pregnancy-related hypertensive disorders	122 (42.2)
Premature rupture of membranes in pregnancies ≥ 37 weeks	45(15.5)
Intrauterine growth retardation (IUGR)	44 (15.2)
Pregnancy > 41 weeks	23 (8)
Diabetes mellitus	6 (2)
Maternal heart disease	6 (2)
Oligohydramnios	6 (2)
Maternal cholestasis	1 (0.3)
Antiphospholipid syndrome	1 (0.3)
Elective induction*	5 (1.7)
Indication not reported in the literature	29(10)
No data	1 (0.3)

*Without clear medical indication, at the request of the patient, or other non-clinical reasons.

for its adequate performance met simultaneously, hence their classification as incorrectly conducted inductions. Table 3 shows other characteristic conditions of the cases considered as failed induction. If instead of using the most updated criterion to define active labor, namely, 6 cm of dilatation, the old value of 4 cm had been used, the proportion of women with a diagnosis of failed induction before reaching the active phase would have been equally high, 66 (61,1 %).

DISCUSSION

In this study, none of the women assigned the failed induction diagnosis met the criteria for a well conducted induction as pre-requisite to accept the validity of such diagnosis (23). In many cases, inadequate maturation methods were used, no objective assessment of cervix status was made before the initiation of maturation or induction, minimum recommended oxytocin perfusion and membrane rupture times were not respected, and no regular increases in oxytocin doses until achieving adequate labor were performed. This resulted in a higher proportion of c-sections in women subjected to labor induction than reported in the literature, ranging between 20 and 30% (24).

As a result of all these findings, the frequency of cesarean section in this study is higher than reported in 156 of the 157 clinical trials included in a systematic review on the subject of induction (14), and comparable to the to the 47.4% found in a clinical trial that included only women with protracted pregnancy and unfavorable cervix, i.e., women with a poor prognosis for vaginal delivery (25).

Oxytocin as the most widely used method for cervical maturation when it was required could

Table 2.
Induction processes, methods and regimens in 289 women with term pregnancies, and neonate characteristics in a referral institution in Medellín (Colombia), 2015-2016

Induction and newborn characteristics	Result
Bishop score at the start of the induction as documented in the clinical record or calculated based on data taken from the pelvic exam: n (%) - 0- 6 - 7-13 - "Favorable" - "Unfavorable" - No data or description	 66 (22.8) 39 (13.5) 33 (11.4) 19 (6.6) 132 (45.7)
Membrane status at the start of the induction: n (%) - Intact - Ruptures - No data	 234 (81.0) 47(16.3) 8 (2.8)
Method employed for cervical maturation: n (%) - Misoprostol - Dinoprostone - Oxytocin - Not required	 3 (1.0) 66 (22.8) 154 (53.3) 66 (22.8)
Labor induction method: n (%) - Misoprostol - Dinoprostone - Oxytocin - Amniotomy plus oxytocin	 3 (1.0) 38 (13.1) 245 (84.8) 3 (1.0)
Total labor induction time Hours (median, 25th-75th percentiles)	17.5 (11-26.4)
Continuous induction: n (%) - Sí - No - No data	 160 (55.4) 127 (43.9) 2 (0.7)
Use of epidural analgesia: n (%) - Sí - No	 111 (38.4) 178 (61.6)
Minimum interval between oxytocin dose changes. Hours (median and percentiles)	2 (1-4.5)
Maximum interval between oxytocin dose changes. Hours Median (25th-75th percentiles)	5 (3-7)

Continuación Tabla 2

Table 2.
Induction processes, methods and regimens in 289 women with term pregnancies, and neonate characteristics in a referral institution in Medellín (Colombia), 2015-2016

Induction and newborn characteristics	Result
Assessment interval regularity: n (%) - Yes - No - No dose changes - No data	 7 (2.8) 207 (82.8) 34 (13.6) 2 (0.8)
Maximum administered dose of oxytocin, mU Mean (Standard deviation - SD)	7.66 (4.65)
C-section indication: n (%) Failed induction Cephalopelvic disproportion Compromised fetal wellbeing Others	 108(78.3) 13 (9.4) 11 (7.9) 6 (4.4)
Birth weight (in g). Mean (SD)	3071 (492.3)
1 minute APGAR score. Median (25th-75th percentiles)	8 (8-9)

be the first explanation for the excess number of c-sections performed in women with induction, considering that systematic reviews support the use of misoprostol (26), prostaglandins (27), or mechanical methods (28), and oxytocin is not part of the recommendations from the various organizations (20, 29, 30).

The higher proportion is explained by inadequate induction management. An objective assessment of cervical status before initiating induction was carried out in only one-third of the women. Induction in women with unfavorable cervix reduces the odds of successful induction (31). The majority of c-sections were carried out as a result of a failed induction diagnosis which was made before the recommended criteria and induction times were met.

Labor induction was achieved with oxytocin in the majority of women. Systematic reviews (32, 33) support low-dose and high-dose oxytocin regimens as an adequate labor induction method in cases of favorable cervix. Usually, a dose of 8-12 mU/min is needed for adequate labor, with a maximum dose of 30 mU/min (20, 29); however, in order for the dose to be effective, continuous perfusion must be ensured, with regular dose adjustments every 15 to 40 minutes until good uterine activity is achieved, which was not the case in this study.

As part of the strengths of this study it is important to highlight the review of all sequential births in a 17-month period, reducing the potential selection bias. Additionally, a comprehensive search of the necessary information was conducted in the clinical records and complementary entries. The most important strength of this study is that it highlights a series of modifiable factors, unlike what happens in most of the studies in the literature which focus on the identification of clinical, social or demographic factors, many times not amenable to intervention (34). Moreover, there is a paucity of published studies, both nationally and internationally, about the adequate assessment

Table 3.
Characteristics of the 108 pregnant women who underwent c-section with a diagnosis of failed induction in a referral institution in Medellín (Colombia), 2015-2016

Nulliparous One or more previous deliveries	74 (68.5) 34 (31.5)
Cervical maturation method Misoprostol Dinoprostone Oxytocin No maturation required	 1 (0.99) 27 (25.0) 67 (62.0) 13 (12.0)
Maximum oxytocin dose in patients with failed induction diagnosis and poor or no uterine activity: n (%) - 1-7 mU/min - 8-12 mU/min - 13-25 mU/min - 25-30 mU/min	 32 (56.1) 13 /22.8) 12 (21.1) 0 (0)
Quality of uterine activity at the time of diagnosis - No activity - Poor - Good - No data	 42 (38.9) 23 (21.3) 31 (28.7) 12 (11.1)
Cervical dilatation at the time of failed induction diagnosis: n (%) - 0-5 cm - 6-10 cm - No data	 85 (78.7) 15 (13.8) 8 (7.4)
Time without cervical changes at the time of diagnosis dilatation or active labor phase arrest. Hours (median, interquartile range)	2 (1.66-2.75)
Membrane status at the time of failed induction diagnosis: n (%) - Intact - Ruptured - No data	 67 (62) 38 (35.1) 3 (2.77)
Time between membrane rupture and failed induction diagnosis. Hours, median (25th-75th percentiles).	7 (3.3-19)

of labor. On the other hand, weaknesses include the retrospective nature of the study, because deficiency or absence of many data in the clinical records may influence the interpretation of the results. For example, in a significant percentage of patients (63.6%) it was impossible to gain objective information about the degree of cervical maturation in order to classify the initial intervention as either maturation or induction. Similarly, it is not possible to distinguish between the end of the cervical maturation process and the start of induction with favorable cervix, requiring an assumption regarding induction process and time from the moment in which any of the methods was applied for the first time. However, considering that the objective was to assess the process implemented at the present

time in the institution, this absence of information becomes a relevant finding requiring action.

This lack of data would have a connotation of bias in a study claiming to make inferences or extrapolations to other populations. However, in this case, it provides additional support of the lack of adherence to the protocols and the resulting incorrect or untimely decisions.

CONCLUSION

The excess number of cesarean sections found among women subjected to labor induction in our institution could be related to flaws in the induction process and the incorrect diagnosis of failed induction.

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Conflict of interest: None declared.