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Original article

Comparing expectant management and spontaneous labor approaches in studying the effect of labor induction on cesarean delivery

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ABSTRACT

Purpose: Evidence of the impact of labor induction on cesarean delivery (CD) remains inconclusive because of differing methodological approaches. A spontaneous labor comparison group describes patterns retrospectively, whereas an expectant management comparison group prospectively evaluates a decision to induce. We examined the influence of comparison group on the association between labor induction and CD.

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Methods: We studied 166,559 mother-newborn dyads from 14 National Perinatal Information Center member hospitals, 2007–2012. We included singleton births 34–42 completed weeks' gestation and excluded women with contraindications to vaginal delivery. We calculated risk ratios (RR) adjusted for hypertensive and diabetic disorders, intrauterine growth restriction, parity, and maternal age.

Results: When comparing induction to spontaneous labor, induction had significantly lower risk for CD at weeks 34–35 (adjusted RR [95% confidence interval (CI)]: 0.6 [0.5, 0.7] for week 34 and 0.7 [0.6, 0.8] for week 35) and higher risk at weeks 37–41 (adjusted RRs [95% CIs]: 1.8 [1.6, 2.1], 2.1 [1.9, 2.2], 1.8 [1.7, 1.9], 1.9 [1.8, 2.0], and 1.6 [1.5, 1.7], respectively). When comparing induction to expectant management, adjusted RRs [95% CIs] were significantly below 1.0 for week 34 (0.8 [0.7, 0.9]), week 36 (0.9 [0.8, 0.9]), and week 37 (0.9 [0.8, 0.9]), and were only elevated at week 40 (1.4 [1.3, 1.4]) and week 41 (1.4 [1.3, 1.5]). *Conclusions:* Using two different methodological approaches with the same sample, we confirm that comparing labor induction to spontaneous onset of labor, instead of expectant management of pregnancy, does not fully inform clinical practice and may lead to an exaggerated estimate of the risk of CD. © 2016 Elsevier Inc. All rights reserved.

Introduction

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http://dx.doi.org/10.1016/j.annepidem.2016.04.009 1047-2797/© 2016 Elsevier Inc. All rights reserved. Labor induction is common in the United States, and although generally considered to be safe when there are no contraindications to vaginal delivery, there has been much speculation that labor induction increases the risk of cesarean delivery [1-4]. Observational studies comparing labor induction to spontaneous onset of labor have found an increased risk of cesarean delivery among induced women [5-12]. However, when labor induction is compared to expectant management (defined as continuing pregnancies), a decreased risk of cesarean delivery among induced women has been found in some [13-17], but not all studies [6,18].

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Randomized controlled trials of labor induction versus expectant management have found decreased or no difference in risk of cesarean delivery [19–23].

Studies address two different questions depending on the comparison group used: "Is cesarean delivery more common following induced or spontaneous labors?" (a retrospective approach with spontaneous labor as the comparison) or "Does inducing labor at this time result in higher risk of cesarean delivery than not inducing at this time?" (a prospective approach with expectant management as the comparison). The expectant management comparison is more relevant to clinical practice because the choice for care is between inducing labor or not inducing labor at that time, not between induced labor and spontaneous labor [13]. The spontaneous labor comparison is useful for describing patterns without implications for interventions. In contrast to most previous studies that considered only one of these comparison groups, we directly examined differences in the associations between labor induction and cesarean delivery using different comparison groups within a single data set. The goal of this analysis was to quantify the direction and magnitude of differences in estimates depending on the method used to compare labor induction and cesarean delivery.

Materials and methods

We studied linked maternal and newborn records from National Perinatal Information Center/Quality Analytic Services (NPIC/QAS). NPIC/QAS is a nonprofit organization that collects and analyzes inpatient perinatal data from member hospitals throughout the United States and disseminates aggregate results to its members. Records include administrative discharge data supplemented by detailed health information including gestational age and birthweight. Our sample was based on data from newborn discharges between January 1, 2007, and December 31, 2012, from 50 NPIC/QAS hospitals that were members for the entire 6-year study period. The study was approved by the Women & Infants Hospital Institutional Review Board (Project 13-0039), which is the research oversight committee for NPIC/QAS, and determined to be exempt from further review by the Brown University Institutional Review Board (#1401000978).

Records were linked within hospital and year by the medical record number or billing number on the maternal record and the maternal medical record number on the newborn record. Among more than 1.3 million newborn records, 88% were linked to a maternal record. Hospitals could submit different types of data (maternal medical record number, billing number, other number, none) on the newborn record for linkage by calendar quarter-year and tended to have very high or very low link rates by guarter. We examined link rates by hospital and calendar year and excluded 955 records from hospital-year strata with less than 10% link rates, resulting in a starting sample of 1,214,783 linked mother-newborn dyads (Fig. 1). Gestational age at birth was reported as completed weeks. We defined valid gestational age as 20-44 completed weeks and found 70% of records to have a nonmissing and valid gestational age. Similar to link rates, the proportion of hospitals reporting gestational age for a given year was very high or very low. Therefore, we excluded all records from 72 hospital-year strata with less than 10% of records with valid gestational age, to protect against biases resulting from gestational age reported only on particular records. Throughout the article, any noted gestational age refers to completed weeks gestation, that is, 37 weeks means 37 completed weeks gestation, or 37 0/7 weeks to 37 6/7 weeks.

Although parity is requested for all records for the NPIC/QAS data, it is only provided by some of the participating hospitals. Since number of prior births is an important factor in the relationship between labor induction and cesarean delivery, we restricted the

sample to 14 hospitals with 226,596 mother-newborn dyads with valid parity data. Parity was categorized as primipara (no previous live births or stillbirths) or multipara (at least one previous live birth or stillbirth). Stillbirths without newborn records (most stillbirths, as this is the expected protocol) were not included in the study beyond the maternal-newborn record linking step, and we excluded an additional 40 linked records with stillbirth indicated on the maternal record. We also excluded records with maternal age calculated to be less than 8 years or greater than 64 years (n = 2; [24]). Since the main outcome was cesarean delivery versus vaginal delivery, we excluded women with potential contraindications to vaginal delivery who would typically require cesarean delivery. Such restrictions also resulted in exclusion of most women not at risk for labor induction. Exclusions included pregnancies with multifetal gestation (n = 7,992), placenta previa (n = 1,080), cephalopelvic disproportion (n = 4,586), nonvertex presentation (n = 10,015), prior cesarean delivery (n = 35,467), and abnormalities in the shape or position of the uterus (n = 855; [2,24]), resulting in a final sample of 166,559 (Fig. 1).

Labor induction was identified by the International Classification of Diseases, Ninth Revision (ICD-9) procedure codes 73.1 (Other surgical induction of labor), 73.01 (Induction of labor by artificial rupture of membranes), and 73.4 (Medical induction of labor). Cesarean delivery was identified through the All Patient Refined Diagnosis Related Group (APR-DRG) code 540, which is based on the ICD-9 procedure codes 74.0 (Classical cesarean section), 74.1 (Low cervical cesarean section), 74.2 (Extraperitoneal cesarean section), 74.4 (Cesarean section of unspecified type), and 74.99 (Other cesarean section of unspecified type; [25]). We adapted an algorithm based on ICD-9 diagnosis codes to further classify cesarean deliveries without labor induction as either scheduled prelabor (cesarean delivery without any diagnosis codes indicative of active labor) or occurring during labor (cesarean delivery with at least one diagnosis code indicative of active labor; Supplemental Table 1; [26,27]). Spontaneous labors included (1) records without any ICD-9 procedure codes for labor induction or cesarean delivery and (2) cesarean deliveries with at least one ICD-9 diagnosis code indicative of active labor. There were no missing data for labor induction, spontaneous labor, cesarean delivery, or any medical conditions because these variables were defined based on the presence or absence of ICD-9 codes.

We conducted analyses using both spontaneous labor and expectant management comparison groups. First, we calculated risk ratios for cesarean delivery among induced labor versus spontaneous labor for all deliveries 34-42 weeks and also within each gestational week. This comparison group included spontaneous labors ending in vaginal or cesarean delivery but excluded all prelabor cesarean deliveries. Second, we calculated risk ratios for cesarean delivery among induced labor versus expectant management for each week from 34 to 42 weeks. For a given week, the labor induction group included all deliveries with labor induction during that week, whereas the expectant management group included spontaneous labor deliveries in that same week and all deliveries, regardless of delivery method, that occurred in subsequent weeks [28]. Prelabor cesarean deliveries occurring in the same week as the induction were excluded from the expectant management group; however, prelabor cesarean deliveries in subsequent weeks were included. For example, for the analysis at 37 weeks, we compared labor inductions at 37 weeks to deliveries at 37 weeks not involving labor induction or prelabor cesarean delivery plus all deliveries at 38-42 weeks.

We repeated the first two analyses controlling for the following suspected confounders: any diabetic disorder, any hypertensive disorder, intrauterine growth restriction (IUGR), parity, and maternal age [13,18,20,29–31]. We then repeated the analysis with

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