

A nationwide cross-sectional survey of episiotomy practice in China

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Summary

Background A restrictive use of episiotomy was recommended by the obstetric society in China, but limited information on the epidemiology and the effects of restrictive use of episiotomy on maternal and fetal outcomes have been published.

Methods The China Labor and Delivery Survey is a cross-sectional investigation with a cluster random sampling scheme in 2015-2016 with the aim to describe detailed epidemiology of labor and delivery in China. We calculated the episiotomy rate by parity using the survey data. Associated factors of episiotomy were selected using mixed models with a random effect for the hospital-level clustering. Logistic regression models were fitted to examine the effects of mediolateral episiotomy on maternal and neonatal outcomes among the propensity score-matched women.

Findings The episiotomy rate among vaginal births was 41.7% [95% confidence interval (CI): 40.1% - 43.2%] in nulliparae and 21.5% (95% CI: 19.4% - 23.5%) in multiparae in China. Associated factors of episiotomy included pre-pregnancy BMI, maternal diseases, and obstetric factors. More than half of episiotomies in nulliparae and one-fourth in multiparae had no indications. Mediolateral episiotomy without indicators increased the risk of 3rd or 4th degree perineal laceration [odds ratio (OR) = 2.64, 95% CI: 1.08-6.48] in nulliparae without neonatal benefits.

Interpretation Episiotomy was performed more than medically necessary in China. Mediolateral episiotomy without indications more than doubled the risk of 3rd and 4th degree perineal laceration in nulliparae without neonatal benefits.

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Keywords: episiotomy; China; maternal outcome; neonatal outcome; epidemiology

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Introduction

Episiotomy became widespread since 1920s as a surgery to prevent perineal laceration and associated maternal and infant morbidity. Although routine prophylactic episiotomy was performed during the 1980s to the mid-1990s, concerns on the potential complications associated with episiotomy arose during this period.¹ Since 1996, a large volume of literature has concluded that routine episiotomy is unnecessary and may even increase the risk of 3rd or 4th degree perineal laceration.²⁻⁴ The World Health Organization (WHO) and other professional societies recommended restrictive

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Research in context

Evidence before this study

The World Health Organization and professional societies recommended restrictive over routine episiotomy since 1990s, given the evidence on the risks of the procedure and no benefits of routine use. But limited information has been published on the episiotomy practice in China at a country level. We used PubMed and China National Knowledge Infrastructure (CNKI) to search for studies published from Jan 1, 1990 to Dec 31, 2020 using the terms “episiotomy”, “midline episiotomy”, “mediolateral episiotomy”, and “episiotomy, epidemiology” and the reference lists of retrieved studies. The latest Cochrane systematic review published in 2017 including 12 studies (6177 women) that compared restrictive episiotomy with routine episiotomy policy. The meta-analysis indicated that restrictive episiotomy policies resulted in a decreased rate of severe perineal/vaginal trauma (risk ratio [RR] 0.70, 95% CI 0.52 to 0.94) without adding risks of other short-term or long-term adverse outcomes, e.g., blood loss at delivery, Apgar score less than seven at five minutes, perineal infection, perineal pain, dyspareunia, urinary inconvenience, and genital prolapse. The subgroup analysis by type of episiotomy showed no significant difference on the rate of severe perineal/vaginal trauma between restrictive and routine use of episiotomy in subgroups with midline or mediolateral episiotomy (RR 0.74 [95% CI: 0.51, 1.07] and 0.62 [95% CI: 0.37, 1.07], respectively). Missing information on the type of episiotomy in many studies and the confounding by the indications for performing episiotomy, e.g., prolonged second stage of labor, placenta abruption, in the association between episiotomy and perineal laceration resulted in no clear consensus regarding the effects of mediolateral episiotomy on maternal and neonatal outcomes.

Restrictive episiotomy was recommended in China since 2000s. According to a national survey in 2003, the overall episiotomy rate was 44.9% in China at a country level. It is unknown whether the rates have decreased since the evidence-based recommendation. In the absence of information on the temporary episiotomy practice in China and a clear consensus on the effects of mediolateral episiotomy on maternal and neonatal outcomes, the potentially avoidable episiotomy and the related risks and/or benefits could not be estimated. Understanding the epidemiology of episiotomy is the first step towards evidence-based clinical practice.

Added value of this study

The current study found that episiotomy was performed in 41.7% (95% CI: 40.1% - 43.2%) of nulliparous vaginal deliveries and 21.5% (95% CI: 19.4% - 23.5%) of multiparous vaginal deliveries. Episiotomy without medical indications accounted for more than half of episiotomies in primiparae and one-fourth in multiparae. Mediolateral episiotomy did not improve perinatal outcomes but increased the risk of 3rd or 4th degree perineal laceration by more than 2.5-fold in nulliparae.

Implications of all the available evidence

Mediolateral episiotomy without medical indications increased the risk of 3rd or 4th degree perineal laceration without gaining neonatal benefits. Episiotomy was performed more than medical necessary in China. Great efforts are warranted to reduce unnecessary episiotomy through evidence-based education and training.

over routine episiotomy since 1990s, although no ideal rate of episiotomy is suggested.^{1,5-9} However, practice change is not easy and may take time.

After the evidence-based recommendation of restrictive over routine episiotomy was promoted, the episiotomy rate decreased in high-income countries. For example, the rate reduced from 25% in the United States in 2004 to 9.4% in 2011; from 58% in France in 1996 / 1997 to 26.8% in 2010, and then to 19.9% in 2014. In a prospective observational study in Hong Kong, Lai et al.¹⁰ demonstrated a reduction of episiotomy rate from 73.3% in 2006 to 26.8% in 2007 / 2008 since the implementation of restrictive episiotomy policy. But in some middle-income countries, e.g., China, the rate has not decreased substantially.^{1,9,11} Understanding the epidemiology of episiotomy is the first step towards evidence-based clinical practice. According to a national survey, the overall episiotomy rate was 44.9% in Mainland China in 2003.¹² Episiotomy rates higher than 80% were also reported in sampling surveys during 2001 to 2003, which also showed a large variation among hospitals and regions.^{13,14}

Very limited information has been published on the episiotomy practice in China at a country level. Furthermore, while midline episiotomy has been demonstrated as a risk factor for 3rd and 4th degree lacerations, the effects of mediolateral episiotomy (the more common type of episiotomy¹⁵ performed in China) remain unclear.^{16,17} In Europe where the mediolateral episiotomy is also more frequently used,² the Euro-Peristat showed a significant increase in severe perineal tears rate alongside with the decrease of episiotomy rate (except for Germany and Norway), which was consistent with a national study in France from 2007 to 2014.^{11,18} But other studies showed no increase in severe perineal tears associated with the performance of restrictive episiotomy.^{4,19} Unfortunately, there is often insufficient information to estimate the potentially avoidable episiotomy and related risks and/or benefits due to missing information on the type of episiotomy (midline or mediolateral) in many studies.^{2,15} Finally, there are insufficient objective criteria to recommend episiotomy. Currently, prolonged second stage of labor, a high probability of perineal tears, fetal distress, operative vaginal delivery, and shoulder dystocia are medical indications for episiotomy in China. But clinical judgment remains the best guide for the performance of this procedure.^{2,13,20,21} The indications for performing

episiotomy, e.g., prolonged second stage of labor, placenta abruption, may themselves be confounders in the association between episiotomy and perineal laceration.² It remains a challenge to define a medically necessary rate of episiotomy and the potential side-effects when episiotomy is performed without medical indication.

The aim of this study was to describe the epidemiology of episiotomy in China, and to investigate the effects of selective use of episiotomy on maternal and fetal outcomes e.g., third- or fourth-degree perineal laceration, postpartum haemorrhage, Apgar score at 5 minutes less than four among women without medical indication of episiotomy.

Methods

Study population

The China Labor and Delivery Survey was a multicenter, facility-based, cross-sectional study carried out throughout the country from March 1, 2015 to December 31, 2016. The main objective of the Survey was to describe detailed epidemiology of labor and delivery in China. Hospitals with at least 1000 deliveries a year were eligible for the Survey. We randomly selected six weeks within one year for facilities with 6,000 or more deliveries per year, or ten weeks for those with fewer than 6,000 deliveries per year for data collection. All women with births delivered at 24 or more weeks of gestation or weighing 500 grams or more during the selected weeks were included in the Survey. Data were extracted from medical records and recorded in a standardized form by trained data collectors. We included information on the performance (yes or no) and the type (midline or mediolateral) of episiotomy. This methodology was used in the WHO Global Survey of Maternal and Perinatal Health and the WHO Multi-Country Survey of Maternal and Newborn Health.^{22,23} Detailed description of the methodology has been published elsewhere.²⁴ The study protocol was approved by the Research Project Review Panel of the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction at the Department of Reproductive Health and Research of WHO, and the WHO Research Ethics Review Committee, Geneva, Switzerland, and the ethics committees at the Xinhua Hospital and all participating centers. Because only anonymous clinical information was collected, no individual informed consent was obtained.

To improve the representativeness of the study population, a weight that took into account the number of births in each province in 2016, hospital delivery volume and the sampling fraction was created. The number of births in each province was obtained from the demographic yearbook published by the National

Bureau of Statistical of China (<http://www.stats.gov.cn/tjsj/ndsj/>). We stratified the number of births in a province by hospital levels. The weight was calculated as the inverse probability of sampling at the same hospital level in each province.²⁴ The present study was performed using actual data available in the China Labor and Delivery Survey. For the purpose of this analysis, the study population was restricted to vaginal deliveries with complete information on episiotomy use. We excluded caesarean deliveries and those without information on the mode of delivery; we further excluded deliveries without information on episiotomy (0.6% of the vaginal deliveries). We conducted the analyses in primiparae and multiparae, separately, as labor and delivery differ dramatically between these two groups of women. Thus, deliveries without information on parity were further excluded. The selection process is shown in [Figure 1](#).

Statistical analysis

Episiotomy was treated as both an outcome and an exposure for maternal and neonatal outcomes. Demographic and medical conditions potentially associated with the performance of episiotomy and/or the pregnancy outcomes were prespecified according to our pilot analysis and previously published studies.⁹⁻²⁵ Hospital factors and demographic variables included: hospital level (secondary / tertiary), hospital annual delivery number (< 5000, 5000 - 10000, > 10000); maternal age (< 35 / ≥ 35 years), education level (low: illiterate, primary, and junior school; intermediate: high school, technical school, and junior college; high: college or higher degree), insurance, and pre-pregnancy body mass index [BMI, defined as weight divided by the square of height (kg/m²)]. BMI was categorized into three orders: < 18.5 kg/m² (underweight), 18.5-24.9 kg/m² (normal weight), and ≥ 25 kg/m² (overweight or obesity) according to the WHO classification.²⁶ Related maternal medical conditions were: parity, previous caesarean section, assisted reproductive technology, multiple pregnancy, maternal diseases (hypertension disorders, diabetes mellitus, thyroid diseases, cardiac diseases, kidney diseases, asthma, and disorder of immune system), sexually transmitted diseases, placental abnormalities (placenta previa, placenta abruption, and premature rupture of fetal membranes), and labor / delivery associated factors [fetal presentation, onset of labor (spontaneous or induced), anesthesia or analgesia, mode of delivery (spontaneous, forceps, or vacuum-assisted), prolonged second stage of labor]. We also investigated fetal conditions including fetal distress, gestational age at birth, and birth weight ([Table 1](#)).

Maternal outcomes potentially associated with episiotomy were 3rd or 4th degree perineal laceration, postpartum haemorrhage, admission to an intensive-care unit (ICU) / referral to a higher level hospital / seven

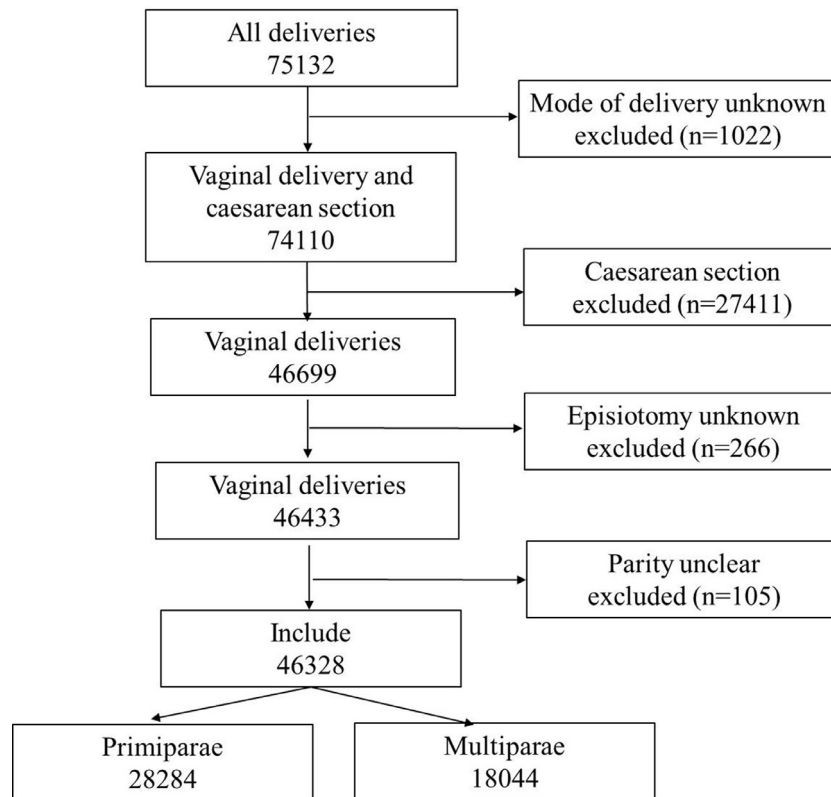


Figure 1. Study flow chart

days or more of postnatal hospitalization, and maternal death.²⁵ The 3rd or 4th degree perineal laceration was defined as an injury to perineum involving anal sphincter complex (external anal sphincter and internal anal sphincter) without or with the disruption of anal epithelium, respectively.² We developed a composite maternal outcome index, which was defined as having any of the adverse maternal outcome mentioned above. A 5-min Apgar score of less than four was used as the adverse neonatal outcome.

We described the episiotomy rate at the national and regional levels (a total of seven administrative geographic regions including northeast, north, east, central, south, southwest, and northwest in China).²⁴ We used the bootstrap resampling method to calculate the 95% confidence interval (CI) of the episiotomy rate.²⁷ A multi-level model (mixed model) was conducted to evaluate the factors potentially associated with episiotomy at the hospital and individual levels based on the preliminary analysis that demonstrated a significant difference of episiotomy rate among hospitals. Each hospital represented one unit of analysis (level two); women nested within the hospital were the analysis unit at level one.⁹ A backward procedure was used to select associated factors, i.e., a variable was retained in the model if the odds ratios (ORs) of any of the other covariates changed more

than 10% after the variable was removed from the model.²⁸

We estimated hospital-specific episiotomy rates based on the selected generalized linear mixed model. A two-step cluster was conducted to group cases with episiotomy into clusters with homogeneous medical conditions.²⁹ According to the results of a cluster analysis, guidelines of episiotomy, and previously published studies,^{2,9,20,21,25} the underlying clinical reasons were further classified as: without medical indicators, anesthesia or analgesia, maternal chronic diseases and obstetrics complications. We focused on women without clinical indication to perform episiotomy, i.e., those who had no pathologic conditions potentially associated with the use of episiotomy. A propensity score method was performed to match cases with/without the use of episiotomy.³⁰ We created a propensity score for each observation to estimate the probability of episiotomy including all exploratory variables listed in Table 1. A caliper of 0.025 in the logits of propensity score was requested for pairs of individuals from groups with/without the use of episiotomy to be matched. An optimal full matching was performed to gain a maximal number of matched pairs. Multivariable logistic regression models were fitted to examine the effects of medialateral episiotomy on maternal and neonatal outcomes

Factor	Primiparae ^a				Multiparae ^a			
	Proportion (%)	Episiotomy rate (%)	Adjusted odd ratios (95% CI)		Proportion (%)	Episiotomy rate (%)	Adjusted odd ratios (95% CI)	
			Model 1 ^b	Model 2 ^b			Model 1 ^b	Model 2 ^b
Hospital class								
Secondary hospital	50.0	40.8	Ref		63.8	23.1	Ref	
Tertiary hospital	50.0	42.6	0.98 (0.43, 2.26)		36.2	18.5	0.90 (0.41, 1.97)	
Hospital annual delivery number								
<5000	44.7	49.3	Ref		57.3	28.6	Ref	
5000-10000	33.5	37.6	0.74 (0.41, 1.33)		29.9	14.8	0.81 (0.46, 1.42)	
>10000	21.8	32.3			12.8	5.0		
Hospital type								
General hospital	41.7	48.9	Ref		56.6	30.3	Ref	
Maternity hospital	58.3	36.5	0.54 (0.21, 1.39)		43.4	10.0	0.40 (0.16, 1.00)	
Maternal age (year)								
< 35	97.8	41.5	Ref		85.8	22.3	Ref	
≥ 35	2.2	48.0	1.38 (1.35, 1.41)		14.2	16.1	1.08 (1.06, 1.09)	
Maternal education								
Low	20.6	39.6	0.85 (0.84, 0.85)		45.5	23.6	1.05 (1.04, 1.07)	
Middle	39.4	41.9	Ref		31.7	18.7	Ref	
High	31.0	40.2	0.98 (0.97, 0.99)		14.6	16.1	2.92 (2.86, 2.99)	
Insurance								
Yes	64.5	42.9	Ref		52.7	24.0	Ref	
No	32.8	38.5	0.93 (0.92, 0.93)		44.6	17.5	1.18 (1.16, 1.19)	
Prepregnancy BMI								
< 18.5 kg/m ²	12.5	42.0	0.86 (0.85, 0.87)		8.5	29.6	1.48 (1.46, 1.50)	1.48 (1.45, 1.50)
18.5-24.9 kg/m ²	53.4	40.5	Ref		49.6	18.5	Ref	Ref
≥ 25 kg/m ²	6.4	43.8	0.94 (0.93, 0.95)		8.4	14.3	0.87 (0.86, 0.89)	0.90 (0.89, 0.92)
Previous caesarean section								
No	-	-	-		94.2	20.1	Ref	Ref
Yes	-	-	-		5.8	43.0	5.56 (5.46, 5.66)	5.39 (5.30, 5.49)
Assisted reproductive technology								
No	94.6	41.1	Ref	Ref	92.9	20.5	Ref	Ref
Yes	5.2	51.2	1.51 (1.49, 1.54)	1.55 (1.52, 1.57)	6.9	34.3	1.76 (1.72, 1.79)	1.84 (1.81, 1.88)
Multiple pregnancy								
No	99.5	41.7	Ref		99.2	21.5	Ref	
Yes	0.5	38.5	1.18 (1.12, 1.24)		0.8	13.3	1.73 (1.63, 1.83)	

Table 1 (Continued)

Factor	Primiparae ^a				Multiparae ^a			
	Proportion (%)	Episiotomy rate (%)	Adjusted odd ratios (95% CI)		Proportion (%)	Episiotomy rate (%)	Adjusted odd ratios (95% CI)	
			Model 1 ^b	Model 2 ^b			Model 1 ^b	Model 2 ^b
Maternal disease								
No	79.7	41.9	-	-	78.1	23.6	-	-
Yes			-	-			-	-
Hypertensive disorders ^c	2.4	46.1	1.55 (1.52, 1.58)		1.9	19.9	1.44 (1.40, 1.49)	
Diabetes mellitus ^d	10.3	41.1	1.13 (1.12, 1.15)		8.8	15.4	1.21 (1.19, 1.23)	1.22 (1.20, 1.24)
Thyroid diseases	3.4	46.6	0.99 (0.97, 1.01)		2.1	15.3	0.60 (0.58, 0.62)	
Cardiac diseases	0.2	17.5	0.25 (0.23, 0.27)		0.1	24.1	1.54 (1.37, 1.73)	1.56 (1.39, 1.76)
Kidney diseases	0.1	61.2	1.87 (1.65, 2.12)		0.03	24.2	1.39 (1.10, 1.75)	1.49 (1.19, 1.88)
Asthma	0.1	41.3	1.25 (1.14, 1.38)		0.04	9.3	0.52 (0.40, 0.68)	0.49 (0.38, 0.63)
Disorder of immune system	0.1	47.9	0.85 (0.78, 0.93)		0.1	11.2	0.50 (0.43, 0.58)	0.46 (0.40, 0.53)
Sexually transmitted diseases	0.8	27.9	0.74 (0.71, 0.77)	0.70 (0.67, 0.73)	0.5	12.0	0.94 (0.88, 1.01)	1.00 (0.94, 1.08)
Placenta previa								
No	99.7	41.7	Ref	Ref	99.8	21.5	Ref	Ref
Yes	0.3	15.8	0.31 (0.29, 0.34)	0.29 (0.27, 0.32)	0.2	2.0	0.09 (0.07, 0.11)	0.09 (0.07, 0.11)
Placenta abruption								
No	99.6	41.7	Ref		99.3	21.5	Ref	Ref
Yes	0.3	40.5	0.83 (0.78, 0.88)		0.6	12.1	0.42 (0.39, 0.45)	0.42 (0.39, 0.45)
Premature rupture of fetal membranes								
No	84.4	41.7	Ref	Ref	86.5	20.5	Ref	Ref
Yes	15.6	41.3	1.00 (0.99, 1.01)	1.01 (1.00, 1.02)	13.2	26.9	1.31 (1.30, 1.33)	1.32 (1.31, 1.34)
Unknown	0.1	60.9	4.95 (4.07, 6.02)	6.04 (5.00, 7.31)	0.3	55.2	8.40 (7.76, 9.09)	9.03 (8.35, 9.77)
Presentation								
Vertex presentation	99.4	41.8	Ref		98.9	21.5	Ref	
Breech presentation and others	0.5	28.4	0.43 (0.40, 0.45) ^f		0.8	18.5	0.98 (0.93, 1.04)	
Onset of labour								
Spontaneous	79.5	41.5	Ref		84.7	21.4	Ref	
Induced	20.0	42.3	0.94 (0.93, 0.95)		14.9	22.2	0.90 (0.89, 0.91)	
Augmentation								
No	75.4	40.3	Ref		84.6	20.3	Ref	
Yes	24.0	46.2	1.26 (1.25, 1.27)		15.1	28.2	1.19 (1.18, 1.21)	
Anesthesia or analgesia								
No	63.1	42.0	Ref	Ref	78.1	21.9	Ref	Ref
Yes	34.7	41.3	1.25 (1.24, 1.26)	1.30 (1.29, 1.31)	19.7	20.8	2.19 (2.16, 2.22)	2.18 (2.15, 2.21)

Table 1 (Continued)

Factor	Primiparae ^a				Multiparae ^a			
	Proportion (%)	Episiotomy rate (%)	Adjusted odd ratios (95% CI)		Proportion (%)	Episiotomy rate (%)	Adjusted odd ratios (95% CI)	
			Model 1 ^b	Model 2 ^b			Model 1 ^b	Model 2 ^b
Mode of delivery								
Spontaneous	96.8	40.1	Ref	Ref	98.9	20.9	Ref	Ref
Forceps	2.1	89.6	9.86 (9.51, 10.22)	10.27 (9.91, 10.65)	0.5	84.3	35.51 (33.07, 38.13)	33.89 (31.59, 36.36)
Vacuum-assisted	0.6	96.4	51.92 (46.88, 57.51)	48.23 (43.56, 53.40)	0.4	89.2	17.62 (16.10, 19.28)	17.65 (16.13, 19.32)
Prolonged second stage of labor^e								
No	87.9	39.5	Ref	Ref	85.9	18.6	Ref	Ref
Yes	10.2	63.8	3.38 (3.34, 3.41)	3.48 (3.44, 3.52)	10.8	47.4	4.27 (4.22, 4.33)	4.28 (4.23, 4.33)
Fetal distress								
No	95.7	39.9	Ref	Ref	98.0	21.1	Ref	Ref
Yes	4.1	82.4	8.09 (7.92, 8.26)	7.93 (7.77, 8.10)	1.8	41.0	2.36 (2.28, 2.43)	2.41 (2.34, 2.49)
Gestational age at birth								
Preterm	6.3	38.2	1.03 (1.02, 1.04)	0.99 (0.97, 1.00)	6.7	17.1	0.62 (0.61, 0.63)	0.62 (0.61, 0.64)
Term	92.4	41.9	Ref	Ref	90.8	21.7	Ref	Ref
Postterm	0.3	54.8	0.70 (0.65, 0.74)	0.66 (0.62, 0.71)	0.4	21.5	1.26 (1.18, 1.34)	1.26 (1.18, 1.34)
Birth weight								
< 4000 g	94.7	41.5	Ref	Ref	92.5	21.7	Ref	Ref
≥ 4000 g	3.7	52.7	2.11 (2.08, 2.15)	2.09 (2.06, 2.13)	5.6	20.8	1.33 (1.31, 1.36)	1.35 (1.33, 1.38)

Table 1: Distribution of characteristics and the associations with episiotomy among primiparae and multiparae, China, 2015-2016

a: Percentages may not sum to 100 due to missing values. Less than 10% of data for each variable was missing, except for BMI (23.4%). We included missing categories for all regression analyses.

b: Model 1: model with all covariates listed. Model 2: model with selected covariates.

c: Hypertensive disorders includes chronic hypertension, gestational hypertension, preeclampsia, and eclampsia.

d: Diabetes includes pre-existing and gestational diabetes mellitus.

e: Prolonged second stage of labor is defined as: the duration of second stage of labor is > 2 hours for the primiparae or > 1 hour for the multiparae.

f: 90% of the births were diagnosed to be born through vaginal delivery at the in-hospital labor diagnosis.

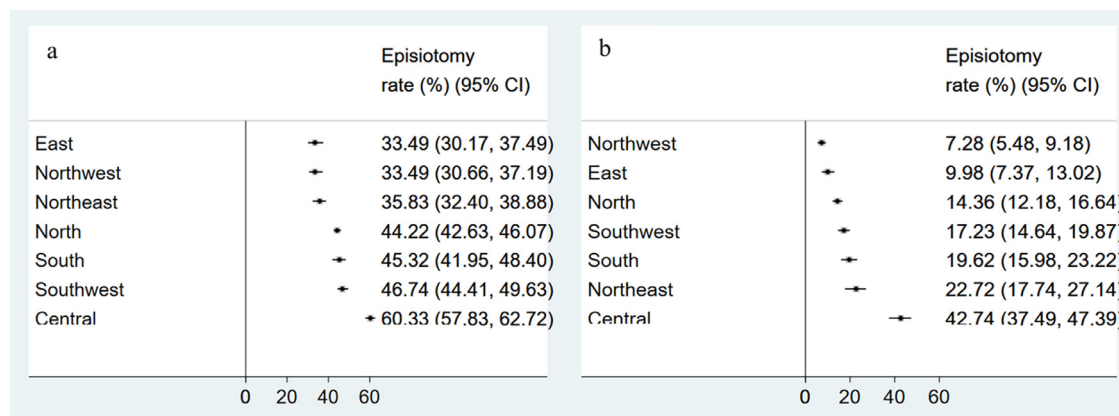


Figure 2. Episiotomy rate (weighted) by location, China, 2015-2016 (A Primiparae; B Multiparae)

among women without medical indication of episiotomy. The analyses were carried out using SAS version 9.4 (SAS Institute Inc, Cary, NC) and Stata version 15.0 (Stata Corporation, College Station, TX).

Role of the funding source

The funders had no role in the study design, data collection, analysis and the interpretation of data; in the writing of the manuscript or the decision to submit the paper for publication.

Results

A total of 75132 births from 95 hospitals in 25 (out of 34) provinces and autonomous regions in China were included in the China Labor and Delivery Survey. In the present study, we included 46328 vaginal deliveries (28284 primiparae and 18044 multiparae) with complete information on the performance of episiotomy (Figure 1). The episiotomy rates differed by parity and geographic region. The overall episiotomy rate was 41.7% (95% CI: 40.1% - 43.2%) in nulliparae and 21.5% (95% CI: 19.4% - 23.5%) in multiparae. The rates among primiparae ranged from 33.5% (95% CI: 30.2% - 37.5%) in East China to 60.3 % (95% CI: 57.8% - 62.7%) in Central China. Among multiparae, the highest episiotomy rate also occurred in Central China (42.7%, 95% CI: 37.5% - 47.4%); the lowest episiotomy rate occurred in Northwest China (7.3%, 95% CI: 5.5% - 9.2%) (Figure 2).

Table 1 lists the demographic and clinical indication to perform episiotomy and factors potentially associated with the performance of episiotomy. According to the models with selected covariates, the associated factors with episiotomy among primiparae included: conception with assisted reproductive technology, sexually transmitted diseases, placenta previa, premature rupture of fetal membranes, anesthesia or analgesia, mode of delivery (spontaneous / forceps / vacuum-assisted),

prolonged second stage of labor, fetal distress, gestational age at birth, and birth weight. In addition, pre-pregnancy BMI, previous caesarean section, and maternal disease (diabetes mellitus, thyroid diseases, cardiac diseases, kidney diseases, asthma, and disorder of immune system) were related to the performance of episiotomy among multiparae.

The mixed model demonstrated significant variations among the adjusted rates of episiotomy at hospital level (Figure 3). In primiparae, the estimated mean hospital rate was 41.8% (95% CI: 34.2%, 49.9%), ranging from 24.4% (95% CI: 18.3%, 31.6%) to 82.6% (95% CI: 79.7%, 85.3%). For multiparae, the mean adjusted hospital rate was 12.1% (95% CI: 9.4%, 15.5%) ranging from 2.6% (95% CI: 1.9%, 3.6%) to 26.3% (95% CI: 21.6%, 31.8%).

A two-step cluster analysis classified the medical conditions associated with episiotomy into four clusters among primiparae and multiparae, respectively (Table 2). In primiparae (average value of Silhouette=0.6), cases of the largest cluster (comprising 35% of the episiotomies) had no underlying medical conditions that may be associated with episiotomy. Clusters 2 (24.3%) and 3 (22.0%) were mixed groups, composed of cases with various obstetrics conditions (e.g., prolonged second stage of labor, premature rupture of fetal membranes, fetal distress and et al.). Cases of cluster 4 (18.7%) had no associated medical conditions except for receiving anesthesia or analgesia. In multiparae (average value of Silhouette=0.3), individuals without any underlying medical conditions constituted the second largest cluster (26.2% of episiotomies). The other clusters included episiotomies related to various medical conditions, e.g., prolonged second stage of labor, premature rupture of fetal membranes, maternal disease, and anesthesia/analgesia. The distribution of the underlying medical conditions related to episiotomy in clusters is shown in Appendix Table 1.

For women without potentially associated medical conditions, episiotomies were performed in 33.5%

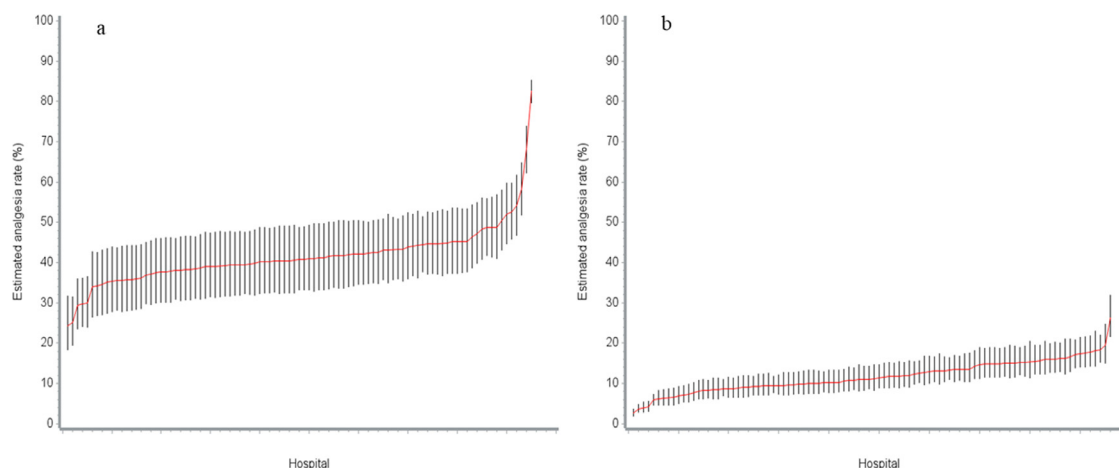


Figure 3. Episiotomy rate at hospital level by parity, China, 2015-2016 (A Primiparae; B Multiparae)

(5529/16553) of primiparae and 13.0% (598/4596) of multiparae. Mediolateral episiotomies comprised 93.6% (5177/5529) and 87.6% (524/598) of the episiotomies performed in nulliparae and multiparae, respectively. Individuals with/without mediolateral episiotomy were matched by a propensity score matching procedure. A total of 16065 primiparae and 4321 multiparae were matched. The sample size of primiparae and multiparae with and without the use of episiotomy is shown in Appendix Table 2. We examined the effects of mediolateral episiotomy on maternal and neonatal outcomes among the matched individuals by parity. In primiparous women, the rate of 3rd or 4th degree perineal laceration was higher in women who had a mediolateral episiotomy (0.4%) than in those who did not (0.06%) (OR=2.64, 95% CI: 1.08 - 6.48), although episiotomy decreased the spontaneous 2nd degree vaginal laceration. The risks of postpartum haemorrhage and admission to ICU or referral to a higher-level hospital, postnatal hospitalization more than seven days or death were not significantly different between the two groups [OR 1.02 (95% CI: 0.83, 1.24) and 1.30 (95% CI: 0.44, 3.82), respectively]. The overall risk of maternal outcome defined as a combination of these individual components was not different between the women with and without mediolateral episiotomy (OR=1.08, 95% CI: 0.89, 1.30). The rate of Apgar score at 5 minutes less than four was not significantly different between the two groups (OR=0.48, 95% CI: 0.17, 1.32). No significant difference in the risk of adverse maternal or neonatal outcome was found in multiparous women (Table 3).

Discussion

Our study found that the episiotomy rate was 41.7% [95% CI: 40.1% - 43.2%] in nulliparous and 21.5% (95% CI: 19.4% - 23.5%) in multiparous vaginal deliveries in

China. Associated factors of episiotomy included pre-pregnancy BMI, maternal diseases, and obstetric factors, which were consistent with previous studies.^{2,9,25} More than half of episiotomies in nulliparae and one-fourth in multiparae had no underlying clinical indication to perform episiotomy. Mediolateral episiotomy without medical indicators increased the risk of 3rd or 4th degree perineal laceration by more than 2.5-fold in nulliparae without gaining neonatal benefit in either nulliparae or multiparae.

A restrictive use of episiotomy was recommended by the obstetric society in China since 2000s,^{12,13,20,21} but information on the episiotomy use at a country level was limited. According to a national survey in 2003, the overall episiotomy rate was 44.9% in China.¹² Whether the rates have decreased since the evidence-based recommendation is unknown. This study showed that the episiotomy rate decreased slightly since then, but is still much higher than that in America, which decreased from 17.3% in 2006 to 9.4% in 2011 since the recommendation of restrict episiotomy by ACOG.^{9,31} Although some studies reported that Asian women were at an increased risk of episiotomy and perineal trauma due to the physiological differences such as a shorter perineum, other researchers found that perineal length of Chinese women was comparable to that of women in other countries including Israel, Turkey and America.²⁵ A hospital in Hong Kong, China, experienced a decrease of episiotomy rate from 73% in 2003 to 27% in 2008 without increasing the risk of 3rd or 4th degree perineal laceration.¹⁰ In addition to clinical indicators, many episiotomies were driven by practitioners' knowledge, attitude, experience, as well as the local culture of episiotomy.³²

Clinical indication to perform episiotomy and factors associated with episiotomy found in the current study are consistent with those in previous studies (e.g., pre-pregnancy BMI, maternal diseases, and obstetric

	Primiparae ^a				Multiparae ^a			
	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 1	Cluster 2	Cluster 3	Cluster 4
Total (number, %)	330933 (35.0)	229906 (24.3)	207471 (22.0)	176385 (18.7)	165004 (34.9)	123519 (26.2)	96884 (20.5)	86903 (18.4)
Medical conditions (%)	None (100.0)	Prolonged second stage of labor (59.6)	Premature rupture of fetal membranes (57.1)	Anesthesia or analgesia (100.0)	Prolonged second stage of labor (43.1)	None (100.0)	Premature rupture of fetal membranes (56.0)	Maternal disease (60.1)
		Anesthesia or analgesia (37.2)	Anesthesia or analgesia (30.3)		Anesthesia or analgesia (36.0)		Previous caesarean section (48.8)	Prolonged second stage of labor (30.4)
		Fetal distress (29.1)	Assisted reproductive technology (29.0)		Assisted reproductive technology (31.4)		Gestational age (23.7)	Birth weight (27.9)
		Mode of delivery (21.6)	Gestational age (28.1)		Prepregnancy BMI (29.4)		Prolonged second stage of labor (15.9)	Anesthesia or analgesia (21.8)
		Birth weight (18.6)	Prolonged second stage of labor (4.8)		Premature rupture of fetal membranes (4.5)		Anesthesia or analgesia (12.2)	Premature rupture of fetal membranes (18.9)

Table 2: Distribution of the top five medical conditions among clusters of conditions associated with the use of episiotomy, China, 2015-2016

^a Average Silhouette=0.6 and 0.3 in the primiparae and multiparae, respectively.

	Primiparae (n=16065)			Multiparae (n=4321)		
	Non-episiotomy (n=10989) (%)	Episiotomy (n=5076) (%)	Adjusted odds ratios ^a (95% CI)	Non-episiotomy (n=3987) (%)	Episiotomy (n=334) (%)	Adjusted odds ratios (95% CI)
Maternal outcomes	633 (5.7)	248 (4.8)	1.08 (0.89, 1.30)	197 (4.9)	11 (3.3)	0.65 (0.28, 1.53)
Third- or fourth- degree perineal laceration	7 (0.06)	19 (0.4)	2.64 (1.08, 6.48)	0 (0.0)	2 (0.6)	-
Second-degree perineal laceration	1661 (15.1)	100 (1.9)	0.10 (0.08, 0.13)	578 (14.5)	8 (2.4)	0.13 (0.06, 0.29)
Postpartum haemorrhage	614 (5.6)	223 (4.3)	1.02 (0.83, 1.24)	196 (4.9)	9 (2.7)	0.51 (0.20, 1.29)
Admission to ICU, referral to a higher level hospital, ≥ 7 days postnatal hospitalization, or death	14 (0.13)	8 (0.16)	1.30 (0.44, 3.82)	2 (0.05)	0 (0.0)	-
Neonatal outcome						
Apgar score at 5 minutes < 4	25 (0.23)	6 (0.12)	0.48 (0.17, 1.32)	5 (0.1)	1 (0.3)	5.99 (0.03, >999)

Table 3: Relationship between mediolateral episiotomy and severe maternal and neonatal adverse outcomes in the propensity score matched sample of women without medical conditions associated with the use of episiotomy, China, 2015-2016

factors).^{2,9,25} The two-step cluster analysis demonstrated that more than half of episiotomies in primiparae and one-fourth in multiparae had no underlying clinical indication to perform episiotomy or factors associated with episiotomy. Furthermore, there were great variations in the estimated hospital episiotomy rates even after the adjustment for associated factors, suggesting that the practitioner's personal knowledge, attitude, experience, and local culture other than clinical indications to perform episiotomy contributed to the use of episiotomy. The evidence-based training and education on episiotomy for birth attendants by health-care professionals has proved to be effective interventions to prevent unnecessary episiotomy.^{25,32} Experiences gained from hospitals with low episiotomy rate in China may also be valuable.

We further explored the effects of mediolateral episiotomy on maternal and neonatal outcomes among women without pathological factors related to episiotomy. We demonstrated that mediolateral episiotomy conducted without medical indicators did not benefit either mother or neonate. Instead, it increased the risk of 3rd or 4th degree perineal laceration in nulliparae. In the present study, episiotomy decreased the 2nd degree vaginal laceration, which is consistent with the result of previous studies.³³ Franchi et al. proposed a sub-classification of the 2nd degree lacerations, i.e., dividing them into two subgroups: spontaneous vaginal laceration less than the average episiotomy and larger than average episiotomy, for the evaluation of the selective episiotomy. Unfortunately, we did not have detailed information on the degree of the laceration to divide the lacerations into subgroups, and, therefore, could not evaluate the impacts of episiotomy on perineal trauma among those with less severe vaginal tear.

As the unnecessary episiotomies accounted for more than half of episiotomies in primiparae and one-fourth in multiparae, evidence-based training to improve providers' knowledge and attitudes towards episiotomy may help to reduce the unnecessary episiotomy. An audit of episiotomy practice and outcomes based on a delivery room registration system may also help to develop a program to reduce unnecessary episiotomy.^{25,32} At the meantime, further studies are needed to address some still unanswered questions in China. For example, when does an assisted vaginal delivery, preterm delivery, and suspected macrosomia need an episiotomy?^{17,34,35}

Limitations and Strengths

The large sample size and complete information on the performance and type of episiotomy of this study allowed us to investigate the contemporary use of episiotomy by parity at the regional and hospital level. Due to the limited information on the type of episiotomy in previous studies, the effects of mediolateral episiotomy^{2,17} remain unclear. Using the China Labor

and Delivery Survey dataset, we could estimate the proportion of mediolateral episiotomy and the effects of mediolateral episiotomy on maternal and neonatal outcomes in China. We were also able to examine the effects of episiotomy using a propensity score matching method to better control for confounding by indications for episiotomy.

This study has some limitations as well. First, hospitals included in the study were not a random sample of all hospitals in China. Some provinces had no participating hospitals; and primary hospitals were not included in the Survey. But only few primary hospitals deliver babies in China, and the annual delivery numbers in the primary hospitals are usually low.²⁴ To improve the representativeness of the study sample, we stratified the sample by hospital level. A weight calculated as the inverse probability of sampling at the same hospital level in each province was assigned to each birth.³⁶ In addition, the quality of information recorded in the medical records could vary among facilities. For instance, the definitions of certain pregnancy complications may have differed from hospital to hospital or from physician to physician. The lack of standardization at the first place may undermine the validity of the estimates to an unknown degree. To minimize the impact, we collected data using a standardized form and uniform definitions of the variables across the facilities during the data collection. In addition, missing values could have affected the data quality. We included the missing value as a separate category in the analysis to minimize the impact of the missing values.

Second, caesarean section is a competing risk event for episiotomy. The episiotomy rate and its impact on the outcomes of interest was affected by caesarean section rate. As China still has a high caesarean rate³⁷, the current rate of unnecessary episiotomy may still be an underestimate if the caesarean rate declines. A high caesarean rate may have also resulted in a selection bias, i.e., patients who had vaginal deliveries may have no clinical indications for episiotomy. Caesarean section is still liberal in the Chinese obstetric practice due to various reasons.^{38,39} In the current study, the caesarean section rate among patients with STD was much higher than those without STD (48.6% versus 36.7%, $\chi^2=28.59$, $P<0.0001$). Among the vaginal deliveries, the proportion of prolong second stage of labor, fetal distress, and shoulder dystocia was lower (although not statistically significant due to the small number of cases) among women with STD when compared with those without STD. Thus, the negative association between STD and episiotomy may be due to selection bias.

Third, we only assessed the effects of mediolateral episiotomy on severe and short-term adverse outcomes. Other less severe adverse outcomes, e.g., sub-classification of the 2nd degree perineal laceration (vaginal laceration less than the average episiotomy and larger than

average episiotomy),³³ Apgar score at 5 minutes less than seven, were not included in the assessment. The long-term outcomes such as pelvic floor dysfunction (urinary or fecal incontinence), pain with intercourse, or pelvic organ prolapse² were not available in this cross-sectional study. More longitudinal information could be helpful to enhance adherence to the restrictive episiotomy strategy.

Fourth, the implementation of a restrictive episiotomy policy is not easy. A sampling survey in 90 public hospitals in Henan Province, China, showed that the performance of episiotomy was driven by previous training, personal experience, and local norms. Almost half of the clinicians considered the current rate of episiotomy (45%) to be right or too low. Changes of knowledge, attitude and practice may take time.^{32,40} Finally, given the nature of a cross-sectional study, we cannot conclude for sure whether the restrictive episiotomy may lead to an increase in severe perineal tears. A future similar study in some years may help to clarify whether the reduction of episiotomy rate may increase or decrease the rate of severe perineal tears.

Conclusions

Episiotomy was performed in more than 40% of nulliparous vaginal deliveries and nearly 20% of multiparous vaginal deliveries in China. Episiotomy without medical indications accounted for more than half of episiotomies in primiparae and one-fourth in multiparae. Mediolateral episiotomy did not improve perinatal outcomes but increased the risk of 3rd or 4th degree perineal laceration by more than 2.5-fold in nulliparae. Great efforts are warranted to reduce unnecessary episiotomy through evidence-based education and training.

Contributors

JFY, YC, LT, ML and JZ participated in the study design. JFY and YC did the data analysis and wrote the first draft. JZ co-wrote the manuscript. HY, QC, YH, JZ, LT, and ML provided critical comments and valuable suggestions. All authors read and approved the final manuscript.

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Data sharing statement

After publication, the data used in this study will be made available upon reasonable requests to the corresponding author. Deidentified participant data will be provided after an approval by the principal investigators and the data management group.

Declaration of Competing Interest

The authors declare that they have no competing interests.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:[10.1016/j.lanwpc.2021.100345](https://doi.org/10.1016/j.lanwpc.2021.100345).

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