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Provision of immediate postpartum contraception among women with a high risk pregnancy in Mexico

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Title: Provision of immediate postpartum contraception among women with a high risk pregnancy in Mexico

Authors

Jacqueline Powell, MD[1]

Evelyn Fuentes-Rivera, MSc[2]

Blair G. Darney, PhD, MPH[1,2,3]

Affiliations

[1] Department of Obstetrics and Gynecology, Oregon Health and Sciences University, Portland, OR

[2] Instituto Nacional de Salud Publica (INSP), Cuernavaca, Mexico

[3] OHSU-PSU School of Public Health, Portland, OR

Corresponding author

Jacqueline Powell, MD.

Address: 3535 SW Corbett Ave, Apt 306, Portland OR 97239

Email: poweljac@ohsu.edu Phone: 608-577-8320

Synopsis

Women with a high-risk pregnancy were not more likely to leave place of delivery with a contraceptive method compared to normal risk women.

Type of Article: Clinical article

Ethics approval

This secondary analysis of publicly available data was deemed non-human subjects research by the Oregon Health and Sciences University IRB prior to data analysis

Informed consent

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All human participants were consented prior to survey administration per ENSANUT protocol guidelines. This is publicly available data and therefore informed consent was not needed to analyze the data.

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We thank all personnel involved in distributing and collecting data from the ENSANUT survey.

Conflicts of Interest

The authors report no conflicts of interest.

Data Sharing

All data is publicly available via ENSANUT.

Word count of main text: 2402

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Abstract

Objective:

We tested whether women who reported high risk pregnancies or deliveries were more likely to receive immediate postpartum contraception prior to discharge compared with normal-risk women in Mexico.

Methods:

This is a retrospective study using the National Health and Nutrition Survey (ENSANUT). We classified women as high-risk based on reported complications in pregnancy and delivery. We used multivariable logistic regression to test the association of high-risk status and receipt of postpartum contraception (any modern method and Tier one methods) prior to discharge.

Results:

Our sample included 5030 deliveries (population N= 3,923,657). Overall, 19.1% of the sample were high-risk. Over 60% of women in the high-risk and normal risk group received immediate postpartum contraception, but a greater proportion of high-risk women received a method (67% vs 61% normal risk; $p < 0.001$). However, in multivariable models, there were no significant differences in receipt of any modern method or Tier 1 method by risk group.

Conclusion:

Women with high-risk pregnancies were not more likely to receive postpartum contraception than the normal risk group, once accounting for socio-demographic and clinical factors. Prenatal and postpartum contraception counseling should address the health effects of high-risk pregnancies and inter-pregnancy intervals to improve maternal health outcomes.

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Strengths and limitations of this study (five short bullet points, one sentence each, relating specifically to the methods)

- Data was sourced from a publicly available nationwide survey that reflects population health data over a 6 year time period
- The classification included many high risk conditions that are recognized across the world
- There was very little missing data
- We controlled for socio-demographic status
- Results are limited by the self-reported nature of the data

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Main Text

Introduction

Postpartum contraception is an integral component of obstetric care. The immediate postpartum period is an optimal time to provide contraception, especially for those women not able to follow up for postpartum care.[1] Providing contraception prior to discharge from place of delivery is important to decrease the risk of short inter-pregnancy intervals (<18 months), which are associated with increased maternal morbidity and mortality.[2,3] Morbidity associated with short interval pregnancies include higher rates of gestational diabetes, third trimester bleeding, preterm rupture of membranes, endometritis, and anemia.[4,5] Both the risk of a short interval pregnancy and the risks associated with short interval pregnancies are exacerbated for women with chronic conditions. Women with chronic medical conditions are at a higher risk of unintended pregnancies and a pregnancy in the setting of poor chronic disease control can lead to adverse pregnancy outcomes and disease progression.[6] For example, women with gestational diabetes experiencing short interval pregnancies have an increased risk of developing type 2 diabetes mellitus in the future.[7] It is important that women with pre-existing conditions and other complications of pregnancy or delivery have access to immediate postpartum contraception to reduce poor outcomes associated with a short interval pregnancy.

In Mexico, there are high rates of chronic medical conditions. Diabetes is responsible for 14% of all deaths in women, and when combined with cardiovascular complications, the disease accounts for 30% of total deaths in women.[8] In addition, 71% of adults in Mexico and 30% of reproductive age women are obese, which is known to be associated with complications during pregnancy.[9,10] In Mexico, 94% of women deliver in facilities and therefore access to immediate postpartum contraception in a health facility is feasible for most of the population.[11]

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While there is a large body of research on high-risk pregnancies,[12] evidence about post-partum contraception in high-risk women or women with chronic conditions is more limited, especially in Mexico. The purpose of this study is to test whether women who reported high risk pregnancies or deliveries were more likely to receive immediate post-partum contraception prior to discharge. Our hypothesis is that women that have experienced a high-risk pregnancy and/or delivery have higher probabilities of using any contraceptive method, and specifically the most effective Tier 1 methods (implant, intra-uterine device [IUD], or sterilization).[13]

Methods

This is a retrospective study using the 2018 round of the Encuesta Nacional de Salud y Nutricion/ National Health and Nutrition Survey (ENSANUT), a publicly available population-based survey.[14] ENSANUT is a face-to-face household survey that is performed every 6 years to evaluate population-level health in Mexico. Within this survey, women who report a live birth during the 6 years prior to survey (2012-2017) are asked about their prenatal care and delivery experience. All participants provide informed consent at the time of survey data collection. We included women of reproductive age (12-49 years old), who report a live birth the 6 years prior to the survey (n=5,030) in our analysis. The analysis of this publicly available data was approved by the Oregon Health & Sciences Institutional Review Board.

The primary outcome was receipt of any modern contraceptive method prior to discharge from place of delivery. Our secondary outcome was focused on the use of a Tier 1 contraceptive method, among the subsample who received a method. Tier 1 methods include the implant, IUD, and sterilization; Tier 2 includes hormonal methods, and Tier 3 includes barrier methods. [13]

Our key independent variable was whether the woman experienced a high-risk pregnancy or delivery. We classified a woman as high-risk if she reported any of the following conditions

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during pregnancy or delivery: diabetes, high blood pressure, eclampsia, hemorrhage or preterm birth. There were just 4 reported cases of HIV, all of whom had other co-morbidities, so they are included in the high-risk group. Other conditions (urinary tract infection, anemia, sexually transmitted infection, threatened abortion, and fetal malpresentation) were not included in our definition of high-risk; these conditions are unlikely to increase maternal and infant morbidity and mortality in a subsequent pregnancy. For example, sexually transmitted infections and urinary tract infections can be treated with outpatient antibiotic regimens and with proper treatment are unlikely pose an increased risk to a subsequent pregnancy or to maternal health overall.[15] We compared sample characteristics using high-risk definitions that included and excluded hemorrhage; there were no significant differences (data not shown) so we elected to retain hemorrhage in our definition of high risk to increase our sample size and because it is one of the leading causes of maternal death across the world.[16]

We included additional socio-demographic and clinical information in our analysis. We included the woman's age at delivery (<20, 20-29, 30-39, 40 and older), indigenous status (if the woman reports speaking an indigenous language) marital status (single, separated, divorced, or widowed and married or cohabitating), educational gap in years defined as the difference between expected level of education based on age and actual current level of education (zero, one or two and three or more), parity (one child, two, and three or more), place of delivery (social security/employment-based facility, Ministry of Health, private), type of birth (vaginal or cesarean delivery), education of household head (none or primary, secondary, high school, and university or more), rural residence (<2,500 habitants), and socioeconomic quintile (1-5, with 1 being poorest, collapsed to 1 and 2 vs 3, 4 and 5 in models), an index developed using Principal

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Components Analysis (PCA) and based on household materials and ownership of consumer goods which ranges from 1-5 with 1 being poorest.[17] We had very little missing data.

Cohort Description and Patient and Public Involvement

The public was first involved in 2018 during survey enrollment for ENSANUT. This is a face-to-face household survey that is performed every 6 years to evaluate population-level health in Mexico. All participants provide informed consent at the time of survey data collection. The analysis of this publicly available data was approved by the Oregon Health & Sciences Institutional Review Board. Research questions were developed to assess for optimization of contraception access in the immediate postpartum period. The public was not involved in the design of this study, as this data is publicly available and this is a nation-wide survey. The public will not be involved in choosing methods and dissemination of study results. We thank the personnel involved in distributing and collecting the survey data.

Analysis

We used descriptive statistics to characterize the sample by pregnancy risk groups (normal risk and high-risk). We next described proportions of individual complications and conditions during pregnancy and delivery. Next, we calculated crude outcomes (any contraceptive use and by Tiers) by risk group. Finally, we developed two logistic regression models to test the association of high-risk status and receipt of postpartum contraception prior to discharge. In the first model, we tested the association between risk status and use of any modern contraceptive method. In the second model, we restricted the sample to women who received a modern method and tested the association of risk status and use of a Tier 1 method. Both models

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included age, parity, place of delivery, mode of delivery, educational gap, rural residence, socioeconomic quintile, marital status, and indigenous status. All analyses used weights to account for the complex survey design; results can be interpreted as population estimates.

We performed two sensitivity analyses. First, we stratified our models by mode of delivery as cesarean delivery is known to be associated with receipt of tier one methods.[11] Next, we excluded women who received immediate postpartum sterilization in order to focus on reversible post-partum contraception. Our results were robust to these specifications and we present only our final models. This study was deemed non-human subjects research by the Institutional Review Board of Oregon Health & Science University (OHSU). We used Stata version 13 for all analyses (Stata Corporation LP. College Station, TX 2013).

Results

Our final sample included 5030 deliveries (N= 3,923,657). Overall 19.1% of the sample were classified as high-risk. The largest age groups were 20-29 (43%) and 30-39 (39%); 10% of the sample were under 20 at the time of last birth, and 8% over 40 years old (Table 1). The majority of women (78%) were married. Cesarean delivery was more common in the high-risk group (66%) compared to normal risk (43%; $p < 0.001$). Half of the deliveries to both normal and high-risk women were in Ministry of Health facilities.

The most prevalent individual condition in our high-risk group was high blood pressure, reported by 63% of women in the high-risk group. Pre-eclampsia was reported by 36% of high-risk women and preterm birth by 33%. Diabetes was reported by 12% of the high-risk population (Table 2).

Over 60% of women in both the high risk and normal risk group left place of delivery with a contraceptive method, but a greater proportion of high-risk women left with a method

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(61% normal vs 67% high risk; p =0.000; Figure 1 left panel). Among the subsample of women who received a method (Fig1, right panel), 85% of normal risk women received a Tier one method compared to 88% of high-risk women (p=0.007). Among women who received a Tier 1 method, sterilization accounted for a third (33%) in the normal risk group compared to 38% of in the high-risk group (p=0.000; data not shown). A higher proportion of normal risk women received IUDs compared with high-risk women (42% normal risk vs 39% high-risk; p=0.011, data not shown).

In our multivariable model controlling for sociodemographic and health system factors, there was no statistically significant difference in use of any modern method prior to discharge from place of delivery was by risk group (aOR = 1.21, CI 0.99 – 1.49; Table 3). Factors associated with receipt of immediate postpartum contraception were younger age (under 20 aOR1.71, CI 1.28-2.28, compared to 20-29 years old) and cesarean delivery (aOR = 1.49, CI 1.26 – 1.78). Use of Tier 1 methods among those women who left place of delivery with a modern method was also not significantly different by risk group (aOR = 1.10; CI 0.79-1.53; Table 3).

Discussion

Our data show that overall in Mexico between 2012 and 2017, nearly one in five deliveries were to high-risk women. A slightly larger proportion of high-risk women left place of delivery with a contraceptive method compared to normal risk women (67% vs 61%). This difference was not statistically significant once we controlled for sociodemographic, clinical, and health system factors, although it nears significance (aOR = 1.21, CI 0.99 – 1.49), suggesting that risk status may be associated with receipt of immediate post-partum contraception even

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accounting for socio-demographic, clinical, and health system factors. Among women who received immediate post-partum contraception, a large majority received Tier 1 methods (85% normal risk, 88% high-risk).

Overall rates of immediate post-partum contraception have risen over time; the previous wave of ENSANUT (births from 2006-2012) showed that overall, 57% of women left place of delivery with contraception.[11] Our findings support this previous work that found that cesarean delivery was strongly associated with receipt of immediate post-partum contraception.[11] However, this previous study did not examine high-risk pregnancies or comorbidities.

Postpartum contraception in high risk pregnancies has not been previously well studied in Mexico. In a population of women with chronic medical conditions in the United States, there was no difference in any postpartum contraception use between 2 and 6 months postpartum compared with healthy women;[18] however, this study did not focus on immediate post-partum contraception. Our findings are similar to another study in a US sample, that showed that while a higher proportion of high risk pregnancies had documentation of Tier one contraceptives compared with normal risk pregnancies, this difference did not persist when controlling for potential confounders.[19] Among Medicaid enrollees with diabetes delivering in California, those with diabetes were more likely to receive permanent sterilization than those without diabetes, however, among those who did not receive permanent sterilization, less than half received reversible contraception in the postpartum period.[20]

We found that nearly 1 in 5 deliveries (19.1%) in Mexico were to women with high-risk pregnancies or deliveries. Our definition of high risk is supported by the Society of Maternal Fetal Medicine[6] and previous research which has used a binary classification as the basis for their analysis.[18] Our proportion of high-risk pregnancies or deliveries is comparable to a US

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cohort studied in 2011 where 24% of women had a pre-pregnancy chronic disease, classifying them as high risk.[18] In a cohort from Germany, 26.6% of pregnant women carried a diagnosis consistent with a chronic medical disease.[21] Among women in our high risk group, 12% had diabetes, similar to previously published data that estimates that gestational diabetes affects 10.3% of reproductive age women in Mexico.[22] However, rates of type 2 diabetes mellitus are estimated at 13.6% of reproductive age women in Mexico,[9] so our overall reported proportion with diabetes (gestational and exiting were not differentiated) is likely underestimated.

Our results must be interpreted with the following limitations in mind. First, our survey data rely on self-reported outcomes and exposures and therefore subject to recall bias. In previous work using the same data source, we found that limiting the sample to births within 2 years of the survey did not change results,[10] suggesting that recall bias is limited. Second, the survey does not differentiate between gestational diabetes and pre-existing diabetes. It is likely that the prevalence of diabetes, gestational or pre-existing, is under-reported. Third, we do not know if women were counseled about immediate postpartum contraception and whether there was emphasis on patient education regarding high-risk pregnancies and avoiding a short interpregnancy interval.

Conclusion

We found that slightly larger proportion of high-risk women left place of delivery with a contraceptive method compared to normal risk women; while this difference was not statistically significant once controlling for sociodemographic, clinical, and health system factors, it neared significance which suggests that risk status may be associated with receipt of immediate post-partum contraception in Mexico. Women experiencing high risk pregnancies should be counseled on the importance of avoiding short inter-pregnancy intervals and postpartum

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contraception. Avoiding short interval pregnancies is important to decrease maternal morbidity and mortality, and immediate postpartum contraception is a key intervention to prevent short IPI. This is especially important in Mexico where there are high rates of chronic medical conditions that can be exacerbated by pregnancy and increase pregnancy related morbidity and mortality.[8–10] Specific counseling about the health effects of high risk pregnancies, medical comorbidities, and inter-pregnancy intervals should be standard to improve maternal health outcomes.[6]

Author Contributions

BGD and JP conceived of the study, EFR and BGD conducted the analysis, JP drafted the manuscript, BGD and EFR reviewed the manuscript and contributed to the intellectual content.

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Table 1: Sample characteristics by risk group, in-facility deliveries Mexico 2012-2017

Contraception	Overall			Normal Risk			High Risk			χ2 p-value+
	100% (n=5030; N=3,923,657)			80.9% (n=4069; N=3,198,376)			19.1% (n=961; N=725,281)			
	Mean	CI 95%		Mean	CI 95%		Mean	CI 95%		
Age										
<20	0.10	0.09	0.11	0.10	0.09	0.11	0.09	0.06	0.11	**0.000**
20-29	0.43	0.41	0.45	0.43	0.41	0.45	0.45	0.41	0.49	
30-39	0.39	0.37	0.41	0.39	0.37	0.41	0.38	0.34	0.42	
40-max	0.08	0.07	0.09	0.08	0.07	0.09	0.08	0.06	0.10	
Indigenous	0.07	0.06	0.08	0.08	0.06	0.09	0.04	0.03	0.06	**0.009**
Married	0.78	0.76	0.79	0.79	0.77	0.81	0.72	0.68	0.76	**0.000**
Educational gap in years*										
Zero	0.77	0.75	0.79	0.77	0.75	0.79	0.78	0.74	0.82	0.302
One or two	0.05	0.04	0.05	0.04	0.04	0.05	0.06	0.04	0.08	
Three or more	0.17	0.15	0.18	0.17	0.16	0.19	0.14	0.11	0.17	
Missing (n=70)	0.01	0.01	0.02	0.01	0.01	0.02	0.02	0.01	0.03	
Parity										
One	0.33	0.31	0.34	0.32	0.30	0.34	0.36	0.32	0.40	**0.000**
Two	0.33	0.31	0.34	0.33	0.31	0.35	0.33	0.29	0.37	
Three or more	0.34	0.33	0.36	0.35	0.33	0.37	0.31	0.27	0.34	
Place of delivery**										
Social security	0.26	0.25	0.28	0.26	0.24	0.28	0.28	0.25	0.32	**0.024**
Ministry of Health	0.49	0.47	0.51	0.49	0.47	0.51	0.50	0.46	0.54	
Private	0.24	0.22	0.26	0.25	0.23	0.27	0.21	0.17	0.25	
Caesarean delivery	0.47	0.46	0.49	0.43	0.41	0.45	0.66	0.62	0.70	**0.000**
Rural (<2,500 habitants)	0.27	0.25	0.29	0.27	0.25	0.30	0.26	0.22	0.29	0.122

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Socioeconomic quintile (1=poorest)	0.24	0.23	0.26	0.24	0.22	0.26	0.26	0.22	0.29	**0.000**
2	0.22	0.21	0.24	0.22	0.20	0.24	0.24	0.20	0.27	
3	0.19	0.18	0.21	0.19	0.17	0.21	0.19	0.16	0.23	
4	0.17	0.16	0.19	0.17	0.16	0.19	0.17	0.14	0.21	
5	0.12	0.10	0.13	0.12	0.11	0.14	0.09	0.07	0.11	
Missing (n=305)	0.05	0.04	0.06	0.05	0.04	0.06	0.05	0.03	0.06	

*Education gap in years is the difference in a woman's current education level from their age appropriate level
**n=1 missing observation
+Chi-squared for group differences (normal risk - high risk including hemorrhage)

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Table 2: Prevalence of specific complications within each risk group

Complication	Overall 100% (n=5030; N=3,923,657)			Normal Risk 80.9% (n=4069; N=3,198,376)			High Risk 19.1% (n=961; N=725,281)		
	Mean	CI 95%		Mean	CI 95%		Mean	CI 95%	
High blood pressure	0.12	0.10	0.13	---	---	---	0.63	0.58	0.67
Threatened abortion	0.14	0.13	0.16	0.06	0.05	0.07	0.49	0.44	0.53
Diabetes	0.02	0.01	0.03	---	---	---	0.12	0.09	0.14
Anemia	0.06	0.05	0.07	0.03	0.02	0.04	0.22	0.18	0.26
Urinary infection	0.14	0.12	0.15	0.06	0.05	0.07	0.46	0.42	0.51
STI	0.00	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.02
HIV	0.00	-0.00	0.00	---	---	---	0.00	-0.00	0.01
Other diseases	0.02	0.01	0.02	0.01	0.01	0.01	0.05	0.03	0.07
Pre-Eclampsia or Eclampsia	0.07	0.06	0.08	---	---	---	0.36	0.32	0.41
Haemorrhage	0.05	0.04	0.06	---	---	---	0.29	0.25	0.33
Obstructed part	0.02	0.02	0.03	0.02	0.01	0.02	0.06	0.05	0.08
Malpresentation	0.05	0.04	0.06	0.03	0.02	0.03	0.17	0.13	0.20
Preterm birth	0.06	0.05	0.07	---	---	---	0.33	0.29	0.37
Complications due a pre-existing disease	0.01	0.01	0.02	0.00	0.00	0.00	0.07	0.05	0.09

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Table 3: Association between pregnancy risk status and immediate post-partum contraceptive use, Mexico 2012-2017

	Use of any modern method (n=5,029) N= 3,923,068	Use of Tier 1 (n=3,164) N = 2,427,653
	odds ratio	odds ratio
High risk	1.21 [0.985 - 1.485]	1.10 [0.787 - 1.526]
Age		
<20	1.71** [1.277 - 2.284]	0.99 [0.657 - 1.480]
30-39	0.82* [0.674 - 0.989]	0.96 [0.703 - 1.301]
40-max	0.79 [0.569 - 1.096]	0.94 [0.554 - 1.582]
Parity		
Two	1.57** [1.273 - 1.928]	1.56** [1.145 - 2.116]
Three or more	2.31** [1.837 - 2.903]	1.95** [1.385 - 2.735]
Place of delivery		
Social security	1.38** [1.122 - 1.699]	1.47* [1.070 - 2.025]
Private	0.23** [0.185 - 0.280]	0.56** [0.389 - 0.814]
Birth type (c-section)	1.49** [1.256 - 1.775]	2.03** [1.539 - 2.669]
Educational gap in years		
One or two years	0.94 [0.652 - 1.347]	1.84* [1.010 - 3.362]
Three or more years	0.77* [0.610 - 0.966]	1.03 [0.734 - 1.449]
Missing	1.06 [0.571 - 1.978]	1.13 [0.360 - 3.568]
Rural (less than 2,500 hab)	0.97 [0.804 - 1.174]	0.97 [0.714 - 1.324]

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Socioeconomic quintile		
1 and 2 vs (3, 4 and 5)	1.08 [0.916 - 1.285]	1.01 [0.771 - 1.317]
Marital status (Married)	1.09 [0.895 - 1.329]	0.67* [0.490 - 0.930]
Indigenous	0.50** [0.372 - 0.664]	1.22 [0.686 - 2.158]

Confidence interval in brackets
** p<0.01, * p<0.05

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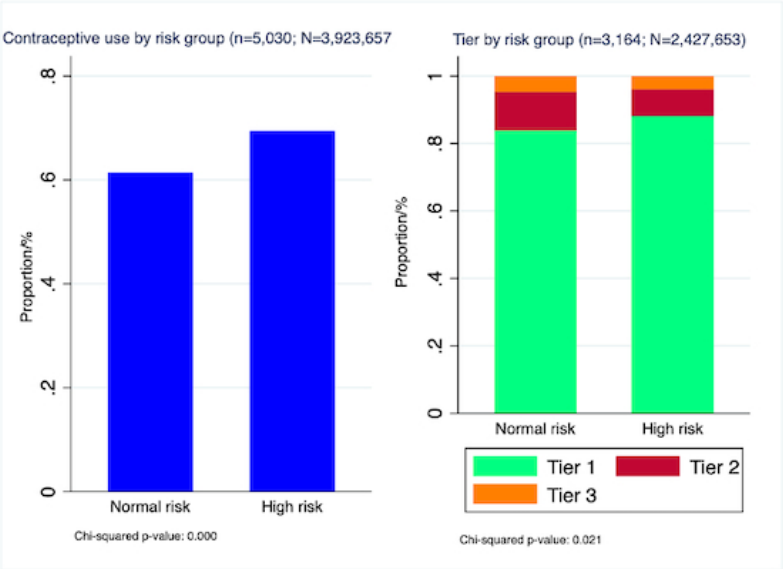
Figure 1 Immediate post-partum Contraceptive use by pregnancy risk status (any method and by Tiers among those receiving a method), Mexico 2012-2017



Note: Data Source, ENSANUT 2018

Immediate postpartum contraceptive use by pregnancy risk status (any method and by Tiers among those receiving a method), Mexico 2012-2017

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*7-8*
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	8-9
		(*c*) Explain how missing data were addressed	8-9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	8-9

Continued on next page

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Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-10
		(b) Indicate number of participants with missing data for each variable of interest	10
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*9-10*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-10
		(*b*) Report category boundaries when continuous variables were categorized	9-10
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12-13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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BMJ Open

Comparison of immediate postpartum contraception among women with a high vs low risk pregnancy in Mexico: A retrospective cohort study

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Title: Comparison of immediate postpartum contraception among women with a high vs low pregnancy in Mexico: A retrospective cohort study

Authors

Jacqueline Powell, MD[1]

Evelyn Fuentes-Rivera, MSc[2]

Blair G. Darney, PhD, MPH[1,2,3]

Affiliations

[1] Department of Obstetrics and Gynecology, Oregon Health and Sciences University, Portland, OR

[2] Instituto Nacional de Salud Publica (INSP), Cuernavaca, Mexico

[3] OHSU-PSU School of Public Health, Portland, OR

Corresponding author

Jacqueline Powell, MD.

Address: 3535 SW Corbett Ave, Apt 306, Portland OR 97239

Email: poweljac@ohsu.edu Phone: 608-577-8320

Synopsis

Women with a high-risk pregnancy were not more likely to leave place of delivery with a contraceptive method compared to normal risk women.

Type of Article: Clinical article

Ethics approval

This secondary analysis of publicly available data was deemed non-human subjects research by the Oregon Health and Sciences University IRB prior to data analysis

Informed consent

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All human participants were consented prior to survey administration per ENSANUT protocol guidelines. This is publicly available data and therefore informed consent was not needed to analyze the data.

Contributorship Statement

BGD and JP conceived of the study, EFR and BGD conducted the analysis, JP drafted the manuscript, BGD and EFR reviewed the manuscript and contributed to the intellectual content.

Competing Interests

The authors report no conflicts of interest.

Funding

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Data Sharing

All data is publicly available via ENSANUT.

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Abstract

Objective:

We tested whether women who reported high risk pregnancies or deliveries were more likely to receive immediate postpartum contraception prior to discharge compared with normal-risk women in Mexico.

Methods:

This is a retrospective study using the National Health and Nutrition Survey (ENSANUT). We classified women as high-risk based on reported complications in pregnancy and delivery. We used multivariable logistic regression to test the association of high-risk status and receipt of postpartum contraception (any modern method and Tier one methods) prior to discharge.

Results:

Our sample included 5030 deliveries (population N= 3,923,657). Overall, 19.1% of the sample were high-risk. Over 60% of women in the high-risk and normal risk group received immediate postpartum contraception, but a greater proportion of high-risk women received a method (67% vs 61% normal risk; $p < 0.001$). However, in multivariable models, there were no significant differences in receipt of any modern method or Tier 1 method by risk group.

Conclusion:

Women with high-risk pregnancies were not more likely to receive postpartum contraception than the normal risk group, once accounting for socio-demographic and clinical factors. Prenatal and postpartum contraception counseling should address the health effects of high-risk pregnancies and inter-pregnancy intervals to improve maternal health outcomes.

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Strengths and limitations of this study (five short bullet points, one sentence each, relating specifically to the methods)

- Data was sourced from a publicly available nationwide survey that reflects population health data over a 6 year time period
- The classification included many high risk conditions that are recognized across the world
- There was very little missing data
- We controlled for socio-demographic status
- Results are limited by the self-reported nature of the data

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Main Text

Introduction

Postpartum contraception is an integral component of obstetric care. The immediate postpartum period is an optimal time to provide contraception, especially for those women not able to follow up for postpartum care.[1] Providing contraception prior to discharge from place of delivery is important to decrease the risk of short inter-pregnancy intervals (<18 months), which are associated with increased maternal morbidity and mortality.[2,3] Morbidity associated with short interval pregnancies include higher rates of gestational diabetes, third trimester bleeding, preterm rupture of membranes, endometritis, and anemia.[4,5] Both the risk of a short interval pregnancy and the risks associated with short interval pregnancies are exacerbated for women with chronic conditions. Women with chronic medical conditions are at a higher risk of unintended pregnancies and a pregnancy in the setting of poor chronic disease control can lead to adverse pregnancy outcomes and disease progression.[6] For example, women with gestational diabetes experiencing short interval pregnancies have an increased risk of developing type 2 diabetes mellitus in the future.[7] It is important that women with pre-existing conditions and other complications of pregnancy or delivery have access to immediate postpartum contraception to reduce poor outcomes associated with a short interval pregnancy.

In Mexico, there are high rates of chronic medical conditions. Diabetes is responsible for 14% of all deaths in women, and when combined with cardiovascular complications, the disease accounts for 30% of total deaths in women.[8] In addition, 71% of adults in Mexico and 30% of reproductive age women are obese, which is known to be associated with complications during pregnancy.[9,10] In Mexico, 94% of women deliver in facilities and therefore access to immediate postpartum contraception in a health facility is feasible for most of the population.[11]

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While there is a large body of research on high-risk pregnancies,[12] evidence about post-partum contraception in high-risk women or women with chronic conditions is more limited, especially in Mexico. Data on provision of postpartum contraception in this population is necessary to ensure high-risk women have access to effective contraception in order to ensure safe pregnancy spacing and prevent maternal morbidity and mortality. The purpose of this study is to test whether women who reported high risk pregnancies or deliveries were more likely to receive immediate post-partum contraception prior to discharge. Our hypothesis is that women that have experienced a high-risk pregnancy and/or delivery have higher probabilities of using any contraceptive method, and specifically the most effective Tier 1 methods (implant, intra-uterine device [IUD], or sterilization).[13]

Methods

This is a retrospective study using the 2018 round of the Encuesta Nacional de Salud y Nutricion/ National Health and Nutrition Survey (ENSANUT), a publicly available population-based survey.[14] ENSANUT is a face-to-face household survey that is performed every 6 years to evaluate population-level health in Mexico. Within this survey, women who report a live birth during the 6 years prior to survey (2012-2017) are asked about their prenatal care and delivery experience. All participants provide informed consent at the time of survey data collection. We included women of reproductive age (12-49 years old), who report a live birth the 6 years prior to the survey (n=5,030) in our analysis. The analysis of this publicly available data was approved by the Oregon Health & Sciences Institutional Review Board.

The primary outcome was receipt of any modern contraceptive method prior to discharge from place of delivery. Our secondary outcome was focused on the use of a Tier 1 contraceptive method, among the subsample who received a method. Tier 1 methods include the implant, IUD,

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and sterilization; Tier 2 includes hormonal methods, and Tier 3 includes barrier methods. [13] We decided to examine Tier 1 methods specifically as this is the most effective method for preventing pregnancy. Additionally, in Mexico, Tier 1 methods are overwhelmingly provided in the immediate post-partum setting; access to Tier 1 methods is limited in a primary care setting and thus immediate post-partum access is crucial.[15,16]

Our key independent variable was whether the woman experienced a high-risk pregnancy or delivery. We classified a woman as high-risk if she reported any of the following conditions during pregnancy or delivery: diabetes, high blood pressure, eclampsia, hemorrhage or preterm birth. There were just 4 reported cases of HIV, all of whom had other co-morbidities, so they are included in the high-risk group.[17] Other conditions (urinary tract infection, anemia, sexually transmitted infection, threatened abortion, and fetal malpresentation) were not included in our definition of high-risk; these conditions are unlikely to increase maternal and infant morbidity and mortality in a subsequent pregnancy. For example, sexually transmitted infections and urinary tract infections can be treated with outpatient antibiotic regimens and with proper treatment are unlikely pose an increased risk to a subsequent pregnancy or to maternal health overall.[18] We compared sample characteristics using high-risk definitions that included and excluded hemorrhage; there were no significant differences (data not shown) so we elected to retain hemorrhage in our definition of high risk to increase our sample size and because it is one of the leading causes of maternal death across the world.[19]

We included additional socio-demographic and clinical information in our analysis. We included the woman's age at delivery (<20, 20-29, 30-39, 40 and older), indigenous status (if the woman reports speaking an indigenous language) marital status (single, separated, divorced, or widowed and married or cohabitating), educational gap in years defined as the difference

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between expected level of education based on age and actual current level of education (zero, one or two and three or more), parity (one child, two, and three or more), place of delivery (social security/employment-based facility, Ministry of Health, private), type of birth (vaginal or cesarean delivery), education of household head (none or primary, secondary, high school, and university or more), rural residence (<2,500 habitants), and socioeconomic quintile (1-5, with 1 being poorest, collapsed to 1 and 2 vs 3, 4 and 5 in models), an index developed using Principal Components Analysis (PCA) and based on household materials and ownership of consumer goods which ranges from 1-5 with 1 being poorest.[20] We had very little missing data.

Cohort Description and Patient and Public Involvement

The public was first involved in 2018 during survey enrollment for ENSANUT. This is a face-to-face household survey that is performed every 6 years to evaluate population-level health in Mexico. All participants provide informed consent at the time of survey data collection. The analysis of this publicly available data was approved by the Oregon Health & Sciences Institutional Review Board. Research questions were developed to assess for optimization of contraception access in the immediate postpartum period. The public was not involved in the design of this study, as this data is publicly available and this is a nation-wide survey. The public will not be involved in choosing methods and dissemination of study results. We thank the personnel involved in distributing and collecting the survey data.

Analysis

We used descriptive statistics to characterize the sample by pregnancy risk groups (normal risk and high-risk). We next described proportions of individual complications and

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conditions during pregnancy and delivery. Next, we calculated crude outcomes (any contraceptive use and by Tiers) by risk group. Finally, we developed two logistic regression models to test the association of high-risk status and receipt of postpartum contraception prior to discharge. In the first model, we tested the association between risk status and use of any modern contraceptive method. In the second model, we restricted the sample to women who received a modern method and tested the association of risk status and use of a Tier 1 method. Both models included age, parity, place of delivery, mode of delivery, educational gap, rural residence, socioeconomic quintile, marital status, and indigenous status. All analyses used weights to account for the complex survey design; results can be interpreted as population estimates.

We performed two sensitivity analyses. First, we stratified our models by mode of delivery as cesarean delivery is known to be associated with receipt of tier one methods.[11] Next, we excluded women who received immediate postpartum sterilization in order to focus on reversible post-partum contraception. Our results were robust to these specifications and we present only our final models. This study was deemed non-human subjects research by the Institutional Review Board of Oregon Health & Science University (OHSU). We used Stata version 13 for all analyses (Stata Corporation LP. College Station, TX 2013).

Results

Our final sample included 5030 deliveries (N= 3,923,657). Overall 19.1% of the sample were classified as high-risk. The largest age groups were 20-29 (43%) and 30-39 (39%); 10% of the sample were under 20 at the time of last birth, and 8% over 40 years old (Table 1). The majority of women (78%) were married. Cesarean delivery was more common in the high-risk group (66%) compared to normal risk (43%; $p < 0.001$). Half of the deliveries to both normal and high-risk women were in Ministry of Health facilities.

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The most prevalent individual condition in our high-risk group was high blood pressure, reported by 63% of women in the high-risk group. Pre-eclampsia was reported by 36% of high-risk women and preterm birth by 33%. Diabetes was reported by 12% of the high-risk population (Table 2).

Over 60% of women in both the high risk and normal risk group left place of delivery with a contraceptive method, but a greater proportion of high-risk women left with a method (61% normal vs 67% high risk; p =0.000; Figure 1 left panel). Among the subsample of women who received a method (Fig1, right panel), 85% of normal risk women received a Tier one method compared to 88% of high-risk women (p=0.007). Among women who received a Tier 1 method, sterilization accounted for a third (33%) in the normal risk group compared to 38% of in the high-risk group (p=0.000; data not shown). A higher proportion of normal risk women received IUDs compared with high-risk women (42% normal risk vs 39% high-risk; p=0.011, data not shown).

In our multivariable model controlling for sociodemographic and health system factors, there was no statistically significant difference in use of any modern method prior to discharge from place of delivery was by risk group (aOR = 1.21, CI 0.99 – 1.49; Table 3). Factors associated with receipt of immediate postpartum contraception were younger age (under 20 aOR1.71, CI 1.28-2.28, compared to 20-29 years old) and cesarean delivery (aOR = 1.49, CI 1.26 – 1.78). Use of Tier 1 methods among those women who left place of delivery with a modern method was also not significantly different by risk group (aOR = 1.10; CI 0.79-1.53; Table 3).

Discussion

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Our data show that overall in Mexico between 2012 and 2017, nearly one in five deliveries were to high-risk women. A slightly larger proportion of high-risk women left place of delivery with a contraceptive method compared to normal risk women (67% vs 61%). This difference was not statistically significant once we controlled for sociodemographic, clinical, and health system factors, although it nears significance (aOR = 1.21, CI 0.99 – 1.49), suggesting that risk status may be associated with receipt of immediate post-partum contraception even accounting for socio-demographic, clinical, and health system factors. Among women who received immediate post-partum contraception, a large majority received Tier 1 methods (85% normal risk, 88% high-risk).

Overall rates of immediate post-partum contraception have risen over time; the previous wave of ENSANUT (births from 2006-2012) showed that overall, 57% of women left place of delivery with contraception.[11] Our findings support this previous work that found that cesarean delivery was strongly associated with receipt of immediate post-partum contraception.[11] However, this previous study did not examine high-risk pregnancies or comorbidities.

Postpartum contraception in high risk pregnancies has not been previously well studied in Mexico. In a population of women with chronic medical conditions in the United States, there was no difference in any postpartum contraception use between 2 and 6 months postpartum compared with healthy women;[21] however, this study did not focus on immediate post-partum contraception. Our findings are similar to another study in a US sample, that showed that while a higher proportion of high risk pregnancies had documentation of Tier one contraceptives compared with normal risk pregnancies, this difference did not persist when controlling for potential confounders.[22] Among Medicaid enrollees with diabetes delivering in California, those with diabetes were more likely to receive permanent sterilization than those without diabetes,

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however, among those who did not receive permanent sterilization, less than half received reversible contraception in the postpartum period.[23]

We found that nearly 1 in 5 deliveries (19.1%) in Mexico were to women with high-risk pregnancies or deliveries. Our definition of high risk is supported by the Society of Maternal Fetal Medicine[6] and previous research which has used a binary classification as the basis for their analysis.[21] Our proportion of high-risk pregnancies or deliveries is comparable to a US cohort studied in 2011 where 24% of women had a pre-pregnancy chronic disease, classifying them as high risk.[21] In a cohort from Germany, 26.6% of pregnant women carried a diagnosis consistent with a chronic medical disease.[24] Among women in our high risk group, 12% had diabetes, similar to previously published data that estimates that gestational diabetes affects 10.3% of reproductive age women in Mexico.[25] However, rates of type 2 diabetes mellitus are estimated at 13.6% of reproductive age women in Mexico,[9] so our overall reported proportion with diabetes (gestational and exiting were not differentiated) is likely underestimated.

Our results must be interpreted with the following limitations in mind. First, our survey data rely on self-reported outcomes and exposures and therefore subject to recall bias. In previous work using the same data source, we found that limiting the sample to births within 2 years of the survey did not change results,[10] suggesting that recall bias is limited. Second, the survey does not differentiate between gestational diabetes and pre-existing diabetes. It is likely that the prevalence of diabetes, gestational or pre-existing, is under-reported. Third, we do not know if women were counseled about immediate postpartum contraception and whether there was emphasis on patient education regarding high-risk pregnancies and avoiding a short interpregnancy interval. Fourth, we do not have data on length of hospital stay in ENSANUT. Longer length of stay could be associated with pregnancy complications and with receipt of

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contraception and thus confound our findings. However, much contraception is provided at time of delivery – immediately post-partum and would thus not be impacted by length of stay.[11] Finally, while we have place of delivery, we do not have data on level of car of the health facilities where women delivered (primary care clinics vs secondary or tertiary hospitals). However, the norms in Mexico dictate that deliveries occur in hospital settings, so we do not anticipate this confounds our results.

Conclusion

We found that slightly larger proportion of high-risk women left place of delivery with a contraceptive method compared to normal risk women; while this difference was not statistically significant once controlling for sociodemographic, clinical, and health system factors, it neared significance which suggests that risk status may be associated with receipt of immediate post-partum contraception in Mexico. Women experiencing high risk pregnancies should be counseled on the importance of avoiding short inter-pregnancy intervals and postpartum contraception. Avoiding short interval pregnancies is important to decrease maternal morbidity and mortality, and immediate postpartum contraception is a key intervention to prevent short IPI. This is especially important in Mexico where there are high rates of chronic medical conditions that can be exacerbated by pregnancy and increase pregnancy related morbidity and mortality.[8–10] Specific counseling about the health effects of high risk pregnancies, medical comorbidities, and inter-pregnancy intervals should be standard to improve maternal health outcomes.[6]

Author Contributions

BGD and JP conceived of the study, EFR and BGD conducted the analysis, JP drafted the manuscript, BGD and EFR reviewed the manuscript and contributed to the intellectual content.

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Table 1: Sample characteristics by risk group, in-facility deliveries Mexico 2012-2017

Contraception	Overall			Normal Risk			High Risk			χ2 p-value+
	100% (n=5030; N=3,923,657)			80.9% (n=4069; N=3,198,376)			19.1% (n=961; N=725,281)			
	Mean	CI 95%		Mean	CI 95%		Mean	CI 95%		
Age										
<20	0.10	0.09	0.11	0.10	0.09	0.11	0.09	0.06	0.11	**0.000**
20-29	0.43	0.41	0.45	0.43	0.41	0.45	0.45	0.41	0.49	
30-39	0.39	0.37	0.41	0.39	0.37	0.41	0.38	0.34	0.42	
40-max	0.08	0.07	0.09	0.08	0.07	0.09	0.08	0.06	0.10	
Indigenous	0.07	0.06	0.08	0.08	0.06	0.09	0.04	0.03	0.06	**0.009**
Married	0.78	0.76	0.79	0.79	0.77	0.81	0.72	0.68	0.76	**0.000**
Educational gap in years*										
Zero	0.77	0.75	0.79	0.77	0.75	0.79	0.78	0.74	0.82	0.302
One or two	0.05	0.04	0.05	0.04	0.04	0.05	0.06	0.04	0.08	
Three or more	0.17	0.15	0.18	0.17	0.16	0.19	0.14	0.11	0.17	
Missing (n=70)	0.01	0.01	0.02	0.01	0.01	0.02	0.02	0.01	0.03	
Parity										
One	0.33	0.31	0.34	0.32	0.30	0.34	0.36	0.32	0.40	**0.000**
Two	0.33	0.31	0.34	0.33	0.31	0.35	0.33	0.29	0.37	
Three or more	0.34	0.33	0.36	0.35	0.33	0.37	0.31	0.27	0.34	
Place of delivery**										
Social security	0.26	0.25	0.28	0.26	0.24	0.28	0.28	0.25	0.32	**0.024**
Ministry of Health	0.49	0.47	0.51	0.49	0.47	0.51	0.50	0.46	0.54	
Private	0.24	0.22	0.26	0.25	0.23	0.27	0.21	0.17	0.25	
Caesarean delivery	0.47	0.46	0.49	0.43	0.41	0.45	0.66	0.62	0.70	**0.000**
Rural (<2,500 habitants)	0.27	0.25	0.29	0.27	0.25	0.30	0.26	0.22	0.29	0.122

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Socioeconomic quintile (1=poorest)	0.24	0.23	0.26	0.24	0.22	0.26	0.26	0.22	0.29	**0.000**
2	0.22	0.21	0.24	0.22	0.20	0.24	0.24	0.20	0.27	
3	0.19	0.18	0.21	0.19	0.17	0.21	0.19	0.16	0.23	
4	0.17	0.16	0.19	0.17	0.16	0.19	0.17	0.14	0.21	
5	0.12	0.10	0.13	0.12	0.11	0.14	0.09	0.07	0.11	
Missing (n=305)	0.05	0.04	0.06	0.05	0.04	0.06	0.05	0.03	0.06	

*Education gap in years is the difference in a woman's current education level from their age appropriate level
**n=1 missing observation
+Chi-squared for group differences (normal risk - high risk including hemorrhage)

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Table 2: Prevalence of specific complications within each risk group

Complication	Overall 100% (n=5030; N=3,923,657)			Normal Risk 80.9% (n=4069; N=3,198,376)			High Risk 19.1% (n=961; N=725,281)		
	Mean	CI 95%		Mean	CI 95%		Mean	CI 95%	
High blood pressure	0.12	0.10	0.13	---	---	---	0.63	0.58	0.67
Threatened abortion	0.14	0.13	0.16	0.06	0.05	0.07	0.49	0.44	0.53
Diabetes	0.02	0.01	0.03	---	---	---	0.12	0.09	0.14
Anemia	0.06	0.05	0.07	0.03	0.02	0.04	0.22	0.18	0.26
Urinary infection	0.14	0.12	0.15	0.06	0.05	0.07	0.46	0.42	0.51
STI	0.00	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.02
HIV	0.00	-0.00	0.00	---	---	---	0.00	-0.00	0.01
Other diseases	0.02	0.01	0.02	0.01	0.01	0.01	0.05	0.03	0.07
Pre-Eclampsia or Eclampsia	0.07	0.06	0.08	---	---	---	0.36	0.32	0.41
Haemorrhage	0.05	0.04	0.06	---	---	---	0.29	0.25	0.33
Obstructed part	0.02	0.02	0.03	0.02	0.01	0.02	0.06	0.05	0.08
Malpresentation	0.05	0.04	0.06	0.03	0.02	0.03	0.17	0.13	0.20
Preterm birth	0.06	0.05	0.07	---	---	---	0.33	0.29	0.37
Complications due a pre-existing disease	0.01	0.01	0.02	0.00	0.00	0.00	0.07	0.05	0.09

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Table 3: Association between pregnancy risk status and immediate post-partum contraceptive use, Mexico 2012-2017

	Use of any modern method (n=5,029) N= 3,923,068 odds ratio	Use of Tier 1 (n=3,164) N = 2,427,653 odds ratio
High risk	1.21 [0.99 - 1.49]	1.10 [0.79 - 1.53]
Age		
<20	1.71** [1.28 - 2.28]	0.99 [0.66 - 1.48]
30-39	0.82* [0.67 - 0.99]	0.96 [0.70 - 1.30]
40-max	0.79 [0.57 - 1.10]	0.94 [0.55 - 1.58]
Parity		
Two	1.57** [1.27 - 1.93]	1.56** [1.15 - 2.12]
Three or more	2.31** [1.84 - 2.90]	1.95** [1.39 - 2.74]
Place of delivery		
Social security	1.38** [1.12 - 1.70]	1.47* [1.07 - 2.03]
Private	0.23** [0.19 - 0.28]	0.56** [0.39 - 0.81]
Birth type (c-section)	1.49**	2.03**

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	[1.26 - 1.78]	[1.54 - 2.67]
Educational gap in years		
One or two years	0.94 [0.65 - 1.35]	1.84* [1.01 - 3.36]
Three or more years	0.77* [0.61 - 0.97]	1.03 [0.73 - 1.45]
Missing	1.06 [0.57 - 1.98]	1.13 [0.36 - 3.57]
Rural (less than 2,500 hab)	0.97 [0.80 - 1.17]	0.97 [0.71 - 1.32]
Socioeconomic quintile		
1 and 2 vs (3, 4 and 5)	1.08 [0.92 - 1.29]	1.01 [0.77 - 1.32]
Marital status (Married)	1.09 [0.90 - 1.33]	0.67* [0.49 - 0.93]
Indigenous	0.50** [0.37 - 0.66]	1.22 [0.69 - 2.16]

Confidence interval in brackets
** p<0.01, * p<0.05

Figure 1: Immediate post-partum contraceptive use by pregnancy risk status (any method and by Tiers among those receiving a method), Mexico 2012-2017

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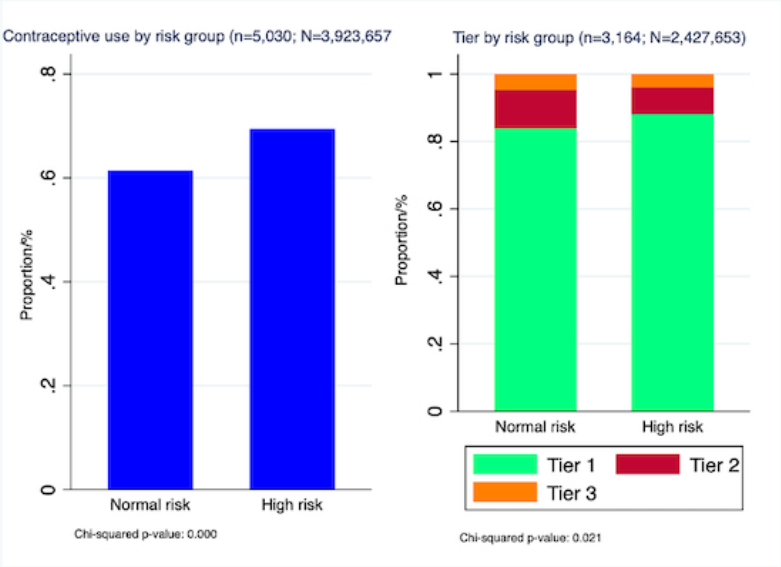
Figure 1 Immediate post-partum Contraceptive use by pregnancy risk status (any method and by Tiers among those receiving a method), Mexico 2012-2017



Note: Data Source, ENSANUT 2018

Immediate postpartum contraceptive use by pregnancy risk status (any method and by Tiers among those receiving a method), Mexico 2012-2017

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*7-8*
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	8-9
		(*c*) Explain how missing data were addressed	8-9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	8-9

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Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-10
		(b) Indicate number of participants with missing data for each variable of interest	10
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*9-10*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-10
		(*b*) Report category boundaries when continuous variables were categorized	9-10
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12-13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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