Title

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Journal

Contraception, 96(1)

ISSN

0010-7824

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Publication Date

2017-05-01

DOI

10.1016/j.contraception.2017.05.005

Peer reviewed

Contraception

Contraception 96 (2017) 41–46

Original research article

An updated assessment of postpartum sterilization fulfillment after vaginal delivery☆,☆☆,★

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Received 17 March 2017; revised 10 May 2017; accepted 21 May 2017

Abstract

Objective: To describe sterilization completion rates after vaginal delivery and indications for unfulfilled procedures.
Study design: We used labor and delivery operating room and delivery logs to identify all women over 20 years of age with a completed live vaginal birth beyond 24 weeks gestation over a 33-month period (March 1, 2012 to November 30, 2014). We reviewed the electronic medical records of all of these patients and identified those who requested a sterilization procedure as indicated in a physician's admission note or antenatal record.
Results: We identified 3514 live vaginal births beyond 24 weeks gestation during the study period of which 219 requested postpartum sterilization. Sterilization occurred in 114 (52%). The most common reason for unfulfilled procedures was lack of valid federally mandated consent (n=46 [44%]). Fifty-nine percent (27 of 46) of these women had little or no prenatal care. Only one (0.5%) woman had documented completion of consent with the required time elapsed prior to delivery and no consent form available. Of the women with valid consent documentation, the most common indication for an unfulfilled procedure was patient refusal (n=30 [51%]). Body mass index was an independent predictor of an unfulfilled procedure ($p<.001$) among women with adequate consent.
Conclusions: Inability to complete federally mandated consent is a principal cause of unfulfilled postpartum sterilization and primarily affects women desiring sterilization who lack sufficient prenatal care. Of women who meet consent criteria, the primary reason women eligible for sterilization did not undergo the procedure was due to withdrawing their request.
Implications: Because women commonly do not undergo a requested sterilization after vaginal deliveries, antepartum counseling should include alternate contraception choices. Documented consent that fulfills all federally mandated criteria remains the most common barrier to requested sterilization after vaginal delivery; providers and policymakers should work together to help unburden women from this mandate.

Keywords: Sterilization; Postpartum; Tubal ligation; PPTL; BTL; Consent

1. Introduction

Female sterilization is used for pregnancy prevention by 25% of all contracepting women in the United States [1]. Sterilization within 48 h of vaginal delivery is effective, safe and convenient for many women [2,3]. However, a known barrier is the requirement for federally mandated consent that includes waiting periods for women seeking permanent sterilization. These forms can be unavailable at the time of delivery or not signed in time if the patient decided late in care to undergo such a procedure. The American College of Obstetricians and Gynecologists recommends that obstetricians identify and eliminate barriers to postpartum sterilization, many of which may be bureaucratic or institutional, including lack of operating room space or personnel, lack of mandated consent, or physician perception of ineligibility [3].

Electronic medical records can potentially prevent lack of availability of federally mandated consent documentation because forms can be scanned into the record; some networks even allow for sharing across institutions in real time. However, previously published evaluations of fulfilled postdelivery sterilizations commonly predate widespread availability of electronic medical records or use of such

☆ Conflicts of interest: None.
☆☆ Financial disclosures: None.
★ Presented in part as a poster abstract at the North American Forum on Family Planning, November 13–15, 2015, Chicago, IL, USA.

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http://dx.doi.org/10.1016/j.contraception.2017.05.005
0010-7824/

records to maintain consent documents [4–6]. In addition, many prior studies include women having a Cesarean delivery who consistently have significantly higher rates of completion of intended sterilization [4,6,7]. About 40–60% of women after vaginal delivery receive a planned sterilization procedure [4–7].

For those women who have adequate consent documentation, up to 50% do not undergo a planned procedure due to changing their minds [7,8]. In addition, lack of operating room space or unavailability of obstetric or anesthesia personnel can account for 10–33% of unfulfilled procedures [4–6,8]. Theoretically, ensuring timely operating room access for women desiring postvaginal delivery sterilization could minimize the risk of not undergoing a procedure due to lack of operating room personnel or a long wait during which time the patient may change her mind. In August 2013, the Department of Obstetrics and Gynecology at the University of California, Davis Medical Center (UCDMC) designated postpartum sterilization procedures as "non-elective," indicating their priority in the labor and delivery operating rooms as second only to urgent or emergent operative or Cesarean deliveries. The change occurred following quality review of a patient who had a delay of more than 2 days for a desired postvaginal delivery sterilization. At the time of the policy change, the department had not evaluated overall procedure completion rates.

We performed this retrospective descriptive study to determine the rate of fulfilled sterilizations and identify potential institutional barriers to this procedure such as lack of operating space, focusing only on women having a vaginal delivery. We compared women with adequate consent who did and did not undergo a sterilization procedure to look for specific variables that may predict an unfulfilled procedure at our institution. Secondarily, we evaluated whether this policy, which intended to improve operating room availability, decreased the interval from delivery to sterilization and changed the rate of unfulfilled postpartum sterilizations after vaginal delivery.

2. Materials and methods

We used labor and delivery operating room and delivery logs to identify all women over 20 years of age with a completed live vaginal birth beyond 24 weeks gestation from March 1, 2012 to November 30, 2014. This time frame represents the number of complete months before (18 months) and after (15 months) the policy change to achieve at least 50 postvaginal delivery sterilization procedures in each cohort. During this time period, the labor and delivery unit did not have any specified policies restricting availability of sterilization procedures based on date or time, other than the policy change itself.

We reviewed the electronic medical records of all of these patients and identified those who requested a sterilization procedure as documented in a physician's admission note or antenatal record. We evaluated these records for valid mandated consent documentation at the time of the delivery admission. In California, patients with medical assistance and federal insurance must undergo a 30-day waiting period and those with private insurance a 3-day waiting period between signing the mandated consent form and having the procedure. A single investigator (KKW) extracted patient demographics, gestational age at delivery, insurance status, day and time of delivery, use of labor epidural analgesia, sterilization rates, and reason for failure to attain a procedure from the electronic medical record into a secure spreadsheet. The University of California, Davis Institutional Review Board approved this study.

We used Fisher's Exact and chi-square testing as appropriate. We assessed predictors of obtaining a desired sterilization among women with valid consent documentation by performing a multivariable logistic regression with all patient characteristics as independent variables. We performed all analyses using SAS® software Version 9.4 (SAS Institute, Cary, NC, USA) and considered a p-value of less than .05 as significant.

3. Results

We identified 3514 live vaginal births beyond 24 weeks gestation at UCDMC during the study period. Overall, 219 women requested sterilization per the medical record, including 108 of 1799 (6.0%) women before and 111 of 1715 (6.5%) women after the policy change. The characteristics of the study population are presented in Table 1. Women without valid consent documentation were more likely to be young (<30 years old) or have public insurance and less likely to have an epidural anesthetic during labor as compared to women with valid consent forms.

Postvaginal delivery sterilization occurred in 114 (52.1%) women. Surgeons performed the majority of completed procedures within 24 h of delivery (79.8%), with similar proportions before (43 of 54, 79.6%) and after (48 of 60, 80.0%) the policy change (p=.96).

The reasons for an unfulfilled procedure are presented in Table 2. We did not encounter more than one reason documented for failure of a procedure to be performed, but six charts had no reason indicated. The most common reason for unfulfilled procedures was lack of valid consent forms, inhibiting 46 (21.0%) women from considering sterilization after delivery and accounting for 43.8% of all unfulfilled procedures. Twenty-seven (58.7%) of these women (23 of whom were having their third through ninth child) had scant or no prenatal care and stated that they desired sterilization upon or after admission. Eleven (23.9%) women, primarily cared for by providers not in our department or institution, had sterilization counseling and consent documents signed too late to meet the state-mandated waiting time; of note, one of these women changed her mind about sterilization upon admission regardless of her invalid consent. Seven (15.2%)

Table 1
Characteristics of Women Desiring Postpartum Sterilization After Vaginal Delivery From March 1, 2012 to November 30, 2014 [*n* (%)]

Patient characteristics	Total, *N*=219	Women with valid consent documents, *n*=173	Women without valid consent documents, *n*=46	p-value*
Age (years)				0.01
≤30	72 (32.9%)	50 (28.9%)	5 (10.9%)	
31–40	128 (58.4%)	108 (62.4%)	31 (67.4%)	
≥41	19 (8.7%)	15 (8.7%)	10 (21.7%)	
Gestational age (weeks)				0.77
24–33 6/7	6 (2.7%)	5 (2.9%)	1 (2.2%)	
34–36 6/7	23 (10.5%)	20 (11.6%)	3 (6.5%)	
37+	190 (86.8%)	148 (85.5%)	42 (91.3%)	
Race/Ethnicity				0.13
White	85 (38.8%)	69 (39.9%)	16 (34.8%)	
Black	39 (17.8%)	25 (14.5%)	14 (30.4%)	
Hispanic	73 (33.3%)	60 (34.7%)	13 (28.3%)	
Asian	15 (6.8%)	12 (6.9%)	3 (6.5%)	
Unknown	7 (3.2%)	7 (4.1%)	0	
BMI (kg/m^2)				0.12
≤29.9	93 (42.5%)	79 (45.7%)	14 (30.4%)	
30.0–39.9	86 (39.3%)	66 (38.2%)	20 (43.5%)	
≥40.0	28 (12.8%)	21 (12.1%)	7 (15.2%)	
Unknown	12 (5.5%)	7 (4.0%)	5 (10.9%)	
Insurance				<0.001
Private	76 (34.7%)	75 (43.4%)	1 (2.2%)	
Public	140 (63.9%)	98 (56.7%)	42 (91.3%)	
Unknown	3 (1.4%)	0	3 (6.5%)	
Parity				0.70
1	8 (3.7%)	5 (2.9%)	3 (6.5%)	
2	37 (16.9%)	30 (17.3%)	7 (15.2%)	
3	69 (31.5%)	55 (31.8%)	14 (30.4%)	
≥4	105 (47.9%)	83 (48.0%)	22 (47.8%)	
Time of delivery†				0.03
0000–0800	66 (30.1%)	52 (30.1%)	14 (30.4%)	
0800–1600	80 (36.5%)	57 (33.0%)	23 (50.0%)	
1600–2400	72 (32.9%)	63 (36.4%)	9 (17.4%)	
Unknown	2 (0.9%)	1 (0.6%)	1 (2.2%)	
Day of delivery				0.33
Sunday to Thursday	168 (76.7%)	130 (75.1%)	38 (82.6%)	
Friday and Saturday	51 (23.3%)	43 (24.9%)	8 (17.4%)	
Epidural use	144 (65.8%)	120 (69.4%)	24 (52.2%)	0.04

* Comparing women with and without valid state sterilization consent documentation.
† Military time.

women with public insurance had adequate counseling throughout prenatal care but decided too late in pregnancy to meet the 30-day waiting period. Only one (0.5%) patient had prenatal notes indicating that the consent form was signed but the documentation was missing at delivery. The second most common reason, women changing their mind and refusing the procedure, occurred in 30 women; comprising 13.7% of the total population of women requesting sterilization, 28.6% of women who did not receive a procedure and 50.8% of women with valid consent who did not receive a procedure.

We assessed predictors related to obtaining a planned postpartum sterilization among women with valid consent documentation (Table 3). Women with a predelivery body mass index (BMI)≥40.0 kg/m^2 were more likely to have an unfulfilled procedure compared to women with a BMI<40.0 kg/m^2 (90.5% vs. 27.6%, p<.001). In multivariable logistic regression with all variables, BMI remained significant (Table 3).

4. Discussion

Our overall rate of fulfilled sterilization of 52% falls within the range of 39–57% previously reported in the literature [4–7]. Although prior studies have evaluated demographic and other factors related to lack of fulfillment of postdelivery sterilization requests, none have thoroughly reported the reasons for unavailability of or not obtaining mandated consent documentation.

Failure to meet sterilization consent requirements still remains one of the most important barriers to receiving a desired postpartum sterilization. In the electronic medical record era, when scanning of consent forms into the medical record can preclude unavailability of the forms, we encountered only one patient for whom documentation was obtained but not available. Almost half of the remaining women on public insurance could have potentially accessed sterilization with a shorter waiting period than 30 days,

Table 2
Reasons for unfulfilled postpartum sterilization after vaginal delivery from March 1, 2012 to November 30, 2014

Indication for failure to complete sterilization	Total, *n*=105	Before policy change*, *n*=54	After policy change*, *n*=51
Inadequate consent documentation†	46 (43.8%)	23 (42.6%)	23 (45.1%)
Changed mind	30 (28.6%)	14 (25.9%)	16 (31.4%)
BMI/Body habitus	14 (13.3%)	7 (13.0%)	7 (13.7%)
Medical comorbidities‡	7 (6.7%)	4 (7.4%)	3 (5.9%)
Not documented	6 (5.7%)	4 (7.4%)	2 (3.9%)
Operating room schedule	2 (1.9%)	2 (3.7%)	0

The p-value for the indications before and after policy change is 0.82.
Data are presented as *n* (%). Each medical record had no more than one reason cited for failure to have a procedure.
* The policy change on August 30, 2013 prioritized operating room access for women desiring sterilization following vaginal delivery.
† State-mandated documentation requires waiting periods after consent of 30-days for public insurance and 3-days for private insurance patients.
‡ Peripartum cardiomyopathy (*n*=1), endometritis (*n*=1), severe preeclampsia (*n*=2) and prior abdominal surgeries (*n*=3).

Table 3
OR for obtaining desired postpartum sterilization after vaginal delivery among women with valid mandated sterilization consent forms (*n*=153)*.

Patient characteristics	cOR	95% CI	p-value	aOR	95% CI	p-value
Age (years)						
≤30	Referent			Referent		
31–40	1.28	(0.85–1.40)	0.59	1.08	(0.44–2.66)	0.86
≥41	1.26	(0.36–4.14)	0.77	1.43	(0.29–6.90)	0.66
Gestational age (weeks)						
24–33 6/7	0.74	(0.12–4.59)	0.87	0.68	(0.08–5.63)	0.77
34–36 6/7	0.74	(0.28–1.94)	0.82	0.90	(0.25–3.26)	0.92
37+	Referent			Referent		
Race/Ethnicity						
White	Referent			Referent		
Black	0.68	(0.27–1.72)	0.47	0.66	(0.22–1.98)	0.46
Hispanic	1.47	(0.69–3.13)	0.35	1.45	(0.54–3.87)	0.46
Asian	0.38	(0.11–1.33)	0.20	0.44	(0.10–1.88)	0.27
BMI (kg/m^2)						
≤29.9	Referent			Referent		
30.0–39.9	0.90	(0.43–1.86)	0.76	0.74	(0.32–1.69)	0.48
≥40.0	0.04	(0.01–0.18)	<0.001	0.02	(0.01–0.13)	<0.001
Parity						
1	Referent			Referent		
2	1.0	(0.15–6.9)	0.69	1.25	(0.14–11.49)	0.85
3	1.63	(0.25–10.67)	0.48	1.19	(0.15–9.5)	0.87
≥4	1.24	(0.20–7.86)	0.58	1.56	(0.20–12.37)	0.67
Insurance						
Private	0.57	(0.30–1.07)	0.08	0.63	(0.26–1.57)	0.32
Public	Referent			Referent		
Time of delivery†						
0000–0800	0.77	(0.36–1.65)	0.51	0.63	(0.24–1.67)	0.35
0800–1600	0.93	(0.43–2.00)	0.86	0.70	(0.27–1.85)	0.48
1600–2400	Referent			Referent		
Day of delivery						
Sunday to Thursday	1.78	(0.88–3.62)	0.11	1.65	(0.66–4.16)	0.29
Friday and Saturday	Referent			Referent		
Epidural use						
No	1.47	(0.73–2.96)	0.29	1.49	(0.60–3.70)	0.39
Yes	Referent			Referent		
Policy change						
Pre	Referent			Referent		
Post	1.2	(0.66–2.31)	0.52	1.84	(0.82–4.15)	0.91

cOR, crude odds ratio; aOR, adjusted odds ratio: CI, confidence interval.
* Excludes 20 of 173 women for whom all characteristic data not available.
† Military time.

which is afforded women with private insurance in our state. Some of these women may still change their minds prior to procedure, similar to those women with valid consent. Still, those women who may be the most desperate for sterilization, women with significant social issues and high parity who fall between the cracks in our system, already have trouble accessing prenatal care and thus are most at risk for not meeting mandated criteria for sterilization consent. Multiple analyses and commentaries have underscored the need for re-evaluating the requirements for this mandated consent process in order to continue to ensure informed consent while respecting patient autonomy and removing barriers to desired procedures, which disproportionally affect socially disadvantaged patients [10–13].

Excluding women who did not have fulfilled sterilization due to lack of valid consent forms for sterilization allows analysis of provider and hospital factors at the time of delivery. We found that more than half of women who did not have a procedure changed their mind about sterilization. This finding is also noted in follow-up qualitative study by Gilliam, et al. [9] of 34 postpartum women with unfulfilled sterilizations, in which the women who had changed their minds cited not only delays in obtaining the procedure, but also fear of the procedure or anesthesia upon learning more details about the surgery, provider influence, and a change in their future pregnancy intentions. Another consideration is that a woman could feel pressured if her provider recommends proceeding with sterilization very shortly after a delivery. These interrelated and complex apprehensions about undergoing a postpartum abdominal sterilization surgery are likely very different from those of a woman who chooses to proceed with an intended sterilization during a scheduled Cesarean delivery.

In our institution, providers on duty in labor and delivery appeared reticent to perform or recommend surgery on obese women with valid consent documentation, specifically those with a predelivery BMI≥40 kg/m^2 [odds ratio (OR)=0.02]; the overwhelming magnitude of this association was unanticipated prior to the study. Approximately one quarter of patients with an unfulfilled sterilization were denied the procedure specifically due to their body habitus. Additional patients may have been dissuaded by the counseling of a reluctant provider, who may heavily emphasize surgical risks or the potential need for a larger incision. Options for addressing this issue include more training for providers or finding providers who are willing to operate on these patients. Of note, in two prior studies, BMI was also noted to be a significant predictor of failure to obtain postpartum sterilization, though not to the extent that it was noted in our population (OR=0.60 and 0.44) [5,7]; in two other studies, BMI was not a significant factor [4,6]. Patients were not commonly denied a procedure due to other medical conditions. Other variables such as time or day of delivery, insurance carrier, age, parity and race did not influence the likelihood of obtaining sterilization in our population.

A strength of this study is that we used individual chart review to identify every patient with a vaginal delivery during this time period, rather than relying on billing codes which can miss potential patients. A limitation of this study is that it is the experience of a single institution with a relatively small number of subjects, limiting our power to make conclusions from secondary analyses. The retrospective nature of this analysis restricted our ability to understand why a patient changed her mind or what other factors not documented in the record may have contributed to an unfulfilled sterilization. In addition, though our rate of postpartum sterilization after vaginal delivery (3.2%) is comparable to the average rate of all hospitals in California (2.8%), it is lower than in other states such as Texas (4.9%), so our conclusions may not be generalizable to institutions where more sterilizations are performed [14].

Prior to this review, we changed policy with the intent to benefit women desiring postvaginal delivery sterilization. To our surprise, we found that even before such a policy change, relatively few women at our institution had an unfulfilled procedure due to lack of operating room availability, and the majority had procedures completed within 24 h of delivery. From a policy standpoint, we successfully eliminated operating room unavailability as a reason for an unfulfilled procedure; for institutions at which lack of operating room space is more common, a similar policy could have a larger impact. On a societal level, we must find ways to decrease the barriers for women seeking postpartum sterilization, whether by modifying the requirements for mandated consent documentation or increasing procedure availability. Just as important, among women with valid documentation, the most common reason for unfulfilled sterilization is because a woman changes her mind about having this permanent procedure. Clinicians should discuss this potential outcome with patients in the antepartum setting and formulate a secondary contraception plan in the event they change their mind or do not receive their procedure for other reasons.

Acknowledgements

The project was supported in part by the National Center for Advancing Translational Sciences, National Institutes of Health, through grant #UL1 TR001860.

References

[1] Daniels K, Daugherty J, Jones J. Current contraceptive status among women aged 15–44: United States, 2011–2013. NCHS data brief, no 173. Hyattsville, MD: National Center for Health Statistics; 2014.

[2] Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. collaborative review of sterilization. Obstet Gynecol 1996;174:1161–70.

[3] American College of Obstetricians and Gynecologists. Access to postpartum sterilization. Committee opinion 503. Washington, DC: American College of Obstetricians and Gynecologists; 2012.

[4] Zite N, Wuellner S, Gilliam M. Failure to obtain desired postpartum sterilization: risk and predictors. Obstet Gynecol 2005;105:794–9.
[5] Seibel-Seamon J, Visintine JF, Leiby BE, Weinstein L. Factors predictive for failure to perform postpartum tubal ligations following vaginal delivery. J Reprod Med 2009;54:160–4.
[6] Thurman AR, Harvey D, Shain RN. Unfulfilled postpartum sterilization requests. J Reprod Med 2009;54:467–72.
[7] Allen RH, Desimone M, Boardman LA. Barriers to completion of desired postpartum sterilization. Med J 2013;96:32–4.
[8] Zite N, Wuellner S, Gilliam M. Barriers to obtaining a desired postpartum tubal sterilization. Contraception 2006;73:404–7.
[9] Gilliam M, Davis SD, Berlin A, Zite NB. A qualitative study of barriers to postpartum sterilization and women's attitudes toward unfulfilled sterilization requests. Contraception 2008;77:44–9.
[10] Borrero S, Zite N, Creinin MD. Federally funded sterilization: time to rethink policy? Public Health 2012;102:1822–5.
[11] Borrero S, Zite N, Potter JE, Trussell J. Medicaid policy on sterilization — anachronistic or still relevant? Med 2014;370:102–4.
[12] Brown BP, Chor J. Adding injury to injury: ethical implications of the Medicaid sterilization consent regulations. Obstet Gynecol 2014;123:1348–51.
[13] Moaddab A, McCullough LB, Chervenak FA, Fox KA, Aagaard KM, Salmanian B, et al. Health care justice and its implications for current policy of a mandatory waiting period for elective tubal sterilization. Obstet Gynecol 2015;212:736–9.
[14] Potter JE, Stevenson AJ, White K, Hopkins K, Grossman D. Hospital variation in postpartum tubal sterilization rates in California and Texas. Obstet Gynecol 2013;121:152–8.