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Long-term outcomes after elective sterilization procedures — a comparative retrospective cohort study of Medicaid patients☆

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ABSTRACT

Objectives: The objectives were to compare the long-term outcomes, including hysterectomy, chronic pelvic pain (CPP) and abnormal uterine bleeding (AUB), in women post hysteroscopic sterilization (HS) and laparoscopic tubal ligation (TL) in the Medicaid population.
Study design: This was a retrospective observational cohort analysis using data from the US Medicaid Analytic Extracts Encounters database. Women aged 18 to 49 years with at least one claim for HS (n=3929) or TL (n=10,875) between July 1, 2009, through December 31, 2010, were included. Main outcome measures were hysterectomy, CPP or AUB in the 24 months poststerilization. Propensity score matching was used to control for patient demographics and baseline characteristics. Logistic regression analysis investigated the variables associated with a 24-month rate of each outcome in the HS versus laparoscopic TL cohorts.
Results: Postmatching analyses were performed at 6, 12 and 24 months post index procedure. At 24 months, hysterectomy was more common in the laparoscopic TL than the HS group (3.5% vs. 2.1%; p=.0023), as was diagnosis of CPP (26.8% vs. 23.5%; p=.0050). No significant differences in AUB diagnoses were observed. Logistic regression identified HS as being associated with lower risk of hysterectomy (odds ratio [OR] 0.77 [95% confidence interval {CI} 0.60–0.97]; p=.0274) and lower risk of CPP diagnosis (OR 0.91 [95% CI 0.83–0.99]; p=.0336) at 24 months poststerilization.
Conclusion: In Medicaid patients, HS is associated with a significantly lower risk of hysterectomy or CPP diagnosis 24 months poststerilization versus laparoscopic TL. Incidence of AUB poststerilization is not significantly different. While some differences in outcomes were statistically significant, the effect sizes were small, and the conclusion is one of equivalence and not clinical superiority.
Implications statement: This propensity score matching analysis confirms that pelvic pain and AUB are common in women before and after sterilization regardless of whether the procedure is performed hysteroscopically or laparoscopically. Moreover, HS is associated with a significantly lower risk of hysterectomy or a CPP diagnosis in the 24 months poststerilization when compared to TL.

1. Introduction

Although trends suggest a declining rate of female sterilization in the United States [1], it remains the second most common form of contraception among US reproductive-aged women [2]. Methods available for interval sterilization (sterilization at a time remote from delivery) include laparoscopic tubal ligation (TL) and hysteroscopic sterilization (HS). TL requires entry into the peritoneal cavity and general anesthesia, whereas HS involves an implant being placed into the fallopian tubes through a hysteroscope.

In an analysis of a large commercial insurance database, women who underwent HS had a higher rate of menstrual dysfunction but a lower rate of hysterectomy and pelvic pain 1 to 5 years postprocedure compared to women who had laparoscopic TL [3]. Another study of the same database showed that during a 12-month follow-up, women who underwent HS versus TL had the same incidence of opioid-

☆ Capsule: In the Medicaid population, hysteroscopic sterilization is associated with a lower risk of hysterectomy and chronic pelvic pain compared to tubal ligation, with a similar incidence of abnormal uterine bleeding.

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managed pelvic pain [4]. Finally, while not comparative, a retrospective
conditions

(chronic headache, low back pain, pelvic pain, and fibromyalgia) are 6 times as likely to experience both acute and chronic pelvic pain (CPP) following the Essure hysteroscopic tubal sterilization procedure [5].

Women with no or public insurance are more likely to undergo sterilization than women with commercial insurance. African American race, less education and poverty also increase the likelihood of sterilization [1,6]. Current data on sequelae after sterilization are limited to women with commercial insurance [3], and it is unknown whether the same outcomes can be expected in a population of women who are publicly insured.

The current study was undertaken to compare the rate of hysterectomy and the diagnosis of CPP or abnormal uterine bleeding (AUB), outcomes also explored by Perkins et al., in the 24 months after sterilization by laparoscopic TL or HS in women who were covered by Medicaid.

2. Materials and methods

2.1. Data source

This retrospective, observational cohort study used data from the US Medicaid Analytic Extracts (MAX) Encounters database, which contains individual-level information on characteristics of Medicaid enrollees. This database includes demographic data (e.g., age, race), information on dispensed prescription drugs identified by a National Drug Code, Medicaid services (e.g. physician services, laboratory/x-ray, clinical services, premium payments, outpatient hospital claims), institutional long-term care services and inpatient services (including diagnoses, procedures, discharge status, length of stay and payment amount). In compliance with the Health Insurance Portability and Accountability Act of 1996, the database comprises fully deidentified data sets. Therefore, this study was exempt from Institutional Review Board overview under the Common Rule (45 CFR x46.101(b) [4]).

2.2. Subjects

Women aged 18 to 49 years who had at least one claim for HS (Current Procedural Terminology [CPT] code: 58565) or interval laparoscopic TL (CPT codes: 58670 or 58671) at any time during July 1, 2009, through December 31, 2010 (Supplementary Fig. 1), were included in this study. The date of the claim for the sterilization procedure was defined as the index date. The study included only women who had 6 months of continuous medical and pharmacy claims data prior to the procedure and at least 24 months after the procedure. The entire study period, including baseline and follow-up, was January 1, 2009, through December 31, 2012. At the time of the analysis, 35 states were available in the 2012 MAX data.

Patients were excluded from the analysis if they underwent postpartum TL during the study period; had already undergone a sterilization procedure during the baseline period; had a claim for pregnancy or delivery within 6 weeks before the index date; had more than one type of sterilization procedure on the index date; had concurrent procedures on the same day as the index sterilization procedure that may have an impact on the study outcomes (Supplementary Table 1); or had a modifier -53 next to the procedure code on the index date, indicating an incomplete procedure.

All available data that met the inclusion and exclusion criteria were included.

2.3. Analysis and outcomes

(ICD-9) diagnostic codes for pelvic pain/lower abdominal pain and AUB (Supplementary Table 2).

Poststerilization CPP was defined as receiving ≥2 diagnoses of pelvic pain/lower abdominal pain on at least 2 separate visits, beginning 2 weeks post index procedure. At least one of these diagnoses had to be received at least 3 months after the index procedure (indicating some degree of chronicity). AUB was defined as ≥2 diagnoses of AUB at least 2 weeks post index procedure with at least one of them occurring beyond 3 months after the index procedure.

2.4. Statistical analysis

All baseline and outcome variables were analyzed descriptively. Percentages and numbers were calculated for dichotomous and polychotomous variables, and compared using chi-square test with p values and 95% confidence intervals (CIs). Means with SDs were calculated for continuous variables and compared using *t* tests, with p values and 95% CI. In addition, standardized differences (effect size [ES]), defined as the absolute difference in sample means divided by an estimate of the pooled SD of the variable, were calculated for each variable. Standardized differences were reported as 100 times the absolute ES difference.

Patient matching was carried out in two steps by the combination of exact match of patient characteristics and propensity score matching (PSM). Exact patient match ensured that the matched patient groups have the same distribution of key baseline patient characteristics (as identified by DeNoble et al. in their study of medical comorbidities common in reproductive aged women), and included baseline pain status (as identified by Yunker et al. in their study of pelvic pain post Essure placement) and the presence of baseline AUB diagnosis codes [5,7]. History of pain was not included in the propensity score as it would provide a good match rather than an exact match. Baseline pain and baseline AUB are considered strong confounders that are important to be matched exactly [5,7]. PSM was then conducted within each of the stratified groups, and additional patient demographic and clinical characteristics were controlled in the PSM that enabled the matched populations to have the same and/or similar baseline characteristics. Multivariable logistic regression analysis was carried out on the entire unmatched sample as a sensitivity analysis to check on the robustness of the findings from the matching analysis. Multivariable logistic regression was used to generate the propensity score, with women having HS versus laparoscopic TL as the dependent variable, and the covariates in the PSM included age (18–24 [reference], 25–29, 30–34, 35–39, 40–44, 45–49); race (White [reference], African American, Hispanic, other race, unknown); Charlson Comorbidity Index (CCI) score (0 [reference] or ≥1); geographic region (North East [reference], South, Midwest, West, other); comorbidities (hypertension, asthma, hypothyroidism, diabetes, obesity); pelvic pain-related conditions (fibroid, benign ovarian neoplasms); prior pregnancy/delivery (during the 6-month baseline but beyond 6 weeks prior to the index date); and oral contraceptive or injectable methods used during a 6-month baseline prior to index. Logistic regressions were also conducted using the unmatched population to compare the risk of hysterectomy, CPP and AUB 24 months post-HS versus laparoscopic TL by controlling patient demographic and clinical characteristics. All statistical analyses were carried out using SAS 9.3.

3. Results

3.1. Patient characteristics

Overall, 14,804 women met the inclusion criteria and had at least 24 months of continuous data poststerilization; 3929 had undergone

The primary outcomes measures were the proportion of women

HS, and 10,875 had undergone laparoscopic TL (Supplementary Fig. 2

older than in
vs. 30.4 [5.9]
laparoscopic TL

ion (10.2% vs.

7.7%; p<.0001), diabetes (5.1% vs. 3.5%; p<.0001) or obesity (6.6% vs. 4.7%; p<.0001). Fewer women in the HS group than those in the laparoscopic TL group received a diagnosis code for a pain condition (chronic headache, low back pain, pelvic pain, fibromyalgia) (35.1% vs. 40.0%; p<.0001). Baseline AUB was higher in the HS group than in the laparoscopic TL group (8.1% vs. 6.4%; p=.0004). Fewer women in the HS group used no prescription contraceptive during the baseline period (no contraceptive use: 63.7% vs. 83.7%; p<.0001). The difference in contraceptive use was most marked for oral contraceptives (8.8% in the HS group vs. 5.3% in the laparoscopic TL group; p<.0001) and for injectables (25.1% in the HS group vs. 7.5% in the laparoscopic TL group; p<.0001). There were also significant differences in race/ethnicity, as shown in Table 1. PSM adjusted baseline characteristics were similar between both groups except for inflammatory bowel disease and low back pain.

Table 1
Baseline demographics in the overall study population and the PSM adjusted population [a].

	Overall study population					PSM adjusted population				
	HS (n=3929)	Laparoscopic TL (n=10,875)	p value	95%CI for difference	Effect size	HS (n=2673)	Laparoscopic TL (n=2673)	p value	95%CI for difference	Effect size
Mean (SD) age, years	31.8 (6.1)	30.4 (5.9)	*<.0001*	−1.62, −1.18	*23.38*	30.9 (5.6)	30.8 (5.7)	.3414	−0.45, −0.16	2.60
Age group, *n* (%)										
18–20 years	3 (0.1)	8 (0.1)	.9561	−0.10, 0.10	0.10	2 (0.1)	1 (0.04)	.5636	−0.09, 0.16	1.58
21–24 years	447 (11.4)	1818 (16.7)	*<.0001*	−6.56, −4.12	*15.41*	328 (12.3)	334 (12.5)	.8033	−1.99, 1.54	0.68
25–29 years	1117 (28.4)	3571 (32.8)	*<.0001*	−6.07, −2.74	9.57	886 (33.2)	884 (33.1)	.9536	−2.45, 2.60	0.16
30–34 years	1107 (28.2)	2865 (26.3)	.0265	0.20, 3.46	4.11	762 (28.5)	757 (28.3)	.8795	−2.23, 2.61	0.41
35–39 years	775 (19.7)	1658 (15.3)	*<.0001*	3.06, 5.90	*11.81*	467 (17.5)	468 (17.5)	.9713	−2.07, 2.00	0.10
40–44 years	369 (9.4)	783 (7.2)	*<.0001*	1.16, 3.23	7.95	200 (7.5)	200 (7.5)	1.0000	−1.41, 1.41	0.00
45–49 years	111 (2.8)	172 (1.6)	*<.0001*	0.67, 1.81	8.48	28 (1.1)	29 (1.1)	.8941	−0.59, 0.51	0.36
Race										
White	2076 (52.8)	6959 (64.0)	*<.0001*	−10.97, −7.34	*18.52*	1603 (60.0)	1599 (60.0)	.9111	−2.48, 2.78	0.31
African American	1152 (29.3)	2225 (20.5)	*<.0001*	7.57, 10.78	*21.48*	686 (25.7)	693 (25.9)	.8268	−2.61, 2.08	0.60
Hispanic	496 (12.6)	1160 (10.7)	.4316	−1.05, 0.44	1.47	293 (11.0)	293 (11.0)	1.0000	−1.67, 1.67	0.00
Other race	96 (2.4)	182 (1.7)	*<.0001*	0.45, 1.51	7.10	36 (1.4)	35 (1.3)	.9049	−0.58, 0.65	0.33
Unknown	109 (2.8)	349 (3.2)	.2706	−1.92, 0.53	2.06	55 (2.1)	53 (2.0)	.8458	−0.68, 0.83	0.53
CCI score, *n* (%)										
0	3313 (84.3)	9252 (85.1)	.2581	−2.07, 0.57	2.09	2474 (92.6)	2477 (92.7)	.8754	−1.51, 1.29	0.43
1–2	558 (14.2)	1509 (13.9)	.6131	−0.94, 1.60	0.94	188 (7.0)	185 (6.9)	.8721	−1.25, 1.48	0.44
3–4	34 (0.9)	68 (0.6)	.1190	−0.09, 0.57	2.79	6 (0.2)	5 (0.2)	.7628	−0.21, 0.28	0.83
>4	24 (0.6)	46 (0.4)	.1413	−0.08, 0.46	2.62	5 (0.2)	6 (0.2)	.7628	−0.28, 0.21	0.83
Comorbidities, *n* (%)										
Hypertension	402 (10.2)	841 (7.7)	*<.0001*	1.43, 3.57	8.74	111 (4.2)	116 (4.3)	.7345	−1.27, 0.89	0.93
Asthma	246 (6.3)	758 (7.0)	.1298	−1.61, 0.19	2.85	97 (3.6)	99 (3.7)	.8843	−1.08, 0.93	0.40
Hypothyroidism	140 (3.6)	348 (3.2)	.2744	−0.30, 1.03	2.01	39 (1.5)	37 (1.4)	.8173	−0.56, 0.71	0.63
Diabetes	202 (5.1)	379 (3.5)	*<.0001*	0.88, 2.43	8.16	47 (1.8)	50 (1.9)	.7585	−0.83, 0.60	0.84
Obesity	258 (6.6)	511 (4.7)	*<.0001*	1.00, 2.74	8.11	65 (2.4)	66 (2.5)	.9295	−0.87, 0.79	0.24
Rheumatoid arthritis	21 (0.5)	47 (0.4)	.4163	−0.16, 0.36	1.47	9 (0.3)	3 (0.1)	.0829	−0.03, 0.48	4.74
IBD	19 (0.5)	34 (0.3)	.1241	−0.07, 0.41	2.71	14 (0.5)	5 (0.2)	*.0386*	0.02, 0.66	5.66
SLE	14 (0.4)	35 (0.3)	.7470	−0.18, 0.25	0.59	0 (0.0)	2 (0.1)	.1572	−0.18, 0.03	3.87
Comorbidities associated with pelvic pain, *n* (%)										
Fibroid	67 (1.7)	125 (1.2)	*.0083*	0.10, 1.01	4.69	4 (0.2)	5 (0.2)	.7387	−0.26, 0.18	0.91
Benign ovarian neoplasm	140 (3.6)	420 (3.9)	.4001	−0.98, 0.38	1.58	44 (1.7)	44 (1.7)	1.0000	−0.68, 0.68	0.00
Endometriosis	19 (0.5)	84 (0.8)	.0619	−0.56, −0.02	3.66	10 (0.4)	11 (0.4)	.8269	−0.37, 0.30	0.60
Prolapse	13 (0.3)	51 (0.5)	.2581	−0.36, 0.08	2.19	9 (0.3)	9 (0.3)	1.0000	−0.31, 0.31	0.00
Preexisting pain during baseline period, *n* (%)										
Pelvic pain	880 (22.4)	2792 (25.7)	*<.0001*	−4.82, −1.74	7.67	522 (19.5)	505 (18.9)	.5551	−1.48, 2.75	1.61
Low back pain	485 (12.3)	1772 (16.3)	*<.0001*	−5.19, −2.71	*11.29*	294 (11.0)	344 (12.9)	*.0349*	−3.61, −0.13	5.77
Chronic headache	301 (7.7)	1014 (9.3)	*.0017*	−2.66, −0.67	5.97	185 (6.9)	187 (7.0)	.9144	−1.44, 1.29	0.29
Fibromyalgia	82 (2.1)	248 (2.3)	.4815	−0.72, 0.33	1.32	42 (1.6)	42 (1.6)	1.0000	−0.67, 0.67	0.00
Any form of pre-existing pain [b]	1378 (35.1)	4353 (40.0)	*<.0001*	−6.71, −3.20	*10.24*	830 (31.1)	830 (31.1)	1.0000	−2.48, 2.48	0.00
AUB, *n* (%)	317 (8.1)	695 (6.4)	*.0004*	0.71, 2.65	6.48	101 (3.8)	101 (3.8)	1.0000	−1.02, 1.02	0.00
Prior pregnancy or delivery, [c] *n* (%)	1692 (43.1)	4793 (44.1)	.2745	−2.82, 0.80	2.04	1159 (41.9)	1154 (41.9)	.8902	−2.47, 2.84	0.38
Contraceptives used during baseline period, [d] *n* (%)										
None	2502 (63.7)	9097 (83.7)	*<.0001*	−21.63, −18.31	*46.55*	2042 (76.4)	2043 (76.4)	.9743	−2.31, 2.24	0.09
Oral contraceptive	347 (8.8)	572 (5.3)	*<.0001*	2.59, 4.55	*13.99*	145 (5.4)	145 (5.4)	1.0000	−1.21, 1.21	0.00
Contraceptive patch	45 (1.2)	133 (1.2)	.7019	−0.47, 0.31	0.72	35 (1.3)	35 (1.3)	1.0000	−0.61, 0.61	0.00
Vaginal ring	106 (2.7)	221 (2.0)	*.0150*	0.09, 1.24	4.38	75 (2.8)	63 (2.4)	.3007	−0.40, 1.30	2.83
Implant	0 (0.0)	9 (0.1)	.0713	−0.14, −0.03	4.07	0 (0.0)	1 (0.04)	.3173	−0.11, 0.04	2.74
Intrauterine system	21(0.5)	71 (0.7)	.4183	−0.39, 0.16	1.54	15 (0.6)	20 (0.8)	.3965	−0.62, 0.25	2.32
Injectable	987 (25.1)	813 (7.5)	*<.0001*	16.20, 19.09	*49.19*	378 (14.1)	376 (14.1)	.9374	−1.79, 1.94	0.21

Note: Values in italics indicate those meeting the criteria for statistical (p value)

Note: Values in italics indicate those meeting the criteria for statistical (p value).
IBD, inflammatory bowel disease; SLE, systemic lupus erythematosus

D, TN, TX, VA,

3.2. Contraceptive use in the overall study population

"No use" of prescription contraceptives poststerilization (2 weeks preindex to 3 months postindex) was significantly higher in the laparoscopic TL group compared to the HS group (97.0% vs. 77.2%; p<.0001, respectively). The difference in contraceptive use poststerilization was most marked for oral contraceptives (HS, 6.4% vs. laparoscopic TL, 1.5%; p<.0001) and for injectables (HS, 14.5% vs. laparoscopic TL group, 0.8%; p<.0001).

3.3. Overall population

In an unmatched analysis, poststerilization hysterectomy and a diagnosis of CPP after sterilization were significantly more common in the laparoscopic TL group than the HS group both at 12 months and 24 months (p<.005 for all) (Table 2). The rates of AUB diagnoses after sterilization procedure were significantly more common in the HS group than the laparoscopic TL group at 12 months (p=.0059) but not at 24 months (p=.3145) (Table 2).

3.4. Postmatching analysis

At 6 months, there were no significant differences between the laparoscopic TL group and the HS group in the rates of poststerilization hysterectomy, diagnosis of CPP or diagnosis of AUB (Table 3). Hysterectomy was significantly more common in the laparoscopic TL group than the HS group at 24 months (3.5% vs. 2.1%; p=.0023). A diagnosis of CPP after sterilization was significantly more common in the laparoscopic TL group than the HS group at 12 months (13.8% vs. 11.7%; p=.0215) and 24 months (26.8% vs. 23.5%; p=.0050). There were no significant differences in the rates of AUB diagnoses after sterilization procedure at 12 months (p=.4334) and 24 months (p=.7629).

3.5. Logistic regression analysis

Logistic regression identified HS as being associated with a lower risk of hysterectomy (odds ratio [OR] 0.77 [95% CI 0.60–0.97]; p=.0274) or a CPP diagnosis (OR 0.91 [95% CI 0.83–0.99]; p=.0336) in the 24 months poststerilization; there was a similar risk of AUB compared to laparoscopic TL (Table 4).

4. Discussion

Both unmatched and PSM analyses of Medicaid patients indicate that pelvic pain and AUB are common in women before and after sterilization whether the procedure is performed hysteroscopically or laparoscopically. Moreover, HS is associated with a significantly lower risk of hysterectomy at 24 months or a CPP diagnosis at 12 and 24 months poststerilization when compared to TL, consistent with earlier reports [3]. Higher rates of AUB were found in the unmatched comparison at 6 and 12 months but not at 24 months; there were no differences in AUB at any time point in the matched analysis.

Consistent with previous reports [8], the publicly insured women in our study underwent sterilization at an average age of about 30 years compared to a mean age of about 37 years for commercially insured women. [3,8]. Consistent with our data, a comparison of Medicaid and commercially insured women undergoing HS or TL found that the Medicaid cohort was more likely to be using an injectable contraceptive and less likely to be using an oral contraceptive prior to sterilization [8]. Medicaid patients had a higher mean CCI score and were more likely to be obese or to have asthma than commercially insured women but less likely to have hypothyroidism [8].

Previous researchers found a significant difference in the rate of AUB during the first year following HS versus TL [3]. This potentially may be explained by the need to continue contraception after HS until a confirmation test has demonstrated proper insert location. Therefore, in the first several months after HS, women are still experiencing the effects of taking, then withdrawing from, hormonal contraception, whereas women undergoing TL can cease using contraceptives immediately after sterilization. In our matched analysis, however, the rate of AUB was similar at 6, 12 and 24 months postprocedure (Table 3). Logistic regression analysis in our study cohort identified baseline obesity, race (African American, Hispanic, other), pain condition, AUB and the use of injectable contraceptives as risk factors for an AUB diagnosis after sterilization.

Reports have emerged about pain developing after HS [5,9,10], but until recently, the studies comparing outcomes after HS and TL were limited by their definitions of pain (e.g., severe pain requiring opioids) [4] or by their short duration of follow-up [11]. In using a definition of pain that was consistent with previous research [3], we found a higher rate of CPP diagnosis after sterilization in patients who underwent TL compared with those who underwent HS (26.8% vs. 23.5%). While the rate of CPP was significantly higher in the TL versus the HS group in this study, the difference is small and unlikely to represent a clinically important difference. Nevertheless, the data from this study are consistent with Perkins et al. in that HS is not associated with more CPP than is TL [3].

These data are an important adjunct to previous database analyses, which have used data from employer-based insurance plans [3] and excluded Medicaid or Medicare patients. According to the Women's

Table 2
Descriptive outcomes of women in the TL cohort and HS cohort during the 24-months follow-up period (unmatched)

	HS (*N*=3929) *n* (%)	Laparoscopic TL (*N*=10,875) *n* (%)	p value	95% CI for difference	Effect size
6-Month outcomes					
Hysterectomy	17 (0.4)	77 (0.7)	.0625	−0.53,−0.02	3.66
Chronic pelvic pain	215 (5.5)	737 (6.8)	*.0043*	−2.16,−0.45	5.44
AUB	88 (2.2)	131 (1.2)	*<.0001*	0.53,1.54	7.96
12-Month outcomes					
Hysterectomy	39 (1.0)	190 (1.8)	*.0010*	−1.15,−0.36	6.49
Chronic pelvic pain	517 (13.2)	1789 (16.5)	*<.0001*	−4.56,−2.03	9.28
AUB	189 (4.8)	413 (3.8)	*.0059*	0.25,1.77	4.99
24-Month outcomes					

Table 3
PSM adjusted descriptive outcomes of women in the TL cohort and HS cohort during the 24-months follow-up period

	HS (*N*=2673) *n* (%)	Laparoscopic TL (*N*=2673) *n* (%)	p value	95% CI for difference	Effect size
6-Month outcomes					
Hysterectomy	10 (0.4)	16 (0.6)	.2382	−0.60, 0.15	3.23
Chronic pelvic pain	127 (4.8)	139 (5.2)	.4504	−1.61, 0.72	2.06
AUB	44 (1.7)	40 (1.5)	.6600	−0.52, 0.82	1.20
12-Month outcomes					
Hysterectomy	25 (0.9)	36 (1.4)	.1566	−0.98, 0.16	3.87
Chronic pelvic pain	312 (11.7)	368 (13.8)	*.0215*	−3.88, −0.31	6.29
AUB	108 (4.04)	97 (3.6)	.4334	−0.62, 1.44	2.14
24-Month outcomes					
Hysterectomy	57 (2.1)	94 (3.5)	*.0023*	−2.27, −0.50	8.36
Chronic pelvic pain	628 (23.5)	717 (26.8)	*.0050*	−5.65, −1.00	7.68
AUB	212 (7.9)	218 (8.2)	.7629	−1.68, 1.23	0.83

Note: Values in italics indicate those meeting the criteria for statistical significance (p value).

Hysterectomy	97 (2.5)	382 (3.5)	*.0015*	−1.64,−0.45	6.13

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Table 4
Logistic regression analysis examining the OR of having different outcomes at 24 months based on type of sterilization procedure and baseline characteristics.

	Hysterectomy		Pelvic pain		AUB	
	OR (95%CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value
Procedure						
Laparoscopic TL (ref)						
HS	0.77 (0.60, 0.97)	*.0274*	0.91 (0.83, 0.99)	*.0336*	1.06 (0.93, 1.21)	.3967
Age						
18–24 years (ref)						
25–29 years	1.17 (0.89, 1.54)	.2603	0.76 (0.68, 0.84)	*<.0001*	0.93 (0.78, 1.10)	.3934
30–34 years	0.99 (0.73, 1.33)	.9413	0.53 (0.47, 0.59)	*<.0001*	0.93 (0.78, 1.12)	.4611
35–39 years	0.97 (0.69, 1.37)	.8731	0.49 (0.43, 0.56)	*<.0001*	0.81 (0.66, 1.00)	.0545
40–44 years	1.00 (0.66, 1.53)	.9871	0.42 (0.36, 0.50)	*<.0001*	1.09 (0.86, 1.40)	.4776
45–49 years	1.04 (0.53, 2.05)	.9126	0.47 (0.35, 0.63)	*<.0001*	0.86 (0.56, 1.33)	.5033
Race						
White (reference)						
African American	0.41 (0.31, 0.55)	*<.0001*	0.74 (0.67, 0.81)	*<.0001*	0.72 (0.62, 0.84)	*<.0001*
Hispanic	0.46 (0.31, 0.69)	*.0002*	1.01 (0.89, 1.15)	.8999	0.66 (0.53, 0.82)	*.0001*
Other Race	0.36 (0.13, 0.98)	*.0449*	0.56 (0.41, 0.77)	*.0004*	0.61 (0.37, 0.99)	*.0463*
Unknown	0.78 (0.45, 1.36)	.3792	0.96 (0.77, 1.19)	.7133	0.79 (0.56, 1.13)	.1961
Geographic region						
Northeast (ref)						
South	1.26 (0.97,1.66)	.0895	0.98 (0.87, 1.09)	.6533	0.90 (0.77, 1.06)	.2158
Midwest	0.88 (0.67,1.17)	.3849	0.98 (0.88, 1.09)	.6879	0.84 (0.71, 0.98)	*.0291*
West	1.25 (0.80,1.94)	.3219	1.25 (1.04, 1.51)	*.0178*	1.13 (0.86, 1.49)	.3888
Unknown	2.12 (1.34, 3.34)	*.0013*	1.23 (0.98, 1.53)	.0717	0.93 (0.66, 1.31)	.6823
CCI score						
0 (ref)						
≥1	1.31 (0.93, 1.85)	.1291	1.31 (1.12, 1.53)	*.0008*	1.24 (0.99, 1.56)	.0615
Comorbidity						
Hypertension	1.16 (0.84, 1.60)	.3769	1.21 (1.05, 1.38)	*.0064*	1.20 (0.99, 1.46)	.0702
Asthma	0.95 (0.61, 1.47)	.8141	1.14 (0.94, 1.38)	.1901	1.01 (0.76, 1.33)	.9744
Hypothyroidism	0.81 (0.48, 1.35)	.4113	1.13 (0.93, 1.39)	.2244	1.22 (0.92, 1.62)	.1705
Diabetes	0.90 (0.53, 1.52)	.6939	1.04 (0.83, 1.31)	.7124	1.09 (0.79, 1.49)	.6133
Obesity	0.65 (0.40, 1.06)	.0871	1.16 (0.98, 1.36)	.0841	1.28 (1.02, 1.62)	*.0373*
Pelvic pain-related conditions						
Fibroid	1.65 (0.86, 3.15)	.1309	1.09 (0.79, 1.52)	.6023	1.38 (0.90, 2.11)	.1375
Benign ovarian neoplasms	2.33 (1.70, 3.19)	*<.0001*	2.06 (1.72, 2.47)	*<.0001*	1.19 (0.92, 1.53)	.1881
Baseline pain	1.95 (1.60, 2.37)	*<.0001*	2.59 (2.40, 2.80)	*<.0001*	1.66 (1.48, 1.87)	*<.0001*
Baseline AUB	2.03 (1.55, 2.66)	*<.0001*	1.40 (1.22, 1.62)	*<.0001*	2.21 (1.86, 2.64)	*<.0001*
Prior pregnancy or delivery [a]	0.94 (0.77, 1.15)	.5465	0.87 (0.80, 0.94)	*.0005*	0.99 (0.87, 1.11)	.8114
Prior contraceptive use [b]						
Oral contraceptives	0.99 (0.67, 1.47)	.9507	1.08 (0.92, 1.26)	.3408	1.15 (0.92, 1.45)	.2262
Injectable contraceptives	1.25 (0.94, 1.67)	.1202	1.11 (0.99, 1.25)	.0724	1.30 (1.10, 1.54)	*.0025*

Note: Values in italics indicate those meeting the criteria for statistical significance (p value).
[a] Six weeks or more before index date.
[b] Within the 6 months prior to the index date.

Database analyses have limitations. The comorbidities and diagnoses used are based solely on ICD-9 or CPT codes, and there is potential for coding errors to occur during data entry. The MAX database has 2012 data for only 35 states; however, the data come from all regions of the United States and are therefore likely to be nationally representative. MAX files contain only Medicaid-paid services and do not capture service use or expenditures during periods of nonenrollment, services paid by other payers or services provided at no charge. This database consists of claims submitted by healthcare providers to insurance companies for reimbursement on behalf of individuals, probably contributing to underreporting of AUB and pelvic pain events as many patients experience these conditions without consulting a healthcare professional [13,14]. In addition, other limitations may be associated with claims data use because data are collected for the purpose of payment and not research. Comorbidities and diagnoses were based solely on ICD-9 or CPT codes. Operationalization of

A strength of our analysis was the exclusion of women who had concomitant gynecologic procedures on the index sterilization date that could have an impact on the study outcome measures. Because many of these procedures are more likely to be performed in one study cohort than the other (eg, lysis of adhesions will only be performed in the laparoscopic group), allowing these additionally treated subjects to remain in the analysis would create an uncontrollable bias. An additional strength of our analysis is the use of the propensity score model, which included all measured baseline covariates potentially associated with treatment assignment and outcomes.

In conclusion, our data demonstrate that the incidence of hysterectomy and CPP in publicly insured women is lower after HS compared to after TL. In propensity score matched analyses, HS is associated with lower odds of having a hysterectomy at 24 months or receiving a diagnosis of CPP at 12 and 24 months, but not 6 months, after steriliza-

Supplementary data to this article can be found online at https://doi.org/10.1016/j.contraception.2017.12.015.

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References

[1] Chan LM, Westhoff CL. Tubal sterilization trends in the United States. Fertil Steril 2010;94:1–6.
[2] Daniels K, Daugherty J, Jones J. Current contraceptive status among women aged 15–44: United States, 2011–2013. NCHS Data Brief 2014:1–8.
[3] Perkins RB, Morgan JR, Awosogba TP, Ramanadhan S, Paasche-Orlow MK. Gynecologic outcomes after hysteroscopic and laparoscopic sterilization procedures. Obstet Gynecol 2016;128:843–52.
[4] Conover MM, Howell JO, Wu JM, Kinlaw AC, Dasgupta N, Jonsson Funk M. Incidence of opioid-managed pelvic pain after hysteroscopic sterilization versus laparoscopic sterilization, US 2005–2012. Pharmacoepidemiol Drug Saf 2015; 24:875–84.
[5] Yunker AC, Ritch JM, Robinson EF, Golish CT. Incidence and risk factors for chronic pelvic pain after hysteroscopic sterilization. J Minim Invasive Gynecol 2015;22: 390–4.
[6] Borrero S, Schwarz EB, Reeves MF, Bost JE, Creinin MD, Ibrahim SA. Race, insurance status, and tubal sterilization. Obstet Gynecol 2007;109:94–100.
[7] DeNoble AE, Hall K, Xu X, Zochowski MK, Piehl K, Dalton VK. Receipt of prescription contraception by commercially insured women with chronic medical conditions. Obstet Gynecol 2014;123:1213–20.
[8] Carney PI, Lin J, Xia F, Law A. Temporal trend in the use of hysteroscopic vs. laparoscopic sterilization and the characteristics of commercially insured and Medicaid-insured females in the US who have had the procedures. Int J Womens Health 2016;8:137–44.
[9] Adelman MR, Dassel MW, Sharp HT. Management of complications encountered with Essure hysteroscopic sterilization: a systematic review. J Minim Invasive Gynecol 2014;21:733–43.
[10] Chudnoff SG, Nichols Jr JE, Levie M. Hysteroscopic Essure inserts for permanent contraception: extended follow-up results of a phase III multicenter international study. J Minim Invasive Gynecol 2015;22:951–60.
[11] Mao J, Pfeifer S, Schlegel P, Sedrakyan A. Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study. BMJ 2015;351:h5162.
[12] U.S. Department of Health and Human Services HRaSA. Women's health USA 2013. In Rockville, MA: U.S. Department of Health and Human Services; 2013.
[13] Liu Z, Doan QV, Blumenthal P, Dubois RW. A systematic review evaluating health-related quality of life, work impairment, and health-care costs and utilization in abnormal uterine bleeding. Value Health 2007;10:183–94.
[14] Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH, et al. The community prevalence of chronic pelvic pain in women and associated illness behaviour. Br J Gen Pract 2001;51:541–7.
[15] Llanos K, Palmer L. Using data on race and ethnicity to improve health care quality for Medicaid beneficiaries. Centers for health care strategies issue brief; 2006.