ORIGINAL RESEARCH

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

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Purpose: Limited research has examined the factors associated with female permanent contraception procedures. This study evaluated the temporal trend in the use of hysteroscopic sterilization (HS) vs laparoscopic sterilization (LS) and characteristics of commercially insured and Medicaid-insured women in the US who have had the procedures.

Methods: Women aged 15–49 years with claims for HS and LS procedures were identified from two MarketScan databases, one consisting of commercial claims and the other Medicaid claims, during the time period of January 1, 2003 to December 31, 2012 and January 1, 2006 to December 31, 2011, respectively. Proportions and characteristics of women who underwent HS or LS procedures were determined. Multivariable logistic regressions were used to identify characteristics associated with the use of HS vs LS.

Results: Commercially insured women who had HS (n=32,012) vs LS (n=64,725) were slightly older (37.2 years vs 36.4 years, respectively, $P<0.001$) but had similar Charlson Comorbidity Index scores. Among commercially insured women, those who had a sterilization procedure during 2008–2012 were more likely to undergo HS (odds ratio: 7.1, $P<0.001$) than those who had a sterilization procedure during 2003–2007. Medicaid-insured women who had HS (n=2,001) were also slightly older than women who had LS (n=12,523; 30.1 years vs 28.8 years, respectively, $P<0.001$) but had a higher mean Charlson Comorbidity Index score (0.32 vs 0.25, respectively, $P<0.001$). Among Medicaid-insured women, the likelihood of having HS vs LS increased 3.3-fold ($P<0.001$) in years 2009–2011 compared to years 2006–2008. Among both populations, older age, obesity, and the use of oral contraceptives within the previous 12 months were associated with having HS vs LS.

Conclusion: Among both commercially insured and Medicaid-insured women, the likelihood of having HS vs LS increased over time.

Keywords: contraception procedures, hysteroscopic sterilization, laparoscopic sterilization

Introduction

Female sterilization is the second most common contraceptive method used in the US, with 15.5% of women aged 15–44 years having used this method during years 2011–2013.[1] Female permanent birth control methods performed as interval procedures (ie, any time remote from delivery) include laparoscopic sterilization (LS) and hysteroscopic sterilization (HS). LS involves one or two abdominal wall skin incisions followed by the insertion of a laparoscope into the peritoneal cavity, insufflation of the cavity with carbon dioxide, and ligation of the fallopian tubes.[2] The procedure generally

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requires use of general anesthesia.[2] In November 2002, a hysteroscopic method of female sterilization, the Essure system (Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ, USA), was approved by the US Food and Drug Administration (FDA) in the US for permanent birth control.[3] The Essure procedure is a nonincisional method of female sterilization, which involves the insertion of a 4 cm long implant into each fallopian tube via hysteroscopy.[3,4] The implant consists of a flexible Nitinol (nickel–titanium alloy) outer coil that anchors the device in the fallopian tube and an inner coil containing polyethylene terephthalate fibers.[4] The polyethylene terephthalate fibers induce benign tissue in-growth that permanently occludes the fallopian tubes.[4] This process occurs over the course of 3 months, and an alternative contraception method must be used in the interim.[3] An Essure Confirmation Test (a modified hysterosalpingogram) is performed at 3 months to confirm appropriate location of the devices and occlusion of the tubes.[3]

A second hysteroscopically placed device, Adiana (Hologic, Inc., Bedford, MA, USA), was approved by the FDA in 2009.[5] Adiana achieves tubal occlusion by tissue in-growth into a silicone matrix placed bilaterally within the fallopian tubes.[5] After the application of radiofrequency energy inside the fallopian tubes, the silicone matrix is deployed into the tubal lumen where the lesion was formed.[5] The endothelial damage caused by the radiofrequency energy encourages a tissue in-growth response primarily consisting of fibroblasts infiltrating the porous structure of the silicone matrix, thereby resulting in occlusion in ~3 months.[5] As with Essure, alternative contraception must be used until bilateral tubal occlusion is confirmed by a hysterosalpingogram confirmation test.[5] Adiana was discontinued from the market in 2012 due to financial reasons.[6] In contrast to laparoscopic methods, HS avoids entry into the peritoneal cavity.[3,4] The procedure does not require use of general anesthesia and may be performed in an outpatient setting.[3,4] The hysteroscopic approach avoids the major morbidity associated with general anesthesia and abdominal surgery.[7] LS, on the other hand, does not require interim contraception for 3 months or a confirmation test.

A US study reported that the annual number of tubal sterilizations declined between 1995 and 2006, and the decline may be attributed to demographic, economic, social, and cultural factors.[8] This study and others have reported that certain characteristics are associated with a greater likelihood of undergoing sterilization procedures.[8,9] These include race (eg, more African American than Caucasian women undergo sterilization), insurance status (eg, more women with no or public insurance than women with private insurance

undergo sterilization), and other factors such as education level, parity, and poverty level.[8,9] Despite the availability of these permanent female contraception procedures for over 10 years, there is a lack of information on the characteristics of women who have HS vs LS. Therefore, the objectives of this study were to evaluate the temporal trend in the use of HS vs LS and the characteristics of women in the US who had the procedures from two large claims databases.

Methods
Study populations
Data of women aged 15–49 years with inpatient or outpatient claims for HS and LS procedures, identified by Current Procedural Terminology codes, were extracted from two Truven Health claims databases (Truven Health Analytics, Ann Arbor, MI, USA), the MarketScan Commercial and Medicaid claims databases during the time period of January 1, 2003, to December 31, 2012, and January 1, 2006, to December 31, 2011, respectively. The MarketScan commercial database encompasses >60 million employees, spouses, and dependents located in all ten US census regions and consists of health care claims data from >100 different insurance companies. The MarketScan Medicaid database pools claims from >36 million Medicaid enrollees from eleven geographically dispersed states. Claims from these databases consist of inpatient and outpatient information, fully integrated health and productivity data, and laboratory data, reflecting treatment patterns and costs in routine clinical practice. The databases facilitate longitudinal studies by providing integrated, standardized, data spanning, extensive time periods and have been used for the analysis of contraceptive use patterns in prior studies.[10–12] In compliance with the Health Insurance Portability and Accountability Act of 1996, the databases consist of fully deidentified data sets, with synthetic identifiers applied to patient-level and provider-level data to protect the identities of both the patients and data contributors. This study was exempt from internal review board oversight in accordance with the Department of Health and Human Services Policy for Protection of Human Research Subjects (45 CFR §46.101(b)(4)).

The study was carried out using these two databases to provide a more comprehensive evaluation of the use of HS and LS among these different study populations. Given the differences in methodology and available data contents, it is not possible to combine information from the two databases. The different timelines are due to the fact that the databases have different data availability. As the data included years 2009–2012, both Adiana and Essure HS procedures could

have been used during these years. Women were required to have 12 months of continuous health and prescription drug coverage prior to the date of the sterilization procedure (index event). Women were excluded if they had another sterilization procedure in the 12 months prior to the index event or if they had a pregnancy or delivery claim within 6 weeks prior to the index event in order to limit the analysis to just the interval procedures.

Measurements

The proportions of women who received HS and LS were determined from the commercially insured and Medicaid-insured study populations separately, as well as stratified by year of index event. Demographics and clinical characteristics, including age, health plan type, US geographic region (commercially insured population only), race (Medicaid-insured population only), prior oral contraceptive use during the 12-month preindex time period, and most recently used prescription contraceptive type prior to sterilization procedure, were evaluated for each study cohort within the study populations. Charlson Comorbidity Index (CCI) scores, which are predictive of 1-year mortality based on a range of comorbid conditions (myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, rheumatologic disease, peptic ulcer disease, mild liver disease, diabetes, hemiplegia, renal disease, diabetes with end organ damage, tumor without metastasis, leukemia, lymphoma, moderate or severe liver disease, metastatic solid tumor, and acquired immune deficiency syndrome),[13] were determined for each woman in the study cohorts as a measure of general comorbidity. Additionally, the proportions of women who had inflammatory bowel disease, asthma, hypothyroidism, obesity, rheumatoid arthritis, diabetes, hypertension, and systemic lupus erythematosus, which were identified by the International Classification of Diseases, Ninth Revision, Clinical Modification Codes, were determined. These chronic conditions were previously examined by DeNoble et al[14] because of their prevalence in reproductive-aged women.

Statistical analyses

For study cohorts, Student's *t*-tests were used to compare differences in age and CCI scores. Other measured demographics and clinical characteristics, along with year groups, were described using descriptive statistics. Logistics regressions were used to identify characteristics of women associated with different likelihoods of having HS vs LS procedures in the two study populations separately. All statistical analyses were carried out using SAS (SAS Institute Inc., Cary, NC, USA).

Results

Study populations

Figure 1 shows the process of selection of women included in the study cohorts. Demographics of cohorts within the commercially insured study population are listed in Table 1. Among the commercially insured study population, 32,012 had HS and 64,725 had LS. Women who had HS vs LS were slightly older (37.2 years vs 36.4 years, respectively, *P*<0.001). The use of HS increased among women over time from 9.7% in years 2003–2007 to 42.9% in years 2008–2012, while the use of LS decreased over time from 90.3% in years 2003–2007 to 57.1% in years 2008–2012.

Demographics of cohorts within the Medicaid-insured study population are listed in Table 2. Among the Medicaid insured study population, 2,001 had HS and 12,523 had LS. Women who had HS vs LS were also slightly older (30.1 years vs 28.8 years, *P*<0.001). Greater proportions of black women (16.4%) and Hispanic women (21.4%) had HS in comparison to white women (11.3%). The use of HS increased among women over time from 7.1% in years 2006–2008 to 20.6% in years 2009–2011, while the use of LS decreased over time from 92.9% in years 2006–2008 to 79.4% in years 2009–2011.

Clinical characteristics of study populations

Clinical characteristics of both study populations are listed in Table 3. In the commercially insured study population, fewer women in the HS group used prescription contraception in the 12 months prior to sterilization than did women who had LS (38.9% vs 55.5%, respectively). No information on nonprescription contraceptive methods is available. The most common type of prescription contraception most recently used prior to having either HS or LS was oral contraceptives (33%–39%). The mean CCI scores of women who had HS and of women who had LS did not significantly differ. Of the chronic conditions evaluated, the most prevalent for both study cohorts within the commercially insured study population were hypertension, hypothyroidism, asthma, and obesity.

Among the Medicaid-insured study population, the proportion of women not using any prescription contraception during the 12 months prior to having a sterilization procedure was smaller for women who had HS than those who had LS (33.9% vs 54.4%). Among women who had HS, the most
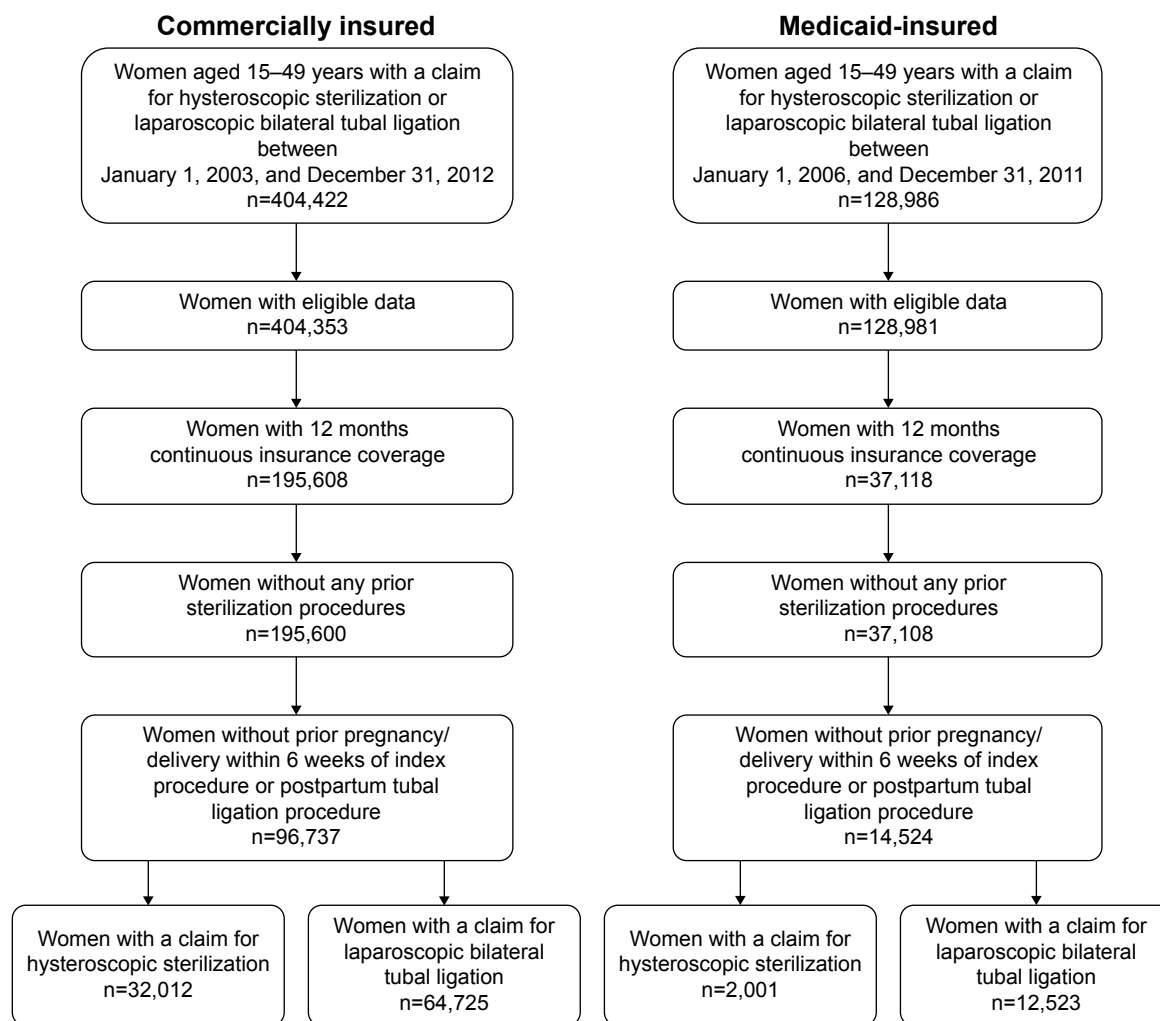
Commercially insured

Women aged 15–49 years with a claim for hysteroscopic sterilization or laparoscopic bilateral tubal ligation between
January 1, 2003, and December 31, 2012
n=404,422

↓

Women with eligible data
n=404,353

↓

Women with 12 months continuous insurance coverage
n=195,608

↓

Women without any prior sterilization procedures
n=195,600

↓

Women without prior pregnancy/ delivery within 6 weeks of index procedure or postpartum tubal ligation procedure
n=96,737

↓

Women with a claim for hysteroscopic sterilization
n=32,012

Women with a claim for laparoscopic bilateral tubal ligation
n=64,725

Medicaid-insured

Women aged 15–49 years with a claim for hysteroscopic sterilization or laparoscopic bilateral tubal ligation between
January 1, 2006, and December 31, 2011
n=128,986

↓

Women with eligible data
n=128,981

↓

Women with 12 months continuous insurance coverage
n=37,118

↓

Women without any prior sterilization procedures
n=37,108

↓

Women without prior pregnancy/ delivery within 6 weeks of index procedure or postpartum tubal ligation procedure
n=14,524

↓

Women with a claim for hysteroscopic sterilization
n=2,001

Women with a claim for laparoscopic bilateral tubal ligation
n=12,523

Figure 1 A patient flow diagram of the selection of women in the commercially insured and Medicaid-insured study populations.

common type of prescription contraception most recently used prior to having HS was injectable contraceptives (37.3%), and for women who had LS, it was oral contraceptives (22.2%). The mean CCI score of women who had HS was significantly higher than that for women who had LS (0.32 vs 0.25, $P<0.001$). Except for rheumatoid arthritis, the evaluated chronic conditions were more prevalent among women who had HS than women who had LS. The proportion of women who were obese in the HS cohort was twice that of women in the LS cohort (15.6% vs 7.4%).

Differences in characteristics of women having HS vs LS

Results of the logistic regression of the characteristics of women having HS vs LS in the commercially insured study population are presented in Table 4. Women who had a sterilization procedure during years 2008–2012 were more likely to undergo HS (odds ratio [OR]: 7.1, $P<0.001$)

than those who had it during years 2003–2007. Older age was associated with a slightly greater likelihood of having HS (OR: 1.03, $P<0.001$). Women in the Northeast were less likely to use HS than women in other US regions (all $P<0.001$). Compared to women in a comprehensive health plan, women with other health plans (eg, exclusive provider organization and consumer-driven health plans) were more likely to use HS (all $P<0.001$), with the exception of women in a point-of-service plan with capitation. Obesity (OR: 1.08, $P=0.03$) was associated with a greater likelihood of using HS, while chronic conditions of asthma (OR: 0.89, $P<0.001$) and hypertension (OR: 0.82, $P<0.001$) were associated with lower likelihoods of using HS. Women with oral contraceptive use during the 12-month preindex period (OR: 1.53, $P<0.001$) were more likely to use HS.

Characteristics of women having HS vs LS for the Medicaid-insured study population are presented in Table 5. The likelihood of using HS in years 2009–2011 increased

Table 1 Demographics of study cohorts within commercially insured study population

	HS		LS	
	n		n	
Total, n	32,012		64,725	
Age (years), mean (SD)[a]	37.2 (5.7)		36.4 (6.0)	
	n	%	n	%
Age group (years)				
15–19	9	0.03	64	0.1
20–24	370	1.2	1,643	2.5
25–29	2,848	8.9	7,331	11.3
30–34	7,098	22.2	15,010	23.2
35–39	10,029	31.3	19,516	30.2
40–44	8,392	26.2	15,560	24.0
45–49	3,266	10.2	5,601	8.7
US region of residence				
Northeast	2,801	8.8	6,577	10.2
North Central	8,792	27.5	15,541	24.0
South	15,063	47.1	31,630	48.9
West	5,139	16.1	10,432	16.1
Unknown	217	0.7	545	0.8
Health plan type				
Missing/unknown	968	3.0	1,826	2.8
Comprehensive	291	0.9	1,442	2.2
EPO	570	1.8	739	1.1
HMO	6,432	20.1	14,003	21.6
POS	3,003	9.4	7,432	11.5
PPO	18,757	58.6	36,251	56.0
POS with capitation	165	0.5	800	1.2
CDHP	1,279	4.0	1,588	2.5
HDHP	547	1.7	644	1.0
Women with sterilization procedure in study years				
2003	0	0.0	3,757	100.0
2004	0	0.0	5,521	100.0
2005	462	6.6	6,491	93.4
2006	887	14.4	5,264	85.6
2007	1,413	23.0	4,727	77.0
2008	2,837	31.9	6,070	68.1
2009	5,311	40.7	7,732	59.3
2010	6,306	45.2	7,630	54.8
2011	7,367	46.9	8,329	53.1
2012	7,429	44.7	9,204	55.3
Index year group				
2003–2007	2,762	8.6	25,760	39.8
2008–2012	29,250	91.4	38,965	60.2

Note: [a]$P<0.001$.
Abbreviations: HS, hysteroscopic sterilization; LS, laparoscopic sterilization; EPO, exclusive provider organization; HMO, health maintenance organization; POS, point of service; PPO, preferred provider organization; CDHP, consumer-driven health plan; HDHP, high deductible health plan.

Table 2 Demographics of study cohorts within Medicaid-insured study population

	HS		LS	
	n		n	
Total, n	2,001		12,523	
Age (years), mean (SD)[a]	30.1 (5.8)		28.8 (5.7)	
	n	%	n	%
Age group (years)				
15–19	0	0	2	0.02
20–24	371	18.5	3,188	25.5
25–29	681	34.0	4,570	36.5
30–34	483	24.1	2,638	21.1
35–39	316	15.8	1,419	11.3
40–44	118	5.9	572	4.6
45–49	32	1.6	134	1.1
Race				
White	1,004	50.2	7,911	63.2
Black	736	36.8	3,758	30.0
Hispanic	79	4.0	290	2.3
Other	182	9.1	564	4.5
Women with sterilization procedure in study years				
2006	207	5.1	3,870	94.9
2007	130	7.9	1,526	92.1
2008	179	11.3	1,402	88.7
2009	371	18.5	1,638	81.5
2010	546	20.7	2,087	79.3
2011	568	22.1	2,000	77.9
Index year group				
2006–2008	516	25.8	6,798	54.3
2009–2011	1,485	74.2	5,725	45.7

Note: [a]$P<0.001$.
Abbreviations: HS, hysteroscopic sterilization; LS, laparoscopic sterilization.

Discussion

In both the commercially- and Medicaid-insured study populations, the use of HS vs LS as an interval sterilization procedure increased over time. Among women who were commercially insured, the use of HS vs LS increased approximately 7-fold from years 2003–2007 to years 2008–2012. The increase was 3.3-fold from years 2006–2008 to years 2009–2011 among Medicaid-insured women. These findings are similar to those observed in a study of women who underwent interval and postpartum sterilization procedures at the Detroit Medical Center between 2002 and 2007, in which the use of Essure HS increased 51%.[15] Among both commercially insured and Medicaid-insured study populations, in comparison to women who had LS, fewer women who had HS were not using any prescription contraception method in the 12 months prior to the procedure. Additionally, the use of oral contraceptives during the 12-month preindex period was associated with a greater likelihood of having HS vs LS for both study populations. Among Medicaid-insured women, women who had HS were more likely to have used injectable contraception most recent to the procedure than

3.3-fold ($P<0.001$) compared to years 2006–2008. Obesity (OR: 1.73, $P<0.001$) and hypertension (OR: 1.18, $P=0.03$) were associated with greater likelihoods of HS use. Additionally, age (OR: 1.03, $P<0.001$), race (black vs white, OR: 1.48, $P<0.001$; Hispanic vs white, OR: 1.58, $P<0.001$; other race vs white, OR: 2.50, $P<0.001$), and having had prior oral contraceptive use (OR: 1.42, $P<0.001$) were all associated with greater likelihoods of using HS vs LS.

Table 3 Clinical characteristics of study cohorts within commercially insured and Medicaid-insured study populations

	Commercially insured				Medicaid-insured			
	HS		LS		HS		LS	
Total, n	32,012		64,725		2,001		12,523	
CCI score, mean (SD)	0.18 (0.6)		0.18 (0.5)		0.32 (0.8)[a]		0.25 (0.7)[a]	
	n	%	n	%	n	%	n	%
Most recent contraceptive type								
None	12,448	38.9	35,890	55.5	679	33.9	6,817	54.4
IUS	1,084	3.4	2,304	3.6	51	2.6	416	3.3
Implant	47	0.2	95	0.2	14	0.7	87	0.7
Injectable	4,994	15.6	2,787	4.3	746	37.3	1,660	13.3
Patch	289	0.9	1,376	2.1	20	1.0	393	3.1
Oral contraceptive	12,363	38.6	21,062	32.5	458	22.9	2,780	22.2
Ring	787	2.5	1,211	1.9	33	1.7	370	3.0
Prior OC use	13,658	42.7	21,901	33.8	588	29.4	3,097	24.7
Chronic conditions								
IBD	190	0.6	354	0.6	5	0.3	29	0.2
Asthma	1,499	4.7	3,008	4.7	195	9.8	1,033	8.3
Hypothyroidism	2,442	7.6	4,515	7.0	84	4.2	426	3.4
Obesity	1,660	5.2	2,643	4.1	312	15.6	932	7.4
Rheumatoid arthritis	256	0.8	491	0.8	9	0.5	69	0.6
Diabetes	1,187	3.7	2,154	3.3	105	5.3	545	4.4
Hypertension	3,468	10.8	7,451	11.5	293	14.6	1,217	9.7
Systemic lupus erythematosus	125	0.4	296	0.5	14	0.7	43	0.3
Any of the chronic conditions	8,497	26.5	16,850	26.0	710	35.5	3,261	26.0

Note: [a]$P<0.001$.
Abbreviations: HS, hysteroscopic sterilization; LS, laparoscopic sterilization; CCI, Charlson Comorbidity Index; IUS, intrauterine system; OC, oral contraceptive; IBD, inflammatory bowel disease.

Table 4 Differences in characteristics of commercially insured women having HS vs LS

Variables	OR	95% wald confidence limits		P-value
		Lower	Upper	
Age	1.03	1.03	1.03	<0.001
Regions vs Northeast				
North Central	1.46	1.38	1.55	<0.001
South	1.24	1.17	1.31	<0.001
West	1.33	1.25	1.42	<0.001
Unknown	0.80	0.67	0.95	<0.01
Health plan vs comprehensive				
Exclusive provider organization	1.73	1.45	2.06	<0.001
Health maintenance organization	1.63	1.41	1.87	<0.001
Point of service	1.50	1.30	1.73	<0.001
Preferred provider organization	1.42	1.23	1.62	<0.001
Consumer-driven health plan	1.66	1.42	1.93	<0.001
High deductible health plan	1.62	1.36	1.94	<0.001
Index year group 2008–2012 vs 2003–2007	7.10	6.80	7.42	<0.001
Chronic conditions: yes vs no				
Asthma	0.89	0.83	0.95	<0.001
Obesity	1.08	1.01	1.15	0.03
Hypertension	0.82	0.78	0.86	<0.001
Prior oral contraceptive use	1.53	1.49	1.58	<0.001

Abbreviations: HS, hysteroscopic sterilization; LS, laparoscopic sterilization; OR, odds ratio.

women who had LS (37.3% vs 13.3%), which may be related to the need for 3 months of contraception after the procedure. The use of prescription contraception requires an encounter with a health care professional. It is therefore possible that women who underwent HS had more health care encounters in the year prior to their sterilization procedure. This may have influenced the selection of HS vs LS. A recent survey study found that among women who received factual information from a nurse about Essure HS and LS procedures, the majority (93%) chose Essure HS over LS.[16] The primary reasons for choosing Essure HS over LS by women who took this survey were cost, fear of incision, and general anesthesia.[16]

Among both commercially insured and Medicaid-insured women, older age was associated with a slightly greater likelihood of having HS than LS; although, it is not likely to be clinically significant. In this study, we did observe that among both commercially insured and Medicaid-insured women, obesity was associated with a greater likelihood of having HS than LS. The association of obesity with having HS vs LS was more prominent among Medicaid-insured women than commercially insured women, which may be related to the higher prevalence of obesity among Medicaid-insured women. Among Medicaid-insured women, women

Table 5 Differences in characteristics of Medicaid-insured women having HS vs LS

Variables	OR	95% wald confidence limits		P-value
		Lower	Upper	
Age	1.03	1.02	1.04	<0.001
Race vs white				
Black	1.48	1.33	1.65	<0.001
Hispanic	1.58	1.21	2.06	<0.001
Other	2.50	2.07	3.03	<0.001
Index year group 2009–2011 vs 2006–2008	3.3	2.95	3.66	<0.001
Chronic conditions: yes vs no				
Obesity	1.73	1.49	2.00	<0.001
Hypertension	1.18	1.01	1.37	0.03
Prior oral contraceptive use	1.42	1.28	1.59	<0.001

Abbreviations: HS, hysteroscopic sterilization; LS, laparoscopic sterilization; OR, odds ratio.

who had HS had higher comorbidity severity than those who had LS, as measured by the CCI score. It is unknown if this finding is related to a desire to avoid peritoneal entry and general anesthesia in women with higher risk factors. It will be interesting in a future study to examine the impact of chronic conditions on the use of HS vs LS now that the Affordable Care Act has mandated complete coverage for the full range of FDA approved contraceptive methods, including interval sterilization procedures.

Education and increasing the availability of contraceptive methods are of great importance, as the National Survey of Family Growth (NSFG) reports that the unintended pregnancy rate is ~50% in the US.[17] A secondary analysis of the NSFG 2006–2010 data on the use of family planning services found that in adult women, 21–45 years old, who conceived between 2006 and 2010, 41% of pregnancies were unintended. Of these unintended pregnancies, 40% occurred in women who had decided that they were finished with childbearing.[18] Choice of contraceptive may help explain this finding. The NSFG data show that in sexually active women who stated that they were finished with childbearing, 56% were using permanent contraception methods; however, 36% were using nonpermanent methods (eg, oral contraceptives, condoms, intrauterine devices, timed intercourse) and 8% were not using any contraception method.[18] This indicates that a large proportion of women who have completed childbearing remain at risk for unintended pregnancy. Although, in comparison to women using other nonpermanent methods, those using intrauterine devices have a much lower risk (0.1%–0.8% first-year failure rate) for unintended pregnancy, which is comparable to the efficacy of HS (0.7%)[3] and LS methods (0.5%–0.7%).[19]

Limitations and strengths of the study

The MarketScan claims databases consist of claims submitted by health care providers for reimbursement, and such claims are subject to possible coding errors. Since the databases are based on large samples, the samples are not random and may fail to generalize well to other populations. There is a lag in data availability for the Medicaid and commercial databases, such that at the time of this study, data were not available for women beyond years 2011 and 2012, respectively. Additionally, due to privacy consideration, the Medicaid database does not allow for the identification of which states were included. As there is variability in the access to sterilization procedures in certain states, this may have had an effect on the characteristics of women who had the different sterilization procedures. A few studies have been conducted on small populations of women who underwent Essure HS or LS;[15,16] however, this study is the first to evaluate the use of HS vs LS among large populations of women with different insurance types, demographics, and clinical characteristics. By design, this study was useful for differentiating certain characteristics of commercially insured and Medicaid-insured women who had HS vs LS, which will likely be informative for health care providers and payers in the US. Although, due to limitations of the databases (eg, Medicaid database does not include data from specific states), the results may not be generalizable to the entire US populations of women with either commercial insurance or coverage by Medicaid. Furthermore, the claims data within the databases does not contain information regarding counseling on the procedures, and this study did not yield data regarding whether women were offered a choice in the two different sterilization procedures.

Conclusion

The use of HS as an interval sterilization method has substantially increased among both commercially insured and Medicaid-insured women. For many, HS is an alternative permanent contraception method that does not require general anesthesia or entry into the peritoneal cavity and can be done in an outpatient setting.

Acknowledgments

Author contributions

PC, JL, FX, and AL participated in the design of the study, data analysis and interpretation, drafting and critically revising the paper and agree to be accountable for all aspects of the work. All authors read and approved the final manuscript.

Disclosure

PC, AL, and FX are employees of Bayer HealthCare Pharmaceuticals Inc. JL is an employee of Novosys Health and served as a paid consultant to Bayer HealthCare Pharmaceuticals Inc. for the development of this study and manuscript. The authors report no other conflicts of interest in this work.

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