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ORIGINAL RESEARCH

Retrospective database analysis of clinical outcomes and costs for treatment of abnormal uterine bleeding among women enrolled in US Medicaid programs

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Background: Women with abnormal uterine bleeding (AUB) may be treated surgically with hysterectomy or global endometrial ablation (GEA), an outpatient procedure. We compared the costs and clinical outcomes of these surgical procedures for AUB among women in Medicaid programs.

Methods: The Truven Health MarketScan® Medicaid Multi-State Database was used to identify Medicaid women aged 30–55 years with AUB who newly initiated GEA or hysterectomy (index event) during 2006–2010. Patients were required to have 12 months of continuous enrollment pre-index and post-index. Baseline characteristics were assessed in the pre-index period; health care utilization and costs (2011 USD), treatment complications, and reinterventions were assessed in the post-index period.

Results: Of 1,880 women who met the study criteria (mean age 40.7 years), 53.4% were Caucasian, 33.1% were African-American, and 2.3% were Hispanic; many (42.8%) received their Medicaid eligibility due to disability. Similar proportions received GEA (50.9%) or hysterectomy (49.1%). At baseline, both groups also had similar Deyo-Charlson Comorbidity scores (0.65), and use of antibiotics (69.4%), nonsteroidal anti-inflammatory drugs (56.3%), and oral contraceptives (5.3%). More hysterectomy patients than GEA patients had a treatment-related complication (52% versus 36%, respectively, $P<0.001$). Initial treatment costs were higher for hysterectomy ($11,270) than for GEA ($3,958, $P<0.001$); monthly gynecology-related costs in the remainder of the year were not significantly different for hysterectomy ($63) and GEA ($16, $P=0.11$).

Conclusion: Hysterectomy was nearly three times more costly than GEA for initial treatment of AUB, and associated with more treatment-related complications. These results may be informative in the context of new federal mandates for Medicaid expansion, which are likely to focus on cost savings through use of outpatient treatments such as GEA.

Keywords: abnormal uterine bleeding, menorrhagia, endometrial ablation, hysterectomy, Medicaid

Introduction

Approximately one-third of women will be affected by heavy or abnormal uterine bleeding (AUB) at some time in their lives.[1] AUB risk factors include age, premenopausal leiomyomata, and endometrial polyps, and AUB is a presenting symptom for the majority of women who undergo a hysterectomy.[2–4] AUB significantly diminishes quality of life, despite the fact that serious complications are rare.[5] A common result of AUB is anemia,

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which can cause weakness, fatigue, unexplained weight loss, mood swings, and impaired cognitive functioning.[5]

AUB treatment can be pharmacological and/or surgical. Options for surgical treatment include hysterectomy, myomectomy, uterine artery embolization, first-generation endometrial ablation methods (including rollerball or laser ablation and transcervical resection of endometrium), and second-generation global endometrial ablation (GEA) methods (including laser intrauterine thermotherapy, cryoablation, and microwave, thermal balloon, or radiofrequency ablation). First-generation endometrial ablation methods require hysteroscopy to improve visualization and require general or regional anesthesia.[4] Second-generation methods can be performed in an outpatient office setting under local anesthesia, without the use of a hysteroscope, and require minimal cervical dilation; they are faster and less technically demanding.[4] Both endometrial ablation and hysterectomy are effective, and are becoming more commonly used as first-line treatment. The choice between them is currently an informed tradeoff, with endometrial ablation methods having high patient satisfaction and a low complication rate, but sometimes requiring reintervention.[4] Surgical treatment with hysterectomy is both effective and permanent, but hysterectomy has greater morbidity and may have higher costs.[4,6]

The cost of these treatments is becoming a larger factor in their selection. As an outpatient treatment, GEA may be viewed as a lower-cost alternative to hysterectomy by insurers such as Medicaid, which currently insures about 12% of US women aged 18–64 years.[7] Medicaid expansion under new federal mandates is expected to extend eligibility to an additional 7 million currently uninsured women aged 19–64 years. Treatment decisions for Medicaid-insured women with AUB will require data on the costs of surgical therapies in this population.

The objective of this study is to describe AUB treatment patterns among women enrolled in Medicaid, and compare the direct health care costs of treating AUB with hysterectomy or with GEA.

Materials and methods

Data source

The study sample was selected from the Truven Health MarketScan® Multi-State Medicaid Database. The database includes the medical, surgical, and prescription drug experience of nearly 31 million de-identified Medicaid enrollees from multiple states, including records of inpatient services, inpatient admissions, outpatient services, and prescription drug claims, as well as information on long-term care and other medical care. All database records are de-identified and fully compliant with US patient confidentiality requirements, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Study population

A cohort of women who underwent GEA or hysterectomy (index event) for the treatment of AUB between January 1, 2006, and December 31, 2010 were identified in the database. Patients were selected using the following inclusion criteria: at least two claims on different dates with a diagnosis of AUB (ICD-9-CM codes 626.2x, 626.4x, 626.6x, 626.8x or 627.0x) in the 12 months prior to the index event, with at least one diagnosis specific to heavy or excessive bleeding (ICD-9-CM codes 626.2x or 627.0x); aged 30–55 years on the index date; and at least 12 months of continuous health plan enrollment prior to (pre-index period) and following (post-index period) the index event. Exclusion criteria included: diagnosis of menopause prior to the index date; diagnosis of a primary cancer at any time during the study period; hysterectomy or removal of a levonorgestrel-releasing intrauterine device during the pre-index period; and indication of pregnancy or delivery in the 90 days prior to the index date.

Analyses

Health insurance claims (medical and prescription drug) for the 12-month pre-index and post-index periods were evaluated for all patients who met the study selection criteria. Records were examined to assess baseline demographic characteristics and pre-index clinical characteristics, as listed in Table 1, including the Deyo-Charlson Comorbidity index.[8]

Intervention-related costs were defined as treatment-related costs as well as the cost of complications and medical care and costs in the 30 days following index; subsequent gynecological health care utilization and costs were captured for the remainder of the 12-month post-index period. Health care costs were taken directly from the paid amount on fully adjudicated claims and included both the insurer and Medicaid payment portions. Health care costs were adjusted to 2011 dollars using the medical care component of the Consumer Price Index.[9]

Treatment-related complications were defined as the presence of any of the following events: cervical occlusion, cervical trauma (including cervical lacerations and hematometra), uterine perforation, bowel perforation, fluid overload, pyometra, and device complications; a second AUB treatment within 30 days; or an inpatient stay or emergency room visit within 2 days of the index procedure (excluding patients with an inpatient index event). For GEA patients, reintervention was defined as the presence of either a second

Table 1 Baseline demographic and clinical characteristics

	GEA		Hysterectomy		*P*-value
	N=957		N=923		
Age (mean, SD)	40.2	5.6	41.2	5.4	<0.001
Age group (N, %)					
30–34	180	18.8%	112	12.1%	<0.001
35–39	272	28.4%	234	25.4%	
40–44	266	27.8%	294	31.9%	
45–49	197	20.6%	231	25.0%	
50–55	42	4.4%	52	5.6%	
Insurance plan type (N, %)					
Comprehensive	428	44.7%	434	47.0%	0.030
Preferred/exclusive provider organization	3	0.3%	0	0.0%	
Point-of-service, with and without capitation	109	11.4%	135	14.6%	
Health maintenance organization	413	43.2%	352	38.1%	
Other and unknown	4	0.4%	2	0.2%	
Patient race (N, %)					
White	525	54.9%	479	51.9%	0.175
Black	297	31.0%	326	35.3%	
Hispanic	20	2.1%	23	2.5%	
Other and unknown	115	12.0%	95	10.3%	
Basis of eligibility status					
Disability	377	39.4%	428	46.4%	0.003
Income	526	55.0%	461	49.9%	
Other/unknown	54	5.6%	34	3.7%	
Charlson comorbidity index (CCI) (mean/SD)	0.69	1.18	0.62	1.08	0.223
Baseline diagnoses of interest (N, %)					
Endometriosis	26	2.7%	86	9.3%	<0.001
Uterine fibroid/polyps	254	26.5%	512	55.5%	<0.001
Anemia	261	27.3%	345	37.4%	<0.001
Depression	306	32.0%	289	31.3%	0.757
Thyroid disease	102	10.7%	105	11.4%	0.619
Medications of interest (N, %)					
Antibiotic use	663	69.3%	641	69.4%	0.937
Oral contraceptives	51	5.3%	48	5.2%	0.901
NSAIDs	530	55.4%	529	57.3%	0.399

Abbreviations: GEA, global endometrial ablation; SD, standard deviation; NSAIDs, nonsteroidal anti-inflammatory drugs.

GEA intervention or hysterectomy at least 30 days after the index event. Adjunctive pharmacotherapy was defined as the use of levonorgestrel-releasing intrauterine system, non-intrauterine system hormonal therapies, or tranexamic acid. Among GEA patients, adjunctive pharmacotherapy and reintervention were described for up to 3 years post-index for patients with available data. The costs of reintervention and adjunctive pharmacotherapy are included in the gynecology-related follow-up costs.

Standard statistical tests were used to compare patient characteristics and outcomes between GEA and hysterectomy patients. Chi-square tests were used for categorical measures and *t*-tests were used for continuous measures.

Results

A total of 1,880 AUB patients met the study inclusion and exclusion criteria. Just over half of these women (n=957) were treated with GEA, while the remainder (n=923) underwent hysterectomy. As shown in Table 1, the GEA cohort was slightly younger than the hysterectomy cohort (mean age 40.2 years versus 41.2 years, respectively, $P<0.001$). Approximately half of the study patients (53.4%) were Caucasian, 33.1% were African-American, and 2.3% were Hispanic. Patients were covered by network-based managed care plans (53.8%) or comprehensive health plans (45.9%). Compared with GEA, a larger proportion of hysterectomy patients received their Medicaid eligibility due to disability (46.4% versus 39.4%, $P=0.003$). Baseline mean Deyo-Charlson Comorbidity Index scores were slightly higher for GEA patients, but not significantly so (0.69 versus 0.62, $P=0.223$). Pre-index medication use was similar between the treatment cohorts; over half of the patients used a prescription nonsteroidal anti-inflammatory drug (56%) and nearly 70% used an antibiotic. Very few patients used

an oral contraceptive (5.3%) during the pre-index period. Hysterectomy patients were significantly more likely to have a diagnosis of uterine fibroids or polyps (55.5% versus 26.5%, $P<0.001$), anemia (37.4% versus 27.3%, $P<0.001$), or endometriosis (9.3% versus 2.7%, $P<0.001$). GEA and hysterectomy patients had a similar baseline prevalence of depression (approximately 32%) and thyroid disease (approximately 11%).

As shown in Table 2, the large majority (93%) of GEA procedures occurred in an outpatient setting, compared with 13% of hysterectomy procedures ($P<0.001$). Expenditures for the intervention and 30-day follow-up care were significantly higher for hysterectomy ($11,270) than for GEA ($3,958, $P<0.001$). Gynecology-related costs for the remainder of the year were also higher for hysterectomy than for GEA but not significantly so ($63 per month versus $16 per month, $P=0.111$). Gynecology-related costs in the remainder of the year were more likely to come from an outpatient setting than an inpatient setting for GEA patients (55% versus 45%), whereas for hysterectomy patients most costs were inpatient in nature (83% versus 17%). While hysterectomy patients were more likely to have a gynecology-related inpatient stay either at index or follow-up, the average length of stay among patients with a gynecology-related inpatient stay was similar between hysterectomy and GEA patients (2.6 versus 2.5 days, $P=0.74$).

More than half (52%) of hysterectomy patients had a treatment-related complication, compared with 36% of GEA patients ($P<0.001$). Women with complications after treatment had higher overall costs associated with treatments in both subgroups. Among GEA patients, patients with complications were 1.4 times more costly than GEA patients without complications, while hysterectomy patients with complications were 1.3 times more costly than other hysterectomy patients without complications.

Reintervention and adjunctive pharmacotherapy in the 3 years following GEA are reported in Table 3. Among the 957 GEA patients who met the study inclusion and exclusion criteria, 529 had 2 years of post-index continuous enrollment and 295 had 3years of post-index continuous enrollment. In the first year following GEA, 10.6% of GEA patients underwent reintervention; 9.4% underwent hysterectomy and 1.1% underwent a second GEA intervention. Reintervention with either hysterectomy or a second GEA was less common in the second (1.1% and 0.0%, respectively) and third year (2.7% and 2.4%). Adjunctive pharmacotherapy decreased over time, with 5.4% of patients using non-intrauterine system hormonal therapies in the first year, 1.1% in the second year, and 0.0% in the third year post-index.

Discussion

The current study describes AUB-related treatment and follow-up costs for Medicaid-enrolled women initiating either GEA or hysterectomy. The total direct costs for treatment and 30-day follow-up were lower for GEA ($3,958) than for hysterectomy ($11,270, $P<0.001$). GEA patients were also less likely to have treatment-related complications (36% versus 52%, $P<0.001$), which increased costs by 40% (30% in hysterectomy patients). These results suggest that GEA may be a cost-saving alternative to hysterectomy for AUB in the Medicaid population.

Table 2 Index intervention and complication characteristics

	GEA		Hysterectomy		*P*-value
	N=957		N=923		
Intervention procedure setting (N, %)					
Inpatient setting	65	6.8%	800	86.7%	<0.001
Outpatient setting	892	93.2%	123	13.3%	
Outpatient hospital surgical setting	814	85.1%	118	12.8%	
Outpatient ambulatory surgical setting (ASC)	14	1.5%	4	0.4%	
Outpatient office setting	61	6.4%	1	0.1%	
Other setting	3	0.3%	0	0.0%	
Intervention and 30 day follow-up costs (mean, SD)	$3,958	$4,276	$11,270	$11,702	<0.001
Monthly costs post-intervention (mean, SD)	$16	$104	$63	$910	0.111
Patients with complications in the 30 days post-index (mean, SD)	347	36.3%	478	51.8%	<0.001
Expenditures of patients with complications in days 1–30 post index	$4,839	$9,303	$12,615	$12,940	<0.001
Expenditures of patients without complications in days 1–30 post index	$3,457	$3,414	$9,825	$10,208	<0.001

Abbreviations: GEA, global endometrial ablation; SD, standard deviation.

Table 3 Reintervention and adjunctive pharmacotherapy

	Year 1		Year 2		Year 3	
	N=957		N=529		N=295	
	N	%	N	%	N	%
Reintervention (N, %)						
Second GEA	11	1.1%	0	0.0%	7	2.4%
Hysterectomy	90	9.4%	6	1.1%	8	2.7%
Adjuctive pharmacotherapy (N, %)						
Non-IUS hormonal therapies	52	5.4%	6	1.1%	0	0.0%
Tranexamic acid	0	0.0%	0	0.0%	0	0.0%
LNG-IUS	1	0.1%	0	0.0%	0	0.0%

Abbreviations: GEA, global endometrial ablation; LNG, levonorgestrel; IUS, intrauterine system.

Previous studies have suggested similar results in populations closely related to AUB.[10,11] In an analysis by Jensen et al, costs incurred by patients with heavy menstrual bleeding, a type of AUB, were compared with costs of patients without heavy menstrual bleeding. The average annual direct medical cost of patients with heavy menstrual bleeding was $5,816, which was $2,533 higher than for their matched controls.[11] After their first diagnosis of heavy menstrual bleeding, patients were followed for an average of 2.3 years. During that follow-up period, 27% did not receive any treatment for heavy menstrual bleeding. Of the 73% who did, 45% underwent uterine-preserving surgical procedures while 19% underwent hysterectomy. Previous studies have documented much higher costs for hysterectomy than for uterine-sparing procedures such as GEA. In an analysis of women with newly diagnosed heavy menstrual bleeding, the mean cost of a hysterectomy episode in women aged 35–39 years was $8,980, compared with $5,288 for ablation (these costs were $9,200 and $5,133 in women aged 40–49 years).[12] Similarly, a cost analysis of women undergoing treatment for uterine fibroids reported adjusted direct medical costs of $10,269 for hysterectomy and $7,303 for endometrial ablation in the year after the intervention.[13]

In our study, reintervention rates following GEA were more common in the first year, with 9.4% of GEA patients undergoing hysterectomy and 1.1% undergoing a second GEA intervention.

Reintervention with either hysterectomy or a second GEA was less common in the second (1.1% and 0.0%) and third year (2.7% and 2.4%). These reintervention rates are lower than previously reported estimates, which likely included more first-generation ablation techniques.[14] However, the current analysis was consistent with other studies in describing higher complication rates for hysterectomy than for GEA.[15] This current analysis also followed patients for up to 3 years post-intervention; however, only 2 and 3 years of follow-up were available on a subset of patients (55% and 31%, respectively) and it is unclear if these patients differed substantively from patients with shorter follow-up.

Implications for Medicaid expansion and affordable insurance exchanges

The results of this analysis may have broad implications in the context of current changes taking place in the Medicaid program. Specifically, these entail new federal mandates from the Patient Protection and Affordable Care Act (PPACA) for Medicaid expansion and the creation of state-based and federally-facilitated competitive marketplaces, or affordable insurance exchanges. The main goal of the PPACA is to provide a range of affordable insurance coverage options through Medicaid and the new exchanges to reduce the number of uninsured in the USA.[16,17] According to plan, the exchanges will achieve this goal by providing an opportunity for qualified individuals and small employers to evaluate and compare high-quality, affordable, and competitively priced private health plans.[18,19] These exchanges will offer a new pathway to insurance coverage for many adults, effectively increasing the number of patients with government-sponsored health insurance.[20]

With women comprising the majority (69%) of the adult Medicaid population,[21] changes in Medicaid will matter to the population of low-income women with AUB. Presently, about 12% of women aged 18–64 years rely on Medicaid for their health care coverage.[22] Medicaid expansion under the PPACA is expected to expand eligibility to an additional 7 million previously uninsured women aged 19–64 years and with incomes below 138% of the Federal poverty level. It is expected that a substantial portion of these women will be childless adults who were not previously eligible for Medicaid coverage and, like current Medicaid enrollees, are more likely to be in poorer health than the general population.[23] Approximately 20% (1.4 million) of newly eligible women in an expanded Medicaid program will have AUB, many of whom will go on to receive costly pharmacological and surgical treatments every year.[24–26]

The results of our analyses indicate that the costs of AUB intervention plus one month of follow-up (combining patients with and without complications) total approximately $4,000 for GEA, considerably less than the $11,300 estimate for hysterectomy. Supposing a conservative 1% annual treatment rate for AUB with either GEA or hysterectomy, Medicaid's expanded coverage of many more AUB patients is likely to require large outlays for these therapies. The high price of the inpatient hospital care required for hysterectomy will

likely cause concern. As a result, state-based and federally facilitated exchanges may focus intently on pharmacological treatments and GEA (particularly in-office GEA procedures) as ways to reduce costs to Medicaid, with a lasting impact on the treatment landscape for AUB in the USA.

Limitations

Administrative claims databases are subject to several limitations. First, although mortality is not a common outcome of AUB and its treatments, data on mortality were not available in describing the complete picture of patient outcomes. Second, administrative claims databases are developed and maintained for the purposes of facilitating health care payments. This suggests that comorbidities and indicators of severity might not be captured accurately because they are not used for payment generation. Third, analysis of individual brands or types of GEA or hysterectomy was prevented by the lack of specificity available in current procedure codes for GEA and hysterectomy. Finally, the study population consists of patients with Medicaid; therefore, the results may not represent all patients with AUB, including the uninsured who may gain insurance coverage through the PPACA.

Conclusion

Overall, the total treatment-related and indirect costs to the Medicaid program were significantly higher for women undergoing hysterectomy compared with women undergoing GEA in the year following the index event ($11,270 versus $3,958, $P<0.001$). Hysterectomy was nearly three times more costly than GEA for the treatment of AUB, with significantly higher rates of treatment-related complications. These results may be relevant to treatment decisions made by Medicaid, which is expanding its coverage as a result of recent legislation, and soon will insure an estimated 1.4 million women with AUB.

Disclosure

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