

ORIGINAL ARTICLE

Treatment patterns for women with new episodes of uterine myomas in an insured population in the US

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ABSTRACT

Introduction: Uterine myomas are the most common benign tumors in reproductive-aged women and a leading reason for gynecologist visits and hysterectomies in the United States. This study examines the treatment patterns of insured women with new episodes of uterine myomas.

Materials and methods: We used administrative claims from a proprietary research database to evaluate services (inpatient, outpatient, and prescription claims) incurred from January 1, 2001 to December 31, 2003. We identified women with CPT or ICD-9-CM codes suggestive of myoma and described treatment patterns for all women with a new episode of myoma and those with abnormal bleeding.

Results: The primary study group included 35 329 women with new episodes of care and

at least three months of data before and after their index date for myoma. Most women (82.9%) had no code for diagnostic testing in the three months before or after the first myoma marker. Of 14 434 women with one year of follow-up, 26.1% had surgery and 24.7% were treated pharmacologically (oral contraceptives, progestins, or gonadotropin-releasing hormone agonists). Over half (55.1%) of women were untreated, including 45% of those with an ICD-9 code that indicated abnormal bleeding.

Conclusions: Women with new myoma episodes rarely had codes for confirmatory diagnostic tests. Many women with myomas go untreated for at least a year. This is true even for those with evidence of abnormal bleeding. Myoma care may be improved through the introduction of new, safe, and effective therapies.

Introduction

Uterine myomas, also referred to as uterine fibroids, leiomyoma, or leiomyomata uteri, are the most common benign tumors in reproductive-aged women. They are among the most common reasons for visits to gynecologists, one of the most common indications for hysterectomy in the United States, and a source of

significant distress to millions of women¹⁻³. Treatment depends on women's symptoms and patient and physician preference. Most myomas are not associated with the presence of symptoms, and only 10–40% of myomas identified by ultrasound in women aged 35–39 were deemed to be clinically relevant⁴. Appropriate treatment depends on the size and location of fibroids as well as the severity of the

symptoms. Symptomatic myomas are likely to present with abnormal bleeding or pain, but bulk symptoms (e.g. bloating, urinary frequency, and constipation), infertility, or subfertility also may occur^{2,3}. These symptoms dramatically reduce women's health-related quality of life^{5,6}. Current treatment options for myomas include watchful waiting, hormonal manipulations, and invasive procedures⁷.

Pharmacological therapy for myomas could include non-steroidal anti-inflammatory drugs (NSAIDs), oral contraceptives (OCs), and hormone therapy (e.g. gonadotropin-releasing hormone agonists (GnRH) or levonorgestrel-releasing intrauterine systems)³. Procedures for treating myomas include surgical options such as hysterectomy and myomectomy, and non-surgical options such as uterine artery embolization (UAE), which is also referred to as uterine fibroid embolization⁸.

Despite the frequency with which uterine myomas are encountered in clinical practice, The Duke Evidence-based Practice Center's landmark report on uterine fibroids found scant evidence for choosing among management options⁹. Selecting among these options requires the gynecologist to take into account clinical symptoms, risks and benefits of each intervention, and women's reproductive desires¹⁰. When treatment is undertaken for myomas, surgical treatment is more commonly implemented than medical treatment⁸. While the risk of recurrence is eliminated when myomas are treated with a hysterectomy, other treatments, such as pharmacotherapy and myomectomy, can preserve or enhance a patient's fertility⁸.

No reports of a large-scale descriptive study of treatment patterns related to myomas were identified in the current literature. This study examined the treatment patterns of many physicians treating insured women with uterine myomas.

Patients and methods

This paper describes the results of a retrospective, observational cohort study using linked medical and pharmacy claims data. The dataset was extracted from a proprietary, Health Insurance Portability and Accountability Act-compliant research database containing information from a non-capitated, managed, fee-for-service, nationally representative health plan. This database is geographically diverse and contains more than five million annual covered lives with integrated enrollment, laboratory, pharmacy, and medical claims data.

The dataset included claims incurred between January 1, 2001 and December 31, 2003 for women with myoma. Women were selected for inclusion in the

dataset if a myoma-related code was present at anytime during the enrollment period. The diagnosis codes of interest were the International Classification of Disease, Ninth Revision – Clinical Modification (ICD-9-CM) diagnosis codes 218.XX (uterine leiomyoma) and 654.1X (tumors of the body of the uterus/normal delivery associated with other indications for care in pregnancy, labor, and delivery). Current Procedural Terminology (CPT) procedure codes of interest were those for myomectomy (58140, 58145, 58146, 58545, 58546, or 58561).

Women with less than one year of continuous enrollment before the index date and three months after the index date were excluded from the study. The analysis was confined to women who presented for new episodes of care to avoid introducing bias by including women who were treated shortly before entering the database (e.g. those who were treated for a myoma and then became members of the health plan). New episodes were defined as the presence of the first diagnosis code for myoma or treatment code for myomectomy after at least one year of continuous benefits coverage without a myoma marker. The date of the first ICD-9 or CPT code indicating myomas was considered the index date of the woman's episode. Women who did not meet the criteria for a new episode were excluded. A limitation of the dataset is that women with a new episode of care may have had a myoma marker at some point more than a year before the index episode.

For the entire study population, the three-month period before and after the index date was examined for the presence of a relevant diagnostic testing code. Diagnostic tests of interest included ultrasound, endometrial biopsies, and complete blood counts (CBCs). Two subsets of patients were examined. The first subset comprised women with at least one year of continuous enrollment after their index date. These women were used to examine treatments for myomas. The second subset comprised women with a code for abnormal bleeding. This subset was examined for both diagnostic testing (those with a minimum of three months' continuous enrollment after the index date) and for treatment (those with a minimum of one year of continuous enrollment after the index date).

Patients were classified as procedurally treated if they had a CPT code consistent with myomectomy, hysterectomy, or uterine artery embolization (UAE). Patients were classified as pharmacologically treated if at least one outpatient prescription claim for OCs, progestational agents, or GnRH agonists was identified during the period of observation. Prescription drug claims were identified in the database using the National Drug Codes (NDC). Prescription and non-prescription pain medications, NSAIDs, iron, herbal,

and over-the-counter medications were not included in the analysis. We used claims from a randomly selected, age-matched comparison group of women without myoma codes during the study period to estimate the prevailing level of non-myoma-related OC use.

Results

The study dataset included claims for 126 667 women with a diagnosis of uterine myomas. Of these women, 28% (35 329) met the inclusion criteria for the group of women with a new episode of care. Patient race or ethnicity is not recorded in the database. The mean age of women with a new episode of care was 43.9 years (Figure 1). Of women with a new episode of care for myoma, 20 528 women also had a diagnosis code for abnormal bleeding. These groups were examined for diagnostic testing associated with myomas. To examine treatment for myomas the population was restricted to women with at least 12 months of continuous enrollment after the index date. There were 14 434 such patients in total. Of these, 9274 also had a code for abnormal bleeding (Table 1).

Table 1. Patient groups analyzed

	Women with new myoma episodes (n)	Women with new episodes and abnormal bleeding (n)
Group studied for use of diagnostic tests	35,329	20,528
Group studied for treatment	14,434	9274

All women with a new episode of myoma

During the six-month period surrounding the index date for the first myoma (three months before and three months after), 63% of patients had at least one office visit. A large majority (82.9%) of these women had not received a diagnostic test for uterine myomas during this period. The most commonly reported diagnostic procedure was ultrasound (8.6%), followed by CBCs (3.8%), and endometrial biopsies (2.6%). Only 1.8% of women had codes for more than one test (Table 2).

Within 12 months of the start of a new episode, 7958 of 14 434 women (55.1%) had no active treat-

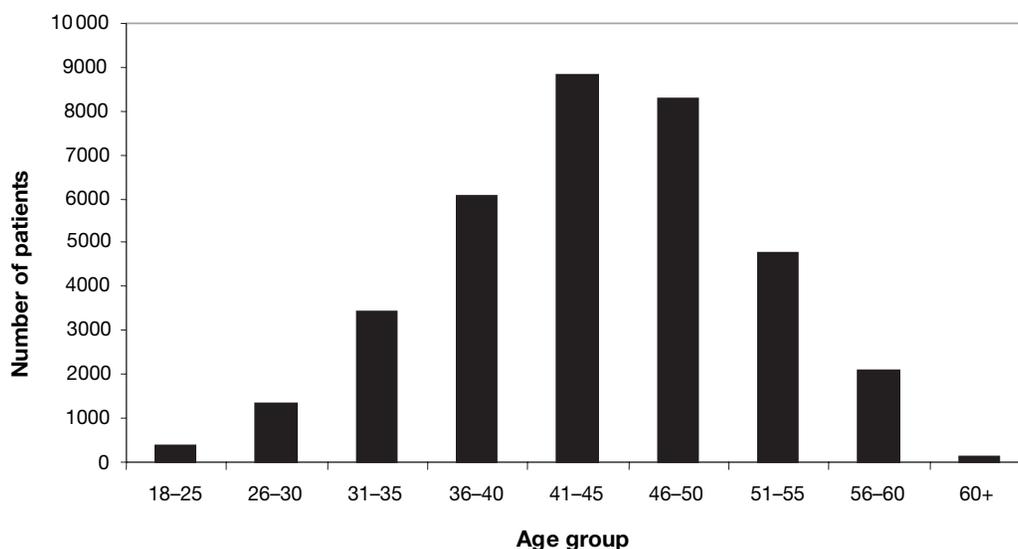


Figure 1. Age distribution of 35 329 women with new myoma episodes

Table 2. Prevalence of diagnostic tests in women with new myoma episodes

Diagnostic test	All women with new episode myoma (n = 35 329)		Women with new episode myoma and abnormal bleeding (n = 20 528)	
	Number	Percent	Number	Percent
Ultrasound	3052	8.6	1815	8.8
CBC	1326	3.8	1011	4.9
Endometrial biopsy/D&C	915	2.6	891	4.3
Multiple tests	635	1.8	565	2.8
No testing	29 296	82.9	16 167	78.8

*Note: Only testing procedures of interest are reported. Some patients received other laboratory tests and were not included in the no-testing category

ment (pharmacologic or procedural) for myomas. The percentage of women with no active treatment was highest among women over age 50 (63.3%) and lowest among women of ages 26–30 (50.2%). The 41- to 45-year-old age group had the largest raw number of women who did not receive any active treatment (1944). During the observation period, 3760 of 14 434 women (26.1%) had a myomectomy, hysterectomy, or UAE. Of these procedures, 82.9% were hysterectomies, 14.7% myomectomies, and 2.4% UAEs. Women aged 41–45 had the highest treatment rates (31.0%) while women aged 18–25 had the lowest (6.7%) (Table 3).

Twenty-five percent of women were dispensed OCs, progestins, or GnRH agonists. The most commonly prescribed medication type was OCs (15.6% of women with new episodes). During an equivalent time-period, 12.7% of age-matched controls without myoma-related claims were dispensed OCs. Approximately 10% of women with myoma received oral progestins. Medroxyprogesterone acetate was the most commonly prescribed oral progestin. The use of OCs and progestins varied little (1–2%) across age groups. Less than 1% of women used GnRH agonists during the 12-month follow-up period (Table 4).

Women with a new episode of myoma and abnormal bleeding

Of the women with abnormal bleeding who had at least six months of data available around their first myoma marker, diagnostic testing was marginally more common than in the overall group (21.2% compared to 17.1% for the group overall). The abnormal-bleeding group had a similar rate of ultrasounds (8.8% vs. 8.6%). The abnormal-bleeding group had a slightly higher rate of CBCs (4.9% vs. 3.8%) and endometrial biopsies (4.3% vs. 2.6%) (Table 2).

We considered the possibility that women had little or no diagnostic testing before the myoma marker simply because they had no visits to gynecologists or primary care providers. However, 73% of women with abnormal bleeding had office visits during the relevant period.

Codes for pharmacologic treatment and procedures were more common in the abnormal-bleeding group, but even in this group 47.3% (4392/9274) had no procedure codes or pharmacologic claims. For women with abnormal bleeding, 27.5% (2551) had a procedure code for hysterectomy compared with 21% in the overall study population. The percentages of women with a procedure code for myomectomy

Table 3. Type of treatment by age group for 14 434 women with new myoma episodes and at least one year follow-up

Age group	No treatment		Pharmacological + procedural		Pharmacological		Procedural		Total by age group
	Number	Percent*	Number	Percent*	Number	Percent*	Number	Percent*	
18–25	69	50.7	7	5.2	58	42.7	2	1.5	136
26–30	249	50.2	28	5.7	171	34.5	48	9.7	496
31–35	651	51.3	95	7.5	346	27.3	177	14.0	1269
36–40	1280	51.4	164	6.6	472	19.0	573	23.0	2489
41–45	1944	52.9	226	6.2	592	16.1	913	24.8	3675
46–50	1889	55.5	202	5.9	599	17.6	713	21.0	3403
51–55	1253	61.7	94	4.6	336	16.5	349	17.2	2032
56–60	623	66.8	28	3.0	141	15.1	141	15.1	933
60+	0	0	0	0	1	100	0	0	1
Total by treatment	7958	55.1	844	5.8	2716	18.8	2916	20.2	14 434

*Proportion within each age group with indicated treatment

Table 4. Use of pharmacologic therapy in women with new myoma episodes and at least one year follow-up

Pharmacologic therapy type	All women with new episodes of myoma (n = 14 434)		Women with new episodes of myoma and abnormal bleeding (n = 9274)	
	Number	Percent	Number	Percent
All medications combined	3560	24.7	2554	27.5
OCs	2253	15.6	1457	15.7
Progestins	1493	10.3	1258	13.6
GnRH agonists	51	0.4	31	0.3

*Note: Some women had prescription drug claims for more than one medication

(4.7%) and UAE (0.8%) in the abnormal-bleeding group were similar to those in the overall study population (3.8% myomectomy and 0.6% UAE). In the abnormal-bleeding group, 27.5% (2554) of women were pharmacologically treated. OCs were the most commonly prescribed medication, followed by progestins and GnRH agonists (Table 4).

Discussion

The rate of diagnostic testing and treatment for myomas in this study was remarkably low. Most women (82.9%) with a diagnosis of myoma did not undergo a confirmatory diagnostic procedure in the three months prior to, or following, the date of their first diagnosis code. Over half (55%) of the women with a new episode of uterine myoma received no active treatment within one year after the condition was noted in the medical claims. The percentage of women without a treatment code was lower but still high (45%) when abnormal bleeding was present.

There may be many reasons for this low rate of diagnostic testing and treatment. Gynecologists may still view myomas as best diagnosed and followed clinically. Alternatively, women whom we identified as having new episodes may have had testing more than a year before their current episode, and their physicians did not feel the need to repeat these tests. The low rate of treatment may reflect a low level of symptoms not requiring treatment. It may also reflect the lack of acceptable treatment options. Hysterectomy is currently the only treatment that ensures permanent relief of myoma symptoms. Perhaps as a result, it was the most common treatment used in our study. Some women do not want to have a hysterectomy. For women wishing to preserve fertility, myomectomy is a more appropriate treatment option than hysterectomy, though it carries a recurrence risk of between 23% to 51% within 3–5 years of the operation^{11–14}. Recent advances in the treatment of myomas have been limited to the introduction of minimally invasive techniques such as UAE and high-intensity focused ultrasound^{15,16}. Recurrence may be more likely and long-term symptom relief less likely with UAE than myomectomy^{17–19}. UAE is generally not performed in women who wish to become pregnant²⁰. As such, these procedures appear most useful in the limited group of women who do not want hysterectomy, yet also do not intend to have children.

For women not undergoing procedures for myomas, pharmacological therapy may be used to treat symptoms. We found low rates of pharmacological therapy use. Women and providers may not be convinced of the benefits of current pharmacologic

treatment options. As the Duke Evidence-Based Practice Center notes, data in the published literature on pharmacologic therapy for myomas are limited. Of the 70 studies the authors identified, 54 related to GnRH agonists, a treatment used by less than 1% of our study population⁹.

A search of The National Guideline Clearinghouse website²¹ yielded only two guidelines on myoma treatment and both underscore the limitations of pharmacologic therapy. One mentions only GnRH agonists and recommends its use in limited circumstances²². The other guideline offers a similarly negative view of pharmacologic treatment options²³: progestins are not recommended 'as there is insufficient evidence of benefit' and OCs are only recommended in that they may increase hematocrit²³.

Myomas are a common condition and are responsible for a substantial decrease in the quality of life in reproductive-aged women^{5–7}. Despite this, our study found that most women did not have diagnostic testing or treatment for new myoma episodes. Information adequate to enable comparison and choice among current therapies might improve the management of myomas. Perhaps the biggest improvement in care, however, would depend on the introduction of pharmacologic therapies that are proven to offer safe and effective symptom relief and treat myomas directly.

Our study has limitations. The amount of clinical detail available for analysis is limited to that reported on administrative claims and does not include information on the rationale behind treatment decisions. For this reason, we did not include prescription analgesics as a myoma-related therapy. This lack of clinical detail also limits our ability to distinguish myoma-related OC use from contraceptive use. We confined our analysis to women who presented for new episodes of care to avoid introducing bias by including women who were treated shortly before entering our database (e.g. those who had a myomectomy, then became members of the health plan from which we obtained our data).

No similar descriptions of treatment patterns in a large, insured population were identified in the literature. Additional studies using medical records, patient surveys, or other clinically detailed sources, would greatly further our understanding of patterns of care for this common condition.

Conclusion

The results of this study suggest that women with a diagnosis of myoma were not likely to receive a confirmatory diagnostic procedure. Women diagnosed with a uterine myoma were also not likely to receive a pharmacologic or procedural treatment even if they also

experienced abnormal bleeding. Additional research into the factors that influence diagnostic testing and treatment decisions for women with uterine myoma could improve the management of women with this condition. Myoma care may be improved through the introduction of new, safe, and effective therapies.

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