

GYNECOLOGY

The direct and indirect costs of uterine fibroid tumors: a systematic review of the literature between 2000 and 2013

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Uterine leiomyoma, commonly called uterine fibroid tumors (UF), are smooth muscle tumors of the uterus that are a common, usually benign, condition in women of reproductive age. The estimated incidence rates vary widely across different studies. The annual incidence rate is estimated at 9.2 cases per 1000 in women 25–44 years old in the United States and 12.7 cases per 100,000 women up to 65 years old in Germany.^{1,2} The most commonly cited incidence estimate in the United States is from Baird et al,³ which estimates the cumulative incidence of UF based on medical records or ultrasound scans to be >80% in black women and nearly 70% in white women by 50 years old.

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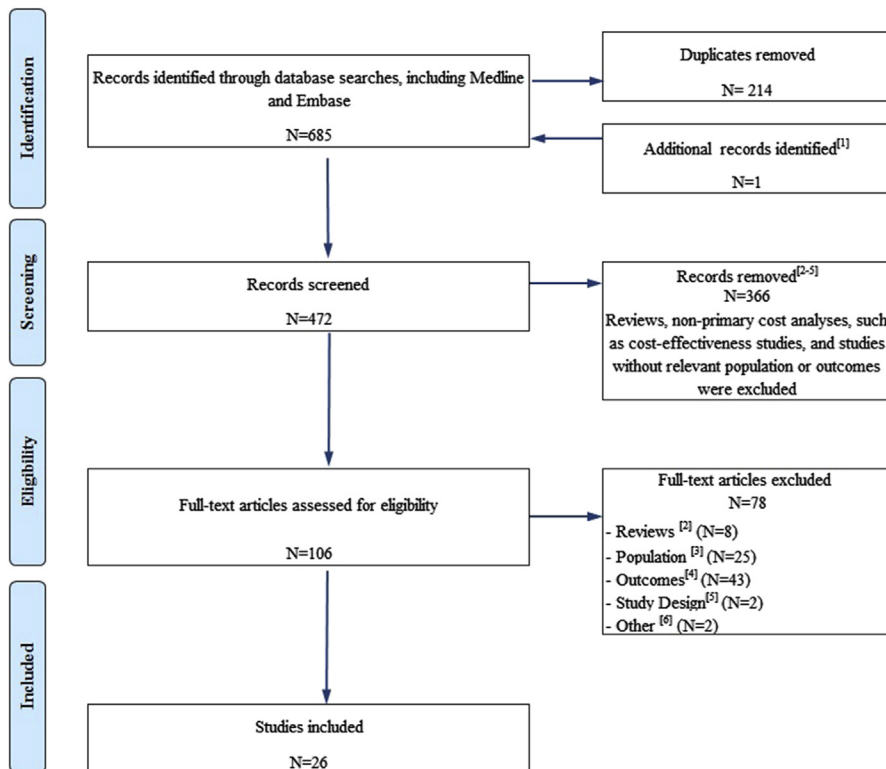
This systematic literature review was conducted to summarize the direct and indirect costs per patient that are associated with uterine fibroid tumors in international studies. A search with predefined search terms was conducted in MEDLINE and EMBASE for studies that were published from January 2000 to November 2013. The review included primary studies that were in English and that reported either direct costs (drug costs, procedure costs, and medical service costs) or indirect costs (such as productivity loss) among patients with uterine fibroid tumors. A total of 26 studies that were identified and included in the data extraction included 19 studies in the United States, 2 studies in the Netherlands, 1 study each in Germany, China, Italy, and Canada, and 1 study reported data that were collected from 3 countries: Germany, France, and England. The studies differed substantially in perspectives that were adopted for analysis, research designs, data elements that were collected, setting, populations, and outcome measurements. Among 3 studies that reported total direct costs during the year after uterine fibroid tumor diagnosis, 2 studies reported an average of \$9473 and \$9319 per patient, respectively; 2 studies reported the excess costs over controls to be \$6076 and \$5427, respectively. The indirect costs per patient ranged from \$2399–15,549, and the excess indirect cost per patient over control groups ranged from \$323–4824 in the year after the diagnosis. The total costs, sum of direct and indirect costs, ranged from \$11,717–25,023 per patient per year, after diagnosis or surgery among patients with uterine fibroid tumors. Compared with control subjects, the additional annual cost ranged from \$2200–15,952 per patient. The results of this systematic literature review highlight the substantial direct and indirect costs that are associated with uterine fibroid tumors to health care payers and society. The large number and the variety of studies identified also emphasize the growing awareness of the significant economic impact of uterine fibroid tumors. Current gaps that were identified through this review warrant further investigation to elucidate fully the economic burden of uterine fibroid tumors, including, but not limited to, burden from the patient's perspective and the entirety of indirect costs.

Key words: direct cost, indirect cost, systematic literature review, uterine fibroid tumor

UF vary greatly by size, location, and symptoms; the treatment options differ accordingly. Although many women with UF are asymptomatic and require no treatment, 30–50% women with UF seek treatment (pharmacologic treatments or surgeries) for heavy and prolonged menstrual bleeding, pelvic pressure, pain, increased urinary frequency, and urgency.^{3–6} Pharmaceutical therapies for UF include a combination of oral contraceptives, nonsteroidal antiinflammatory drugs, gonadotropin-releasing hormone agonists, aromatase

inhibitors, progesterone receptor modulators (eg, ulipristal acetate, mifepristone), and antifibrinolytics (tranexamic acid). They can be used either as adjuvant therapy before surgery or, in certain instances, as the primary treatments for UF. Pharmaceutical therapies can be classified into 2 categories based on their mechanisms: (1) therapy aimed at controlling the symptoms of UF such as progestins, combination oral contraceptives, and antifibrinolytics and (2) therapy aimed directly to reduce the size of fibroid tumor(s) such as

FIGURE 1
Preferred Reporting Item for Systematic Reviews and Meta-Analyses
diagram for the systematic literature review of costs of uterine fibroid
tumors



The flow diagram provides the numbers of studies that were screened, assessed for eligibility, and included in the review; reasons for exclusions at each stage are given. [1] Reviews and other cost-related nonprimary research publications (including cost-effectiveness; cost-utility, cost-consequence, cost-minimization, and cost-benefit analyses) with cost information related to uterine fibroid tumors were reviewed for additional relevant publications. Eight articles were in this category and reviewed for additional relevant publications. One additional publication was identified through this search. [2] Review articles without primary cost data were excluded. [3] Studies without patients with uterine fibroid tumors or studies that focused on patients with uterine fibroid tumors and specific comorbidities were excluded. [4] Studies that did not report any cost information were excluded. [5] Studies that are not primary cost analyses were excluded (eg, budget impact, cost-effectiveness, cost-consequence, cost-minimization, and cost-benefit analyses). [6] Other exclusion criteria included papers in languages other than English and studies of which the full text was not available.

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gonadotropin-releasing hormone agonists and antagonists. However, none of the pharmaceutical therapies are curative.

Hysterectomy, on the other hand, is a curative surgical treatment for UF that prevents future recurrence, but it is not preferred for patients who want to preserve fertility. Alternative procedures include myomectomy, uterine artery embolization (UAE), and magnetic

resonance imaging—guided focused ultrasound surgery. However, these treatments are associated with the risk of tumor recurrence and the need for additional surgeries.⁷⁻¹⁰ In recent years, several new procedures have been approved for the treatment of UF, which includes high-intensity focused ultrasound scanning and radiofrequency ablation.⁷⁻⁹ Given the high prevalence of

UF, the associated debilitating symptoms that affect daily activities and the invasiveness of treatment options, the economic burden of UF is considerable. In the United States, Flynn et al¹¹ estimated a total direct cost of \$3.5 billion (in 2013 USD), including costs for inpatient and outpatient care. Among women who were treated for UF, Becker¹² further estimated a total direct cost of \$4.3 billion (in 2013 USD) and a total indirect cost of \$1.1 billion (in 2013 USD) that would be associated with UF. A later estimate by Cardozo et al¹³ reported a higher total direct cost of \$4.5-10.3 billion among women who sought treatment for UF in the United States. We sought to understand the economic burden that is associated with UF, including direct and indirect costs per patient. A summary of existing evidence will help identify the unmet needs and the need for additional research. Accordingly, the objective of this systematic literature review was to summarize the direct and indirect costs per patient that are associated with UF in research studies that have been published since 2000.

In burden of illness studies, costs that are considered include direct and indirect costs. Direct costs refer to costs that are incurred for providing direct patient care, which include medical costs and nonmedical costs. The medical costs include costs of hospitalization, outpatient visits, drug therapy, and other medical services that are used directly to treat the disease. The nonmedical costs rarely are studied and reported in literature and could include items such as transportation costs. Indirect costs are those related to resource loss because of a certain disease. Indirect costs include items such as costs that are lost because of absenteeism and presenteeism and costs that are associated with leisure time loss and incapacity/lesser capacity for household work. With different study objectives, different perspectives such as hospitals, patients, health care system, third-party payers, employers, or society could be selected in different studies. When a perspective is selected, only cost components that are relevant to that

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