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Clinical and economic consequences of the treatment gap in knee osteoarthritis management

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ABSTRACT

Osteoarthritis affects 27 million American adults of all ages and is a leading cause of disability in middle-aged and older adults. Initial management of knee osteoarthritis symptoms utilizes conservative care although long-term efficacy is poor. Arthroplasty and high tibial osteotomy may be considered for patients with severe pain or disability. We hypothesize that a distinct treatment gap exists for the patient with symptomatic knee osteoarthritis who is unresponsive to conservative care (including simple surgical treatments) yet refuses to undergo or is not an appropriate candidate for more invasive surgical procedures. This treatment gap represents a protracted period in which the patient experiences debilitating pain, reduced quality of life, and a significant financial burden. Approximately 3.6 million Americans linger in the knee osteoarthritis treatment gap and this number will grow to about 5 million people by 2025. The typical knee osteoarthritis treatment gap extends 20 years although the younger osteoarthritis patient is faced with the treatment gap throughout the majority of their adult life. There is great need for a safe, effective, and cost effective treatment option for patients with moderate to severe osteoarthritis that enjoys high patient acceptance.

Background

Osteoarthritis (OA) is a degenerative joint disease with no known cure that is characterized by joint pain and dysfunction caused by progressive articular cartilage loss [1]. Osteoarthritis affects 27 million American adults of all ages [2] with the prevalence exponentially increasing at 50 years of age in men and at 40 years in women [3,4]. This condition is a leading cause of disability in middle-aged and older adults [5]. Aside from compromising physical function and quality of life, OA is also responsible for a substantial economic burden, accounting for $128 billion per year in direct and indirect costs [6–8]. With the continued aging of the population and rising obesity rates, the prevalence of OA is estimated to increase 40% by 2025 [9,10]. Overall, the clinical and economic burden of OA will continue to increase and will remain a major medical problem for decades to come.

Hypothesis

Although a wide range of treatments are available to the patient with knee OA, each option suffers from distinct limitations. Initial management of knee OA symptoms utilizes conservative care including activity modification, weight loss, physical therapy, orthotics, and/or bracing. Anti-inflammatory and/or analgesic medications, intra-articular hyaluronic acid and/or steroid injections, and arthroscopic lavage and debridement are often utilized when initial conservative measures fail although their long-term efficacy is poor [11,12] and they may actually encourage greater mechanical loading of the medial compartment [13], resulting in accelerated OA progression [14,15]. As the disease slowly progresses to cause moderate-to-severe pain and/or disability, total knee arthroplasty represents the mainstay treatment although unicompartmental arthroplasty or high tibial osteotomy (HTO) may be considered in select patients with single compartment disease. Based on this typical treatment algorithm, we hypothesize that there is a definitive treatment gap for the patient with symptomatic knee OA who is unresponsive to conservative care yet refuses to undergo or is not an appropriate candidate for invasive surgical procedures.

This treatment gap, defined as the time from unsuccessful exhaustion of conservative treatment to surgical intervention, is not a benign period. In fact, it represents a protracted period of years and often decades in which the patient experiences debilitating pain, reduced quality of life, and a significant financial burden. The reasons for the treatment gap in knee OA management are threefold—ineffectiveness of conservative measures in the long-term management of OA symptoms, lack of safe and effective

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minimally invasive treatments for knee OA, and a great reluctance or unwillingness of patients to undergo a major and irreversible surgery like arthroplasty or HTO, particularly in the younger OA patient.

Hypothesis evaluation

How many patients are in the treatment gap?

The number of patients that languish in the knee OA treatment gap has not been characterized but may be estimated by extrapolating from relevant sources. The proportion of adults who suffer from symptomatic knee OA is 6% in people 30 years and older [16] and 15.2% in people 45 years and older [17]. Based on the age distribution of the United States population [18], it can be determined that approximately 18 million Americans are currently living with symptomatic knee OA. Of these patients, 23% (4.1 million) have difficulty with ambulation [19], which implies conservative treatment failure and arguably indicates the need for arthroplasty or HTO. However, only 500,000 knee arthroplasties and HTOs are performed each year in the United States, representing 13% of all patients with debilitating symptoms [20]. The remaining 17.5 million Americans suffer from knee OA pain and dysfunction and 3.6 million experience unresolved debilitating pain despite unsuccessful attempts at symptom amelioration with conservative therapy (Fig. 1). This latter group of patients lingers in the treatment gap, represented by failures of conservative therapies but unwillingness to undergo invasive, irreversible knee surgery. The treatment gap will continue to expand with more new patients entering this period after exhausting attempts at conservative care but with fewer patients leaving the gap because of low arthroplasty utilization and increasing life expectancies. Thus, the burden of the treatment gap will likely expand to affect up to 5 million Americans by 2025 [9,10].

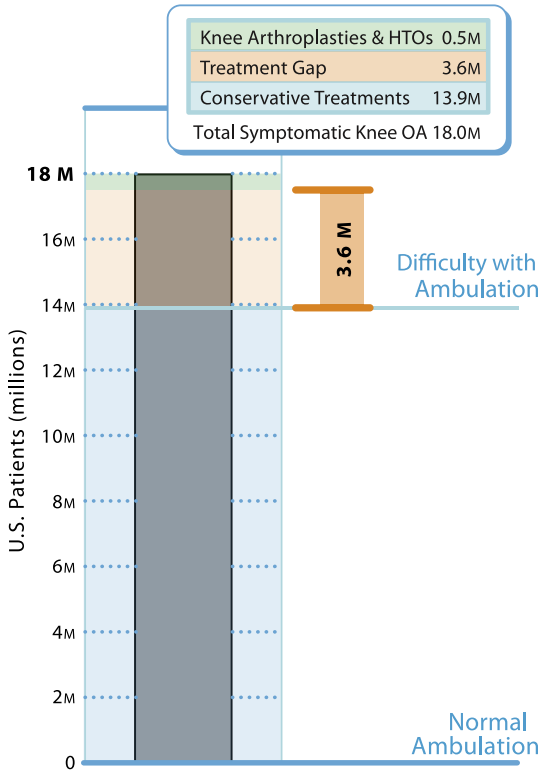

Fig. 1. Estimated number of patients in the treatment gap. Of the 18 million patients with symptomatic knee osteoarthritis in the United States, 3.6 million are in the treatment gap because they have difficulty with ambulation despite conservative care but do not undergo knee arthroplasty or high tibial osteotomy. HTO, high tibial osteotomy; OA, osteoarthritis.

What is the duration of the treatment gap?

The duration of the treatment gap is largely unknown. Conservative treatments such as analgesic and anti-inflammatory medications, bracing, and orthotics are generally initiated at the onset of OA pain. Intra-articular hyaluronic acid injections are usually withheld until at least 3 months of unsuccessful analgesic use. Since these injections offer only short-term relief and the safety and effectiveness of multiple injections over a lifetime are unknown, there is no other accepted treatment to halt or reverse knee OA progression until the end-stage has been reached. The typical patient experiences knee OA symptoms for 9–12 years before choosing to undergo arthroplasty [21–23]. However, the typical duration of the treatment gap is likely much longer than this since few patients who are eligible for arthroplasty actually undergo the procedure. With an average age of symptom onset of 58–61 years [21–23] and a mean US life expectancy of 78 years [24], the average knee OA treatment gap likely approaches 20 years since the majority of patients ultimately refuse arthroplasty (Fig. 2). The treatment gap is of particular concern in the younger OA patient. Given that 38% of OA patients are under the age of 55 years and 10% are under 35 years [25], the younger OA patient is faced with the treatment gap throughout the majority of their adult life.

Who is in the treatment gap?

Thus far, we have identified that at least 3.6 million Americans are in the treatment gap at any given time and that the treatment gap likely endures for an average of 20 years in most knee OA patients, but potentially for 40 or more years in the young OA patient. But what are the characteristics of the patients that comprise the treatment gap? The prevalence of knee OA is strongly related to advanced age with symptom onset generally occurring around 60 years of age [21–23] although OA cases presenting in their 20s and 30s are not uncommon. In fact, 3.0% of OA patients are younger than 25 years, 7.5% are 25–34 years, 12.6% are 35–44 years, and 15.2% are 45–54 years [25]. Therefore, people of all ages may present with this disease and treatment decisions should, in part, consider the wide variation in expected patient life expectancy.

Additional characteristics of knee OA patients are obesity [26] and chronic physical activity [27] or occupational loads [28], all of which contribute to excessive knee joint loading. The typical OA patient also suffers from comorbidities including dyslipidemia, renal impairment, and diabetes [29] and over 4 in 10 OA patients over 35 years of age regularly take antihypertensive medication [30].

Patients who remain in the treatment gap have experienced no or marginal success with conservative treatments. Distinct differences exist in these patients versus those who elect to undergo arthroplasty. The primary predictor of arthroplasty is a willingness to undergo the procedure. Aside from perception of the procedure, patients in poor health and with less severe dysfunction reject arthroplasty more often [31]. Anticipated postoperative outcomes also impact the decision to undergo arthroplasty; common reasons for denying arthroplasty include high perceived surgical risk, reluctance to undergo a surgical procedure, a belief that arthroplasty is ineffective, and unwillingness to accept the potential risk of future revision surgery [32,33]. This last determinant is especially important to the younger OA patient given that arthroplasty survival is shorter in these patients [34] and, therefore, they would be subjected to multiple future surgeries. However, for the patients who reject arthroplasty, no treatment is available to satisfactorily alleviate OA symptoms and, therefore, pain and disability endures