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An assessment of willingness to participate in a randomized trial of arthroscopic knee surgery in patients with osteoarthritis☆

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Abstract

Identifying barriers to recruitment into a randomized clinical trial can help researchers adjust recruitment strategies to maximize enrollment. To determine barriers to enrollment of patients in trials of knee osteoarthritis treatments, we recruited from three centers patients over age 45 who had both knee osteoarthritis and a meniscal tear. We described a hypothetical randomized trial of arthroscopic partial meniscectomy versus non-operative management and assessed patients' willingness to participate in such a trial. We elicited preferences for treatment along with information on age, sex, education level, race, work status, and pain. We examined the association between these factors and willingness to participate in the trial. Orthopedic surgeons identified 106 eligible osteoarthritis patients, of whom 12 could not be reached, 6 refused and 88 (83%) completed interviews. 63% were female, 55% were college graduates, 23% were non-white and mean age was 60±8. The mean WOMAC pain score was 56±23. 22% of patients stated that they were definitely willing to participate in the hypothetical trial, and 24% stated they were probably willing. Subjects lacking strong preferences for treatment stated a greater willingness to

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participate than those with strong preferences (36–14% definitely willing, χ^2 for trend, p=0.005). WOMAC pain score, age, education, work status and race were not associated with willingness to participate. Males were more likely than females to state a willingness to participate (39–11% definitely willing, p=0.005). Since OA affects females disproportionately, a better understanding of barriers to females' participation in trials may enhance future research on treatment of osteoarthritis. Effectively addressing a priori treatment preferences through patient education about the advantages and drawbacks of treatments may increase willingness to participate in trials.

Keywords: Randomized controlled trials; Recruitment; Preferences; Osteoarthritis; Arthroscopy

1. Introduction

Randomized controlled clinical trials are the most rigorous way to determine treatment efficacy. Recruitment into clinical trials, however, is notoriously difficult in general [1–5], and surgical trials in particular face further obstacles to recruitment [6–8]. Low recruitment leads to poor statistical power to detect meaningful differences, subjecting participants to potentially risky interventions with no guarantee that their participation will lead to results of scientific value [9]. From a practical standpoint, low recruitment may prompt a study sponsor to shut down the trial [1,2]. For all these reasons, investigators planning a randomized controlled clinical trial must ensure that recruitment of subjects into the trial will be sufficient to achieve the study aims.

In addressing issues of trial recruitment, investigators have tried to identify barriers to clinician and patient participation [1–3,10], to modify trials to make them more palatable to clinicians and patients [11–13], and to assess differences between those patients who agree to participate in trials and those who refuse [12,14–16]. Some have audiotaped clinician discussions with potential trial participants [11,17], while others have used surveys and focus groups to gather patients' general attitudes towards trial participation [3,5]. Other investigators have conducted surveys and interviews to elicit patient reactions to aspects of a specific trial, their feelings about the interventions proposed, and their potential willingness to participate in the hypothetical trial [10,12,15,16,18–20]. Demographic factors, such as gender, race, age and education level, have been associated in some studies with willingness to participate [1,2,5,14]. Patients' equipoise–that is, their belief that both treatments will be equally efficacious to them–has been shown to be important [10,19,20], as has the extent to which patients wish to control the course of treatment [16]. Finally, the specific treatment that a patient desires may influence willingness to participate in a trial and also compliance and satisfaction with trial participation for those who enroll [21–24].

Halpern has proposed a method called "prospective preference assessment" to improve recruitment for a planned trial, by helping forecast enrollment rates, simulate recruitment, identify problem areas and illuminate differences between participants and non-participants [12,25]. The method involves presenting a hypothetical trial design and using both quantitative and qualitative measures to elicit willingness to participate in the trial along with the motivations and concerns participants have about trial participation. Such interviews also include demographic and disease-specific data to investigate the ways in which people who express willingness to participate differ from those who do not.

We undertook a prospective preference assessment by performing a pilot study in planning for a trial of arthroscopic partial meniscectomy versus non-operative therapy in the setting of osteoarthritis and meniscal tear. Osteoarthritis (OA) is a prevalent and costly condition. One-third of people over age 65

have radiographic evidence of OA [26,27], and there is a 10% prevalence of symptomatic knee OA in the US [28]. Up to 80% of people with knee OA have meniscal tears on MRI [29]. Symptomatic meniscal tears may cause pain, clicking, popping, giving way and locking in the knee. Since pain, however, is also a cardinal symptom of OA, it can be difficult to determine the primary cause of symptoms in patients with OA and meniscal tears.

There are two main types of treatment for people who have both a meniscal tear and OA. One type is non-operative or conservative therapy, which includes the use of non-steroidal anti-inflammatory drugs (NSAIDs), injections of corticosteroids or hyaluronic acid, and exercises to strengthen the knee and increase flexibility.

The other type of therapy is arthroscopic partial meniscectomy (APM), a resection of the torn part of the meniscus to a stable edge. APM is the most common orthopedic procedure performed in the US [30], and over 80% of younger patients have alleviation of their pain post-procedure, with a complication rate of <2% [31,32]. There is some evidence, however, that APM may accelerate the progression of OA [33–35].

Furthermore, the effectiveness of APM in patients with OA is less clear, as rates of pain relief and functional improvement are lower than in patients without OA [31–33,36]. Therefore, the effectiveness of APM in the population of patients with both meniscal tears and OA is uncertain and optimal management of this population is unclear.

In an attempt to define optimal management in this clinical setting, we are planning a randomized trial of APM versus non-operative treatment in patients with both a meniscal tear and OA. Both arms of the trial are active, mirroring the clinical choices that are typically presented to patients with meniscal disorders and OA. In planning this trial, it was critical to understand what proportion of eligible patients in that population would be willing to participate in such a trial and to identify factors associated with patients' willingness to enroll.

Therefore, the aims of our pilot prospective preference assessment study were twofold: (1) to estimate the proportion of eligible patients who would be willing to enroll in a hypothetical trial; and (2) to identify factors associated with willingness to enroll in the trial. This would allow us to make effective changes in trial design and recruitment strategy prior to starting the RCT and to determine whether patients willing to participate in our trial are representative of the general osteoarthritis population.

We hypothesized that stated willingness to enroll in the hypothetical trial will decrease with increased strength of treatment preference.

2. Methods

2.1. Patient sample

We recruited patients in three centers who were age 45 or older, who had acute knee pain for at least 4 weeks with mechanical symptoms indicative of a meniscal tear, and who additionally had radiographic evidence of OA (Kellgren and Lawrence grades I, II, or III) and a strong clinical suspicion of a meniscal tear based on history, physical exam, and radiographic and imaging features. Patients were excluded if they had prior APM on the index knee, a locked knee, severe OA (Kellgren and Lawrence grade IV), or chondrocalcinosis. Participating surgeons identified eligible patients during regular office appointments. Surgeons explained the pilot study to the patients and referred them to the research assistant at each

center. The research assistant either met with the patient in person after the appointment to administer the interview or subsequently administered the interview by telephone; both interview methods used a standardized script. This study was approved by the institutional review boards of the three centers.

2.2. Patient interview

The script explained that the goal of the pilot investigation was to "help plan a research study." The scripted interview presented the two treatment options: APM or "intensified physical therapy and medications." After stating that each treatment succeeds in some patients and fails in others, the script described the proposed randomized trial as the best method for determining which treatment works best and under what circumstances. We then explained the process of randomization.

After the explanation of the hypothetical randomized clinical trial, patients rated their willingness to participate in such a trial on a five-point scale (definitely yes, probably yes, not sure, probably not, definitely not). Patients then explained (in open ended format) the reasons for their response. Patients were then asked if they had a preference between the treatments. If they did, we asked which treatment they preferred and whether they slightly or strongly preferred that treatment. They additionally answered a free response item explaining the reasons for their treatment preference. During the interview, the research assistant also administered the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) 5-item pain scale [37] and asked questions about race/ethnicity, education level and work status.

2.3. Statistical analysis

Willingness to participate was evaluated as a three-category variable: (1) definitely willing to participate, (2) probably willing to participate or unsure, and (3) probably or definitely not willing to participate (referred to simply as "not willing"). We dichotomized the treatment preference variable, either for surgery or physical therapy plus medications, into the categories "strong preference" versus all other responses, which were categorized as "no strong preference."

We examined the association of age, sex, education, race, work situation and WOMAC pain score with both willingness to participate and strength of preference. Age was defined as a continuous variable. Education was categorized as high school or lower, some college or technical college, or college graduate or higher. Race was defined as white or non-white. Work situation was categorized as working either full- or part-time, not working due to knee or other health problems, and retired/otherwise not working. WOMAC pain scores were scaled from 0 to 100 with 100 representing no pain and 0 maximum pain. Chi-square and *t*-test were used to examine the association between categorical and continuous variables, respectively.

3. Results

Eleven orthopedic surgeons identified 119 patients at three centers. Of these, 13 (11%) were found ineligible either because they had undergone prior surgery on the index knee or because they were less than 45 years of age. Of the 106 eligible patients, six (6%) refused to participate and 12 (11%) could not be reached, leaving 88 (83%) patients who completed the interview.

Table 1
Distribution of participants by willingness to participate

Factor	Definitely willing (n=19)	Probably willing or unsure (n=30)	Not willing (n=39)	Total (n=88)	p-value
Age (mean±SD)	58±8	59±9	62±8	60±8	0.25
Sex					
Male	13 (39)	7 (21)	13 (39)	33	
Female	6 (11)	23 (42)	26 (47)	55	0.005
Education					
High school or lower	5 (36)	5 (36)	4 (29)	14	
Some college or technical college	4 (15)	10 (39)	12 (46)	26	
College graduate	10 (21)	15 (31)	23 (48)	48	0.57
Race					
Nonwhite	4 (20)	9 (45)	7 (35)	20	
White	15 (22)	21 (31)	32 (47)	68	0.49
Work status					
Working	13 (25)	17 (33)	22 (42)	52	
Not working due to knee/health	4 (36)	4 (36)	3 (27)	11	
Retired or otherwise not working	2 (8)	9 (36)	14 (56)	25	0.28
WOMAC pain score (mean±SD)	56±24	56±18	56±26	56±23	0.99

Table 2
Distribution of participants by strength of treatment preference

Factor	Strong preference (n=57)	No strong preference (n=31)	p-value
Age (mean±SD)	61±8	59±8	0.43
Sex			
Male	18 (55)	15 (46)	
Female	39 (71)	16 (29)	0.12
Education			
High school or lower	9 (64)	5 (36)	
Some college or technical college	15 (58)	11 (42)	
College graduate	33 (69)	15 (31)	0.64
Race			
Nonwhite	12 (60)	8 (40)	
White	45 (66)	23 (34)	0.61
Work status			
Working	34 (65)	18 (35)	
Not working due to knee/health	7 (64)	4 (36)	
Retired or otherwise not working	16 (64)	9 (36)	0.99
WOMAC pain score (mean±SD)	59±23	50±22	0.07

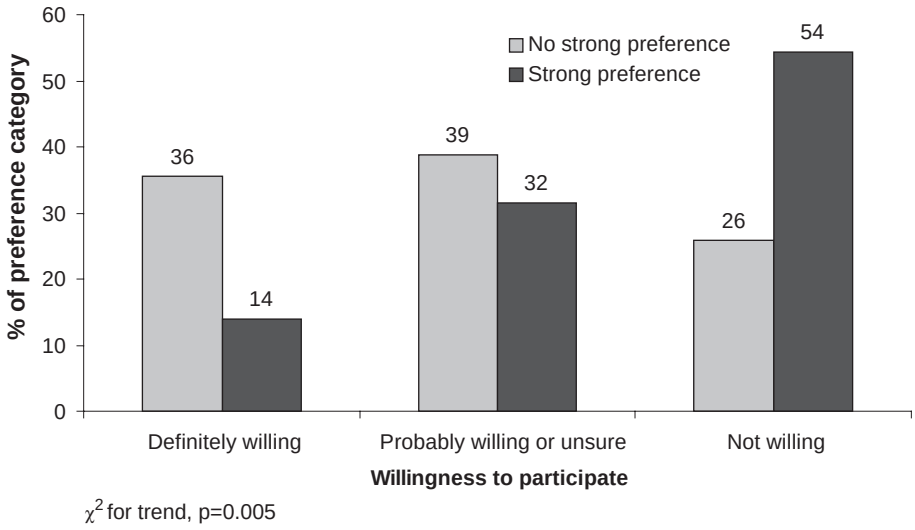

Fig. 1. Strength of preference and willingness to participate.

Of the 88 interviewed, 63% were female, 55% were college graduates, 23% were non-white, 59% were working full or part time, and the mean age was 60±8 years (range 45–81). The mean WOMAC pain score was 56±23.

Nearly half of the participants expressed some degree of willingness to participate in the hypothetical trial, with 22% saying they were definitely willing, 24% probably willing, 10% unsure, and 21% and 24% probably and definitely not willing to participate, respectively. The majority of patients, 65%, had a strong preference for treatment of their knee problem.

Patients willing to participate did not differ from patients less likely to participate with respect to age, education, race, work status or WOMAC pain score (Table 1). Males, however, were more likely than females to state a willingness to participate, with 39% of males and 11% of females stating they were definitely willing (p=0.005). Table 2 shows the distribution of strength of treatment preferences. Sex, age, education, race, work situation and WOMAC pain score did not show a significant association with strength of preference for one treatment or the other.

Willingness to participate and strength of preference were strongly related (Fig. 1), with 36% of patients that had no strong preferences for treatment being definitely willing to participate in a randomized trial compared to 14% of those with strong preferences (χ^2 for trend, p=0.005).

4. Discussion

We used the recently described technique of prospective preference assessment [25] to estimate participation in a planned randomized controlled trial of arthroscopic surgery versus non operative therapy in patients with symptomatic meniscal tears and concomitant osteoarthritis. Over one-fifth of participants stated a definite willingness to participate in a randomized trial, and another one-third stated probable willingness to participate or were unsure. Such hypothetical questioning about willingness to take part in a randomized trial has been shown to correlate with actual subsequent trial participation in an

AIDS vaccine trial with participants at high risk for the disease [12]. While the hypothetical assessment of willingness to participate is helpful in planning trials, it is important to understand that this measure is not precise. For example, in the vaccine trial, some participants who expressed hypothetical willingness to participate did not enroll, and a few who expressed unwillingness to participate eventually did enroll.

We found that males were more likely than females to state a willingness to participate in a hypothetical trial, reflecting findings from other similar studies [13,19]. It is unclear whether men are also more likely to participate in actual trials. It is plausible that women decline because they have greater caretaking responsibilities [2] or that they have greater mistrust of the medical establishment [38]. One study found that women appeared to have a better understanding of a hypothetical trial design than men and that they also expressed unwillingness to participate at higher rates than men [13]. These findings may relate to differing levels of risk aversion between women and men, though the literature on this issue is sparse and inconclusive [39]. OA is more prevalent in females than in males [40], and ensuring the inclusion of women in trials is crucial to the future impact of OA research. It is also worth noting that 63% of our survey participants were female, while most studies of meniscectomy have greater numbers of men than women [41]. Our cohort was older relative to many studies of meniscectomy, and female representation in such studies increases with increasing age of cohort. These findings, however, raise the question of whether there are different rates of operation between males and females presenting with meniscal tear and OA.

As expected, willingness to participate was strongly associated with strength of treatment preference (Fig. 1), with those having stronger preferences being less willing to participate in a randomized trial. This finding is consistent with prior literature [10,16,20] and has face validity. Patients who strongly prefer one treatment over another will more often find randomization troubling, as they could possibly get a less desired treatment. Clinical equipoise is the ethical requirement for doing trials [42], and a physician's equipoise has been linked to trial participation and successful recruitment by physicians [1,2,4,11,43]. A *patient's* equipoise, however, may be the key to the decision to enroll in a trial comparing two readily available treatment options: our data suggest that to be willing to participate, patients must believe that either treatment will be of equal benefit [10,19,20,44–47]. This may not be true of a trial offering a new treatment not otherwise available, where the chance of receiving a novel therapy is a possible inducement to enrollment.

In addition to the hypothetical nature of the question on willingness to participate, the survey is cross-sectional, and we do not know how willingness to participate and treatment preferences change over time. It is possible, for example, that someone with a strong treatment preference could learn more about the pitfalls of the preferred treatment or of advantages of the other, and thereby develop greater willingness to participate in a randomized trial. It is also possible that more knowledge could lead to a stronger preference for one treatment, leading to decreased willingness to participate. Some studies have shown that greater understanding about trial and treatment details leads to lower willingness to participate in trials, though little research has been done on this question [13,20]. We did not assess patient understanding of the trial design or of the treatments for their knee problem, so we cannot address this question.

The modest sample size and three-center design precluded examination of the effect of surgeons and centers on willingness to participate or on treatment preferences. Within the context of trial recruitment, physician presentation of a trial can have an effect on patients' willingness to participate [11,17] and can lead to different levels of recruitment from each physician [4]. Different centers may have an effect on recruitment, with possible factors including varying levels of staff experience and

motivation to aid in recruitment and varying patient experience with clinical research. These factors may affect patients' willingness to participate and merit further study. We also did not assess clinical factors such as body mass index and physical activity which are associated with OA. It is possible that such factors could be associated with willingness to participate in OA trials, creating concerns about generalizability of trial results.

The recruitment stage for randomized controlled trials should include eliciting patient preferences, to ensure that all potential participants accurately understand the efficacy of each treatment, to ensure generalizability, and to understand the effects of preferences on enrollment rates among potentially eligible patients and on trial outcomes for those who are randomized. As our data show, treatment preferences are strongly related to willingness to be randomized. Educating all potential participants, particularly those who have strong preferences based upon anecdotal evidence or false perceptions about the effectiveness of the treatments [48], may help them understand and perhaps even develop equipoise about the treatments. This, in turn, may increase patients' willingness to participate and maximize recruitment. For patients who agree to participate, knowing pre-existing preferences is essential, as those who do not get their preferred treatment may be less compliant with treatment, drop out or cross over more often, or have worse outcomes not based on the effect of treatment [24]. If preference for one treatment is greater in the study population, this effect will bias the results of treatment [22,23], especially if one treatment requires high levels of patient participation, such as physical therapy [21]. Education during the recruitment stage may increase the number enrolled who are without treatment preferences, which may increase compliance with treatment and reduce dropout from a trial.

In summary, the prospective preference approach efficiently assists investigators in assessing how many eligible patients may be willing to participate in a randomized trial. This method also provides some assessment of the differences between those who are willing and not willing to participate, and understanding such differences is a prerequisite to addressing them. Investigators can elicit the range of treatment preferences in those willing and unwilling to participate in randomized trials and include evidence-based information about treatment options to minimize impact of treatment preferences on willingness to participate.

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