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Comparative Effectiveness Research/HTA

A Randomized Controlled Trial of Two Distinct Shared Decision-Making Aids for Hip and Knee Osteoarthritis in an Ethnically Diverse Patient Population

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ABSTRACT

Objectives: To evaluate the use of decision aids for hip and knee osteoarthritis (OA) regarding the potential risks and benefits of different treatment options. **Methods:** A prospective, randomized controlled trial was conducted of 147 patients with advanced hip or knee OA to compare the effect of two decision aids (booklet-only vs. booklet with DVD). **Results:** Both decision aid programs were well received and demonstrated improvements in patient knowledge and willingness to participate in treatment decisions. The decision aids, however, had a marginal effect on patient willingness to participate in OA management, with an increase of 0.11 and 0.6 on a scale of 2 ($P = 0.58$) between groups. **Conclusions:** The decision aids were accepted for most patients and effective in improving patient knowledge and willingness to participate in the decision process. Nevertheless, the addition of a more expensive DVD to the booklet program did not improve patient acceptance or knowledge.

Keywords: decision aids, hip athroplasty, hip replacement, knee arthroplasty, knee replacement, shared decision making.

Introduction

At present there are no effective medical treatments to stop or reverse disease progression of hip and knee osteoarthritis (OA). Available treatments including total hip arthroplasty (THA) and total knee arthroplasty (TKA) can help relieve symptoms, which improves function and substantially reduces pain in patients with end-stage hip or knee OA unresponsive to conservative medical treatments [1]. In 2009, more than 1 million total hip or knee replacements were performed in the United States [2]. Furthermore, THA and TKA prevalence rates have increased, and this trend is expected to continue in the coming years [3].

Despite the benefits of total joint arthroplasty, the procedures are associated with significant risks that patients must consider when making a treatment decision. It is a quality-of-life operation. Consequently, the indications for THA and TKA depend heavily on patients' preferences as well as their condition-specific factors such as symptoms and degree of disability [4].

One strategy for helping patients make a decision about treatment choices is to practice shared decision making (SDM). SDM involves a two-way exchange of information between patient and physician to make an informed clinical decision that incorporates the patient's preferences and values to optimize outcomes [5]. Evidence suggests that SDM strategies are effective in enhancing patient decision quality or the degree to which treatment decisions reflect the preferences of fully informed patients, especially for preference-sensitive procedures such as total joint arthroplasty [6]. For this to happen, patients need to have adequate information to understand their disease and the treatment options, which can impact their treatment choice as well as their outcome [7]. Nevertheless, there are concerns about the implementation of SDM in orthopedics, including lack of physician time to participate and its potential interference with clinical workflow [8,9]. Consequently, the practice has not been widely embraced or adopted in orthopedics [8].

Patient decision aids are tools that provide evidence-based information regarding the available treatment options for a clinical problem and the potential risks and benefits of different treatment strategies, which are useful for facilitating SDM [10,11]. Patient decision aids can reduce decisional conflict and improve patient satisfaction by clarifying patients' values and preferences and by helping patients factor them appropriately in their treatment decision [11]. For those interested in pursuing an SDM strategy, the optimal decision aid remains an unsettled issue.

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Given the increasing time constraints on physicians caring for patients with hip and knee arthritis and the cost for the development and updating of various decision aids, information regarding the effectiveness and patient acceptance of various decision aids as well as physician adoption of such SDM tools is important [12,13]. The ideal format for decision aid programs is, however, not known. The purpose of this study was to compare two patient decision aid programs for hip and knee OA. One program included an educational DVD and booklet, whereas the other consisted of the booklet only. DVD-based programs are expensive and need to be updated frequently, and it is not known whether they offer any additional benefit to booklet-only programs. We conducted a prospective, randomized controlled trial to compare the effects of the decision aid programs on patient knowledge, decision-making participation, satisfaction, and treatment preferences in a diverse patient group with advanced arthritis of the hip or knee. A secondary aim included an assessment of baseline knowledge regarding OA and its treatment options and the measurement of the impact of the decision aids on patient knowledge following a review of such programs.

Methods

Study Design

This was a prospective, randomized controlled trial evaluating the effects of two patient decision aid programs on knowledge improvement satisfaction and treatment choices in patients with hip and knee OA. One program consisted of the booklet only (control group), and the other program included the use of an educational DVD in combination with the booklet (intervention group). The educational material was meant to be equivalent in content, discussing the concept of SDM, the pathophysiology of arthritis, and the treatment options (both surgical and nonsurgical) as well as providing information regarding joint replacement and its recovery and information for patients to consider when making their decision with their physician. The video adds patient testimonials and physician interviews to reinforce the material presented in the booklet.

The study was approved by the institutional review boards at the institutions involved.

Eligibility Criteria

Patients were considered eligible if they 1) had a diagnosis of advanced OA of the hip or knee by clinical designation (at least 10° limited range of motion in more than one direction or the presence of pain or both); 2) had a radiographic designation of advanced OA (joint space narrowing >0.5 mm, osteophyte formation, or grade III or IV on the Kellgren-Lawrence or Li scale); 3) were candidates for total hip or knee replacement; 4) were at least 21 years old; and 5) were psychosocially, mentally, and physically able to fully complete questionnaires. Patients were excluded if they had previously undergone THA or TKA. Other exclusion criteria included primary diagnosis of a disease other than OA, inability to speak or read English, cognitive impairment, and patient refusal to complete study questionnaires.

Identification and Recruitment of Study Participants

Study participants were identified and screened by five orthopedic physicians during a consultation visit at a large academic medical center in an urban environment. Informed consent was provided to qualifying patients, and study materials were administered immediately after the consultation and signing of the informed consent.

Randomization

Study participants were randomized to a control group or an intervention group using a computer-generated random list with unequal blocks. On the basis of this random assignment, patients were given one of two decision aids—a DVD and a booklet or a booklet only. The booklet used for each group was identical. The decision aids were developed by Health Dialog with the Foundation for Informed Medical Decision Making and were titled "Treatment Choices for [Hip *or* Knee] Osteoarthritis." Subjects were given the option to review the study materials after their consultation visit in the medical office premises or to take them home to review.

Procedures

Subjects completed several validated self-administered baseline questionnaires, including the EuroQol five-dimensional questionnaire (EQ-5D), the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index, and the short form 12 health survey (SF-12) [14–16], to evaluate health-related quality-of-life and functional outcomes. Formal questionnaires designed to evaluate knowledge about OA, baseline treatment choice, stage of decision making, satisfaction, and decision-making values and preferences were completed at baseline and at follow-up 2 to 4 weeks later. Patients' ratings of the decision aid program were also assessed. Demographic information collected included age, ethnicity, sex, education, and insurance type.

Outcome Measures

The primary outcome measures for the study were differences in patient knowledge (see Appendix A in Supplementary Materials found at http://dx.doi.org./10.1016/j.jval.2016.01.006) at the 2- to 4-week follow-up period, decision-making participation, and satisfaction about OA treatment education. Surveys were administered by a study research coordinator, and not by the treating physician. Patients completed a five-item knowledge questionnaire on facts about hip or knee OA disease progression and THA or TKA. The total score ranged from 0 (no correct answers) to 5 (all correct answers). One point was assigned for each correct knowledge questionnaire answer. Patients were also asked to rate their satisfaction regarding their education and knowledge about the available OA treatment choices as one of the following: 1) dissatisfied, 2) doubtful, 3) moderately satisfied, 4) satisfied, or 5) very satisfied. Satisfaction scores were assigned values of 1 for "dissatisfied" up to 5 for "very satisfied." For the satisfaction scale, a score of 3 or higher denoted satisfaction with OA education and knowledge. Decision-making participation was assessed using two items with three response categories (patient, doctor, and both), asking patients about their willingness to take part in the decision-making process about OA pain management and surgery. The total score differences from preoperative baseline and 2- to 4-week postoperative follow-up visit were used as primary outcome measures.

Secondary study measures evaluated included patient rating of the decision aid tool, change in treatment preferences, and stage of decision making. A six-item questionnaire was used to determine the acceptability of the patient decision aid by asking for patients' opinions of general aspects of the decision aid, including length, overall rating, and usefulness in improving understanding of OA treatment choices and management. All patient decision aid usefulness ratings were measured on a scale of 1 (not useful at all) to 4 (extremely useful). Treatment preferences were determined using three response categories (unsure, nonsurgical treatment, and surgical treatment). Patients' stage of decision making was assessed using a scale of 1) not yet thought about the options, 2) considering the different options,