Shared Decision Making in Patients with Osteoarthritis of the Hip and Knee

Results of a Randomized Controlled Trial

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Background: Despite evidence that shared decision-making tools for treatment decisions improve decision quality and patient engagement, they are not commonly employed in orthopaedic practice. The purpose of this study was to evaluate the impact of decision and communication aids on patient knowledge, efficiency of decision making, treatment choice, and patient and surgeon experience in patients with osteoarthritis of the hip or knee.

Methods: One hundred and twenty-three patients who were considered medically appropriate for hip or knee replacement were randomized to either a shared decision-making intervention or usual care. Patients in the intervention group received a digital video disc and booklet describing the natural history and treatment alternatives for hip and knee osteoarthritis and developed a structured list of questions for their surgeon in consultation with a health coach. Patients in the control group received information about the surgeon's practice. Both groups reported their knowledge and stage in decision making and their treatment choice, satisfaction, and communication with their surgeon. Surgeons reported the appropriateness of patient questions and their satisfaction with the visit. The primary outcome measure tracked whether patients reached an informed decision during their first visit. Statistical analyses were performed to evaluate differences between groups.

Results: Significantly more patients in the intervention group (58%) reached an informed decision during the first visit compared with the control group (33%) ($p = 0.005$). The intervention group reported higher confidence in knowing what questions to ask their doctor ($p = 0.0034$). After the appointment, there was no significant difference between groups in the percentage of patients choosing surgery ($p = 0.48$). Surgeons rated the number and appropriateness of patient questions higher in the intervention group ($p < 0.0001$), reported higher satisfaction with the efficiency of the intervention group visits ($p < 0.0001$), and were more satisfied overall with the intervention group visits ($p < 0.0001$).

Conclusions: Decision and communication aids used in orthopaedic practice had benefits for both patients and surgeons. These findings could be important in facilitating adoption of shared decision-making tools into routine orthopaedic practice.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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A commentary by Terence J. Gioe, MD, is linked to the online version of this article at jbjs.org.

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Osteoarthritis of the hip and knee affects millions of Americans. The clinical manifestations range from mild pain causing minimal impairment to severe pain and disability, resulting in limited mobility and poor quality of life. Treatment alternatives range from activity modification, weight loss, physical therapy, and nonsteroidal anti-inflammatory medications to more invasive therapies, such as injections, osteotomy, and total joint arthroplasty. These treatments expose patients to potential risks as well as possible benefits; therefore, physicians should incorporate patient preferences about the value, timing, and likelihood of these risks and benefits when developing a treatment plan with their patients. Shared decision making refers to a set of principles that can be employed by patients and their physicians to explicitly incorporate patient preferences and values into clinical decision making. The benefits of shared decision making, including improved decision quality, enhanced knowledge of medical conditions and treatment alternatives, and reduced anxiety around medical decision making, have been established across many conditions[1-5]. Furthermore, policy experts have suggested that shared decision making may lead to more appropriate utilization of health-care services, and therefore may address unwarranted variation in utilization of preference-sensitive treatments such as total joint arthroplasty.

Despite the documented benefits of shared decision-making tools, adoption among orthopaedic surgeons is limited. The reasons for this limited adoption may include the perception among surgeons that shared decision-making tools might unfairly portray the potential adverse consequences of surgical interventions, and therefore might make patients less likely to choose surgery. Surgeons may also be concerned with the possibility that employing shared decision-making techniques could impede the efficiency of a surgeon's practice and the cost and logistical expense associated with implementation of shared decision-making tools. Meanwhile, health-care purchasers, payers, and policymakers continue to tout the benefits of shared decision making. However, unless surgeons embrace the value of shared decision-making methods in terms of improving the quality, patient-centeredness, and efficiency of care, they are unlikely to endorse them as valid to their patients and to incorporate them into their practice.

Other investigators have attempted to evaluate the use of shared decision-making tools in patients with hip and knee osteoarthritis[6-8]. However, the results of these studies are subject to meaningful bias, as patients were not randomly allocated to different treatment arms and patients who may not even be considered as candidates for total joint arthroplasty were included in the studies. The purpose of this study was to evaluate the impact of shared decision-making tools on patient knowledge, efficiency of decision making, treatment choice, and patient and provider satisfaction with the process of using shared decision-making tools in patients with advanced osteoarthritis of the hip or knee.

Materials and Methods

Participant Recruitment

One hundred and twenty-three patients referred to two academic medical centers (the University of California, San Francisco and Stanford University) for evaluation of an arthritic hip or knee were recruited between September 2011 and May 2012. This study was approved by the institutional review boards at both the University of California, San Francisco and Stanford University. Potential subjects were identified from clinic schedules and were called to assess their eligibility and to obtain verbal consent. When patients came for their clinic visit, written consent was obtained. Patients were eligible for the study if they had a primary diagnosis of osteoarthritis of the hip or knee, it was their first time seeing an orthopaedic surgeon for this problem, and they had no history of a lower-extremity joint arthroplasty. Patients were ineligible if they could not read or speak English or had a previous appointment with another orthopaedic surgeon for evaluation of the arthritic hip or knee. Eligibility was also limited to patients who were considered medically appropriate for total joint arthroplasty on the basis of well-established clinical and radiographic criteria, including a history of pain refractory to nonoperative management and radiographic findings consistent with advanced osteoarthritis of the hip or knee.

Interventions

The interventions that we used were a combination of decision and communication aids of the type shown in systematic reviews to increase patient knowledge[9], question asking[10], and information recall[11]. The decision aid was a digital video disc (DVD) and booklet regarding the natural history and treatment alternatives for osteoarthritis of the hip and knee produced by the Informed Medical Decisions Foundation[12] and Health Dialog[13]. As opposed to most patient education materials that are commonly distributed by orthopaedic practices, which focus primarily on surgical treatment and outcomes, the decision aid explicitly compares the risks and benefits of surgical and non-surgical options in a balanced fashion. A second component of our intervention was a question-listing telephone consultation with a trained health coach to assist the patient in constructing a list of questions that he or she would like to ask his or her surgeon into an organized, focused, one-page document, with use of the Situation, Choices, Objectives, People, Evaluation, and Decisions (SCOPED) question-listing intervention previously investigated in the context of decision making by patients with cancer[14-17].

Procedures

Patients who were eligible and consented to participate in the study were randomized to either the intervention group or the control group with use of the sealed envelope method. The randomization was blocked with use of random permuted blocks in groups of four, six, or eight to help ensure that the groups were balanced.

Subjects randomized into the intervention group were mailed the decision aid to review before their consultation with the health coach. After the telephone appointment with the health coach, the health coach e-mailed the list of questions to the patient to review and to edit. The health coach brought printed copies of the patient's list of questions to the appointment for the surgeon and the patient. After the appointment, the health coach mailed subjects in the intervention group a compact disc audio recording of the consultation with the surgeon with a printed copy of the surgeon's dictated note to assist with information recall and deliberation of treatment options.

Subjects randomized into the control group were mailed existing materials used in the surgeons' practices to review before their appointment. These materials consisted of a map and directions to the clinic and a one-page informational handout about the signs and symptoms, diagnosis, and treatment options for hip and knee osteoarthritis. Control subjects were called the day before their appointment to confirm their appointment and to verify that they had received the materials.

Both groups of patients completed surveys (see Appendix) assessing their knowledge, preferences, and stage in decision making before and immediately after their initial consultation with the surgeon and again six weeks after their appointment. Surgeons also completed a short survey (see Appendix) immediately after the appointment, assessing their impressions of the consultation. For all study subjects, the health coach was present in the examination room during the consultation to audio record the consultation, to record the length of the patient's time in the examination room, to record the time that the surgeon spent in the examination room, and to make notes on observations regarding the interaction between the patient and the surgeon.

This trial is registered at ClinicalTrials.gov (NCT01492257). Full details of the trial protocol can be found at ClinicalTrials.gov.

Outcomes, Measures, and Instruments

Our primary outcome measure tracked whether patients arrived at an informed decision during their first visit with a surgeon. We defined "informed" as scoring above 50% on a previously validated knowledge survey[18]. This survey instrument tests nineteen basic facts related to osteoarthritis of the hip and knee (see Appendix). We measured whether patients had arrived at a decision by the number of patients who reported, at the end of their first visit, that they were at stage 3 ("have already chosen") on the previously validated stage of decision-making instrument[19,20]. Our hypothesis was that a higher proportion of patients in the intervention group would arrive at an informed decision during the first visit as a result of being more knowledgeable and being prepared for their visit, thus conserving resources while advancing quality. Our secondary outcomes included treatment choice, patient and provider satisfaction, and length of consultation time.

Statistical Analysis

In a prior non-randomized pilot study, we found that 80% of patients in the intervention group arrived at an informed decision after the first visit, compared with 40% in the control group[21]. On the basis of estimates of the eligibility and accrual rate among patients referred to the University of California, San Francisco and Stanford arthroplasty practices and our previous experience with the pilot study, we expected to enroll 120 patients over twelve months. In the pilot study, the estimated difference in the proportion of patients who had a positive primary outcome (being more informed and having higher knowledge) between the control group and the intervention group was 0.4 (the estimated proportion was 0.4 for the control group and 0.8 for the intervention group). With a sample size of sixty subjects per group, based on a two-sided, pooled Z-test of proportions at a significance level of $\alpha = 0.05$, we had just over 80% power to detect a significant difference if the increase in probability from baseline was 0.25 (0.40 versus 0.65) and 90% power if the increase was 0.29 (0.40 versus 0.69)[21,22]. Our planned sample size allowed us to have a high power with reduced effect sizes and to accommodate additional sources of variability, including multiple sites, surgeons, health coaches, and other predictors that could influence the primary outcome.

Our analysis was carried out in two stages. First, we used the Fisher exact test to compare the raw proportions of patients arriving at an informed decision during the first visit between the intervention and control groups. Second, we tested for potential confounding effects of additional predictors, such as stage of decision making, treatment decision, and number of months since initiation of the study, by fitting a multiple logistic regression model and by determining the significance of predictors individually, in additive combinations, and in interactions. As surgeons were not blinded to the intervention, we included calendar time as a predictor in the logistic regression model, which enabled adjustment for potential contamination in our study comparison, such as surgeons changing their behavior with control patients on the basis of their experiences with intervention patients. For secondary outcome measures, our exploratory analyses compared proportions between intervention and control groups with use of the Fisher exact test without adjustment for multiple comparisons.

Source of Funding

This work was supported by a grant from the Robert Wood Johnson Foundation (RWJF). Funds were used to pay for salaries, employee benefits, and other direct costs such as office operations, communications, meetings, travel, surveys, and contracts. The funding source did not play a role in the investigation.

Results

Patient Disposition

During the time period of the study, 733 new patients were scheduled for an appointment with one of two arthroplasty surgeons at the University of California, San Francisco (K.J.B.) or Stanford (J.I.H.); 40% were excluded after the initial review. Four hundred and forty-three patients were contacted and were assessed for eligibility by study staff; 135 patients (31%) did not meet inclusion criteria after telephone screening, seventy-five patients (17%) were unreachable by phone (patients were called up to five times by a research associate), and thirty-five patients (8%) declined to participate. One hundred and ninety-eight patients who consented to participate were randomized into either the intervention group (n = 95) or the control group (n = 103). Among the ninety-five patients randomized into the intervention group, eleven patients were excluded because there was insufficient time for the intervention, the patient canceled his or her appointment, or the patient chose to withdraw from the study, and twenty-three patients were withdrawn by the principal investigators because they did not have a primary diagnosis of osteoarthritis, they were not considered surgical candidates, they were deemed cognitively unfit to participate, or they had Workers' Compensation insurance. Among the 103 patients randomized to the control group, fourteen patients were excluded because they canceled their appointment or they chose to withdraw from the study, and twenty-seven patients were withdrawn by the principal investigators because they did not have a primary diagnosis of osteoarthritis, they were not considered a surgical candidate, they had already seen another surgeon for the hip or knee osteoarthritis, they were cognitively unfit to participate, or they had already participated in the shared decision-making study at the other study site. Sixty-one candidates in the intervention group and sixty-two candidates in the control group were included in the analysis (Fig. 1).

Patient Demographic Characteristics

Patient characteristics were similar in both groups (see Appendix). The majority of patients were over sixty years of age, were female, were non-Hispanic, had completed at least some college education, had earned more than $50,000 per year as reported in 2011 and 2012, and were insured by either private insurance or Medicare.

Primary Outcome

Thirty-five patients (58.3%) in the intervention group reached an informed decision during the first visit compared with twenty patients (33.3%) in the control group (p = 0.01) (Table I).

For each passing month in the study, we estimated a reduction of 9%, with a range of a reduction of 22% to an increase of 6%, in the odds of a patient experiencing the primary outcome (informed and in an advanced stage of decision making after the first visit) compared with a patient not experiencing the primary outcome (either not being informed enough or not being far enough along in the stage of decision making) (see Appendix). This odds ratio was not significantly distinguishable from zero, so the data are inconclusive with respect to whether or not there is an effect over time. This means that we did not statistically detect a contamination effect, as might have occurred if surgeons had been changing their counseling practices in the control group on the basis of their experiences with the intervention.

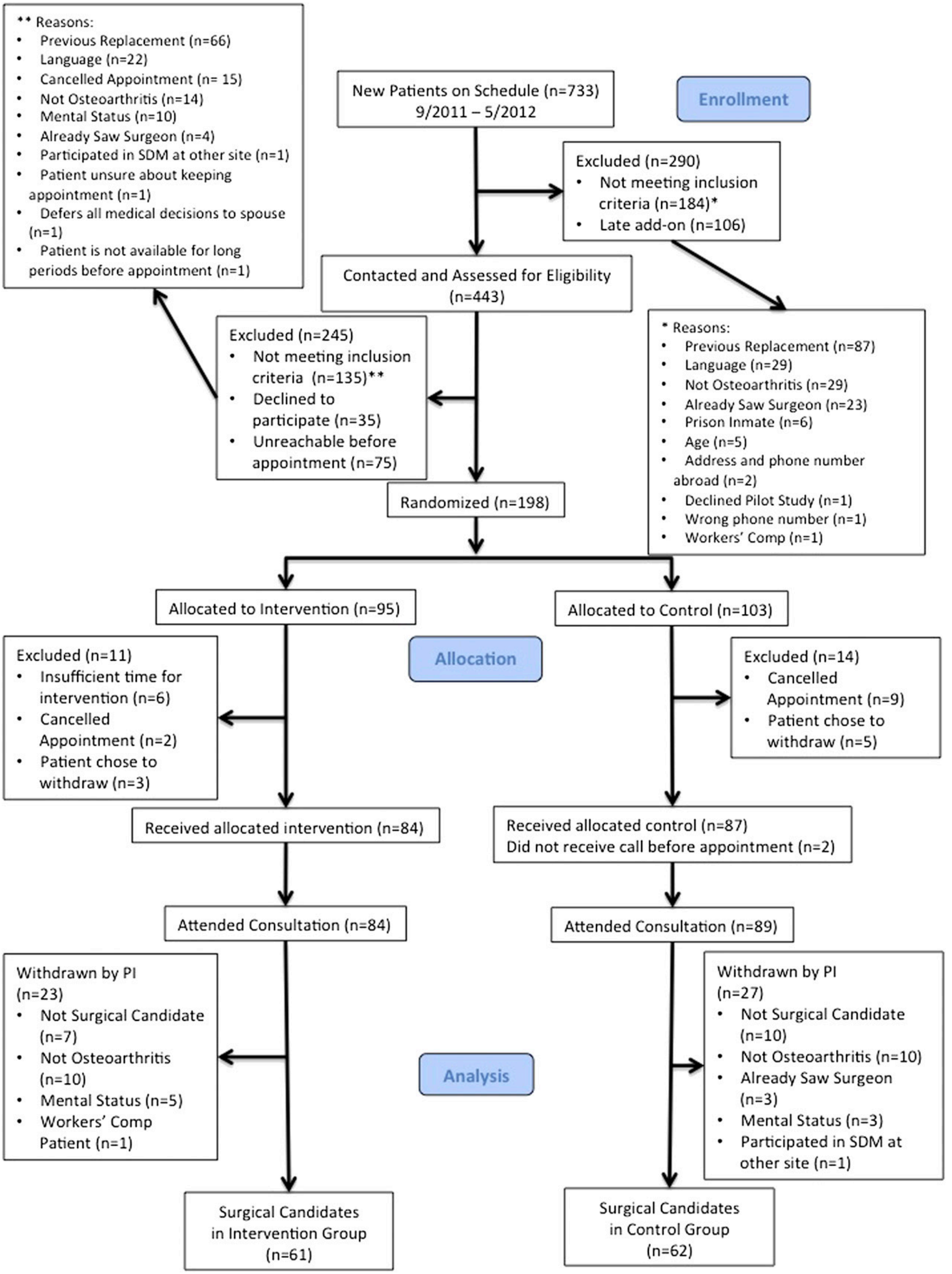

Fig. 1
A Consolidated Standards of Reporting Trials (CONSORT) diagram of participants. PI = principal investigator, SDM = shared decision making.

TABLE I Patients Who Arrived at an Informed Decision After the First Office Consultation*

	Control Group† (N = 60)	Intervention Group† (N = 60)
No informed decision	40 (66.7%)	25 (41.7%)
Informed decision‡	20 (33.3%)	35 (58.3%)

*Significance for both groups was set at p < 0.05. The p value for this comparison was p = 0.01. †The values are given as the number of patients, with the percentage in parentheses. ‡We are missing responses in this category, resulting in sixty patients in each group.

Secondary Outcomes

The intervention group reported significantly higher question self-efficacy, for example, confidence in knowing what questions to ask their doctor (p = 0.0034). A higher proportion of patients in the intervention group were at a higher stage of decision making immediately prior to their appointment, as evidenced by the fact that more patients in the intervention group reported that they had already chosen an option (25.0% in the intervention group versus 16.1% in the control group) or were close to choosing an option (26.7% in the intervention group versus 19.4% in the control group) before their appointment, although this difference did not reach significance (p = 0.06) (see Appendix). After the appointment, there was no significant difference (p = 0.48) between the intervention group (62.3%) and the control group (69.4%) in their choice of surgical or non-surgical treatment (see Appendix). Patients in both groups reported similarly high satisfaction (p = 0.17) with their consultation (see Appendix).

When comparing the intervention group with the control group, surgeons rated the appropriateness of questions asked by patients in the intervention group higher (p < 0.0001), thought that patients in the intervention group asked a greater number of appropriate questions (p < 0.0001), reported higher satisfaction with the efficiency of the intervention group visits (p < 0.0001), and were more satisfied overall with the intervention group visits (p < 0.0001) (see Appendix).

There was no significant difference in the average total time of the consultation (fifty-four minutes in the intervention group versus fifty-one minutes in the control group [p = 0.38]) or the average time that the patient spent face-to-face with the surgeon (twenty-one minutes in both groups [p = 0.91]) (see Appendix).

Discussion

Patients with hip or knee osteoarthritis who accessed decision and communication aids through a coaching intervention were more likely to reach an informed decision after their first visit with an orthopaedic surgeon. This finding has important implications for the adoption of shared decision-making programs, which promote patient engagement in their care, confidence in their decision making, and efficient use of resources such as patient and clinician time. Similar to previous investigators[6,9,23], we found that patients were more knowledgeable about the risks and benefits of various treatment alternatives for osteoarthritis of the hip or knee, were further along in their decision-making pre-consultation, and had more confidence in knowing what questions to ask their surgeon, on the basis of their responses to our pre-consultation survey. Surgeons also believed that patients who engaged in shared decision making asked more appropriate questions and made more efficient use of their time during their office visit. These findings could facilitate greater adoption of shared decision-making methods among orthopaedic surgeons, although many issues remain to be resolved.

Despite the well-documented benefits of shared decision-making tools, they are not commonly used in orthopaedic surgery. There are currently many barriers to adoption, including the costs and logistical challenges associated with the implementation of shared decision-making programs, lack of familiarity and training in shared decision-making methods among surgeons, and a limited comparative effectiveness research base available for developing decision aids[24,25]. To facilitate widespread adoption of shared decision-making tools in orthopaedics, further work is needed to simplify and to reduce the cost of implementation, perhaps through the use of non-medically trained volunteers as coaches. Moreover, many health-care stakeholders have portrayed shared decision making as reducing utilization rates[6,9] of elective surgical procedures such as total knee arthroplasty, which could make surgeons less eager to adopt these potentially value-enhancing tools, particularly in a fee-for-service payment system.

Contrary to the findings of Arterburn et al.[6], who used an observational study design, our randomized controlled trial found no significant difference in surgery rates between shared decision-making intervention and control patients. However, the investigators in that study reported that among patients with prevalent osteoarthritis of the hip or knee who were considered better surgical candidates, those patients who received decision aids were much more likely to choose operative treatment than those who did not. It should be noted that our study only included patients who were deemed to be medically appropriate for total joint arthroplasty on the basis of well-accepted clinical and radiographic criteria. However, our study was not powered to detect differences in utilization of surgical or non-surgical treatment, and we experienced differential loss to follow-up between the two groups that may have biased our results. Still, our findings, as well as the subgroup analysis from the study by Arterburn et al.[6], suggest caution in assuming that shared decision-making programs will lead to lower surgical utilization rates, particularly among patients who would be deemed medically appropriate for surgery. Even if shared decision-making programs do lead to lower surgical utilization rates, our results imply that surgeons may be able to practice more efficiently if they use decision and communication aids and coaching to help patients arrive at an informed decision during their first visit.

Our study had several notable limitations. We were limited to data from two surgeons (K.J.B. and J.I.H.) practicing at two academic medical centers in Northern California, with a high percentage of relatively affluent, well-educated patients. Additional study will be necessary to determine if our findings are generalizable to other surgeons in other practice settings. Because our study population was limited to patients with hip or knee osteoarthritis who were candidates for surgery, the eligibility of patients could not be confirmed until their visit with the surgeon, even though some shared decision-making interventions took place prior to the visit. This is a limitation and potential barrier to the use of decision and communication aids in patients with osteoarthritis in general, as the diagnosis is not always certain prior to referral to an orthopaedic surgeon. Also, because the study team interacted more with patients in the intervention group than those in the control group, we could have potentially overlooked more cognitive deficits in the control arm, leading patients in that arm to have more difficulty arriving at an informed decision during the first visit. The surgeons were not blinded to the intervention, and their favorable ratings may have arisen from a motivational bias to see the intervention succeed.

In summary, decision and communication aids used in orthopaedic surgical practice had beneficial effects to both patients and surgeons. These findings could be important in facilitating the adoption of shared decision-making tools into routine surgical practice. Future efforts will need to focus on facilitating the implementation of shared decision-making programs and incentives for patient and provider adoption of these potentially value-enhancing tools.

Appendix

eA Tables showing patient demographic characteristics, a comparison of intervention and control groups on secondary outcomes, and an analysis if the primary outcome (informed decision) was affected by additional potential sources of variability and a shared decision-making survey are available with the online version of this article as a data supplement at jbjs.org. ■

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