CLINICAL RESEARCH STUDY

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Use of a Decision Aid to Improve Treatment Decisions in Osteoporosis: The Osteoporosis Choice Randomized Trial

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ABSTRACT

OBJECTIVE: Poor adherence to therapy, perhaps related to unaddressed patient preferences, limits the effectiveness of osteoporosis treatment in at-risk women. A parallel patient-level randomized trial in primary care practices was performed.

METHODS: Eligible postmenopausal women with bone mineral density T-scores less than −1.0 and not receiving bisphosphonate therapy were included. In addition to usual primary care, intervention patients received a decision aid (a tailored pictographic 10-year fracture risk estimate, absolute risk reduction with bisphosphonates, side effects, and out-of-pocket cost), and control patients received a standard brochure. Knowledge transfer, patient involvement in decision-making, and rates of bisphosphonate start and adherence were studied. Data came from medical records, post-visit written and 6-month phone surveys, video recordings of clinical encounters, and pharmacy prescription profiles.

RESULTS: A total of 100 patients (range of 10-year fracture risk, 6%-60%) were allocated randomly to receive the decision aid (n = 52) or usual care (n = 48). Patients receiving the decision aid were 1.8 times more likely to correctly identify their 10-year fracture risk (49% vs 28%; 95% confidence interval [CI], 1.03-3.2) and 2.7 times more likely to identify their estimated risk reduction with bisphosphonates (43% vs 16%; 95% CI, 1.3-5.7). Patient involvement improved with the decision aid by 23% (95% CI, 13.6-31.4). Bisphosphonates were started by 44% of patients receiving the decision aid and 40% of patients receiving usual care. Adherence at 6 months was similarly high across both groups, but the proportion with more than 80% adherence was higher with the decision aid (n = 23 [100%] vs n = 14 [74%]; $P = .009$).

CONCLUSION: A decision aid improved the quality of clinical decisions about bisphosphonate therapy in at-risk postmenopausal women, did not affect start rates, and may have improved adherence.

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Osteoporosis or osteopenia affects approximately 44 million people aged 50 years or more in the United States.[1] Adherence to effective treatment could reduce the morbidity and mortality of this condition, particularly among postmenopausal women.[2-5] Bisphosphonates can reduce the risk of fractures in postmenopausal women,[6] but 50% of patients prescribed these agents in oral form discontinue therapy within 1 year.[7,8]

The treatment of osteoporosis has evolved to include an estimation of a patient's risk of an osteoporotic fracture in the next 10 years.[1] This estimate considers not only the bone mineral density results (the main guide to therapy in the recent past) but also the personal and family history that has been shown to affect fracture risk.[9] Clinicians can now avoid the technical language of bone mineral density "T-scores" that limits access to patient participation in treatment decisions[10] and focus on estimated fracture risk, a patient-important outcome.[11]

CLINICAL SIGNIFICANCE

- Treatment nonadherence limits the effectiveness of osteoporosis treatment.
- A decision aid for use during the consultation improved postmenopausal women's knowledge about their fracture risk and pros/cons of treatment and their participation in osteoporosis treatment decisions.
- Approximately half of the patients in each of the fracture risk categories chose to take bisphosphonates; the decision aid had weak, if any, impact on treatment uptake or 6-month medication adherence.

Decision aids are evidence-based tools that facilitate decision-making by describing the available options and their salient attributes. Their use in clinical consultations has led to improvements in measures of the quality of treatment decisions for pharmacologic preventive interventions.[12] In promoting deliberation, these aids could help explore and clarify patient preferences and improve knowledge of the safety and efficacy of bisphosphonates, aspects that have been related to bisphosphonate adherence.[13-15] Thus, decision aids offer a simple, low-cost, and potentially effective way to improve poor adherence to bisphosphonates. Currently, there are only limited data supporting the use of decision aids in general for improving adherence to medications.[16]

We have developed the Osteoporosis Choice decision aid following a previously reported approach for decision aids in general,[17,18] and of this one in particular.[19] This study sought to evaluate its efficacy when used in the primary care of postmenopausal women at risk for osteoporotic fractures.

MATERIALS AND METHODS

Design

To evaluate the decision aid, we conducted a multicenter randomized trial. All study procedures were approved by the Mayo Clinic Institutional Review Board. The protocol for this trial has been reported in full.[19] A summary of our methods follows.

Setting and Participants

We conducted the trial in 10 general medicine and primary care practices affiliated with the Mayo Clinic and located within a 60-mile radius of Rochester, Minnesota. Eligible patients were postmenopausal women, age 50 years and more with bone mineral density levels consistent with a diagnosis of low bone mass (osteopenia) or osteoporosis, who were not already taking bisphosphonates or other prescription osteoporosis medications (other than vitamin D and calcium), who their clinicians found eligible for bisphosphonate therapy and had a follow-up appointment with that clinician, and who were available for a phone follow-up 6 months after randomization. Women who could not read English or had, in their clinicians' judgment, major learning barriers such as visual or hearing impairment or dementia that would compromise their ability to give written informed consent (or use the decision aid) were excluded from this trial.

Interventions

The Osteoporosis Choice decision aid provides the patient's individualized 10-year risk estimate risk of having a major osteoporotic fracture (ie, clinical ["symptomatic"] spine, forearm, hip, or shoulder fracture), calculated using data from the patient's medical record (completed by direct query to patient or clinician as needed) using the online FRAX tool as implemented during the course of the study. Fracture risk was presented in 1 of 3 categories selected arbitrarily: less than 10%, 10% to 30%, and greater than 30% 10-year fracture risk (Figure 1). The decision aid also showed the absolute risk reduction in fracture risk with alendronate, assuming a treatment-related reduction in overall osteoporotic fracture risk of 40%.[20] In addition, the decision aid described the potential downsides of taking bisphosphonates. The decision aid also prompted further discussion with the question "What would you like to do?" Patients were not to have access to the decision aid before the consultation, clinicians were to discuss the decision aid with intervention patients during the consultation, and patients took the decision aid home.

In addition to usual care (ie, review of bone mineral density results without fracture risk calculation or graphic representation of treatment benefit), patients randomized to the control group received the National Osteoporosis Foundation booklet, "Boning Up On Osteoporosis: A Guide To Prevention and Treatment."

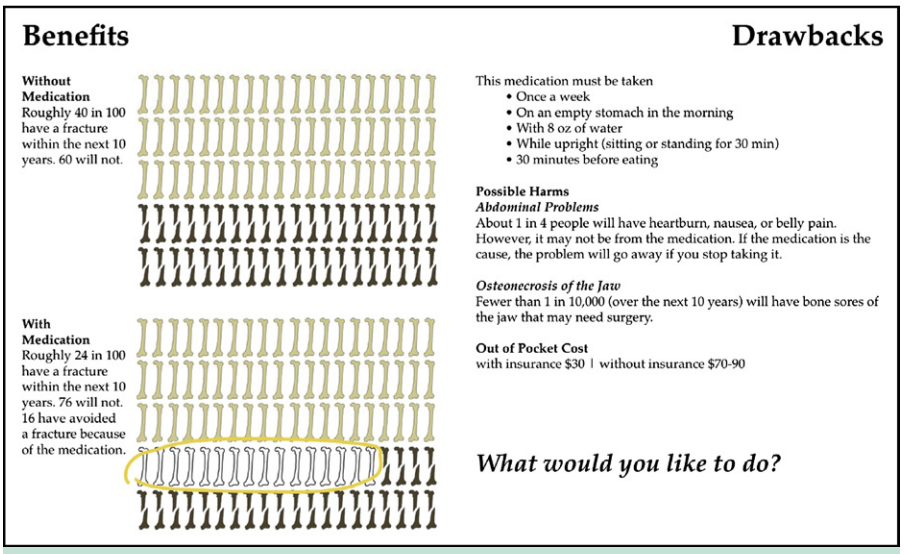

Figure 1 Osteoporosis Choice decision aid for a patient with a 10-year fracture risk of 50%.

Randomization

A computer-generated allocation sequence randomized patients 1:1 in a concealed fashion (using a secure study website) to control (usual care + booklet) or intervention (Osteoporosis Choice decision aid). After randomization, data collectors and data analysts were blind to allocation.

Outcomes and Data Collection

Data collection included medical record review, post-visit questionnaires for patients and clinicians, analysis of video recordings of the visits where patients and physicians agreed to be recorded, and pharmacy prescription profiles and follow-up telephone interviews to assess medication starts and adherence at 6 months. The patient questionnaire assessed patient knowledge, satisfaction with knowledge transfer, and decisional quality (using the 16-item Decisional Conflict Scale[21]). We scored each video recorded visit using the OPTION scale,[22] which allows an observer to quantify the extent to which clinicians are able to involve patients in the decision-making process. We also assessed trust using the Trust in Physician Scale.[23] The clinician's survey asked which decision the patient made, the clinician's confidence in that patient's understanding of the information offered, and the clinician's prediction of patient action (start and adherence to bisphosphonates at 6 months). We used a 12-item checklist to the video-recorded encounters to determine fidelity (use of the decision aid as planned) in encounters using the decision aid and contamination (clinicians who have used the decision aid with a patient recreating elements of the aid when seeing a control patient) in encounters not using the decision aid.[19]

To assess medication adherence at 6 months, we telephoned patients and asked Haynes' single-item adherence question ("Have you missed any of your pills in the last week?").[24,25] We also obtained pharmacy records to assess adherence and persistence to oral bisphosphonates[26,27] and estimated the proportion of patients who had 80% or greater adherence to bisphosphonates.

Statistical Considerations

Given our resources, we set out to enroll 100 patients. We estimated that this sample size could provide 92% power (assuming equal variances between groups, $\alpha = 0.05$) to detect a gain in 2 of 9 specific knowledge questions answered correctly (assuming the control group would answer 4 questions correctly) and have 80% power ($\alpha = 0.05$) to detect a 35% improvement in 6-month adherence rates from 65% to 88%.[19]

With randomization at the patient level and a low patient-to-clinician ratio, adjusting for clustering by clinician was not needed. Because few physicians had more than 1 patient in the study, we explored possible clinician contamination descriptively (Appendix, online). Hypotheses were tested using Wilcoxon rank-sum tests to compare medians and chi-square or Fisher exact tests to compare frequencies. All analyses were based on 2-sided tests at significance level of 0.05. Consistent with the intention-to-treat principle,[28] we sought to avoid missing data, and all patients were analyzed in the arm to which they were randomized. All analyses were computed using SAS (SAS Institute, Inc, Cary, NC).

Role of the Funding Source

This trial was funded by the Mayo Clinic Foundation for Medical Education and Research. The funding source had no role in the design, conduct, or decision to publish results of this trial.

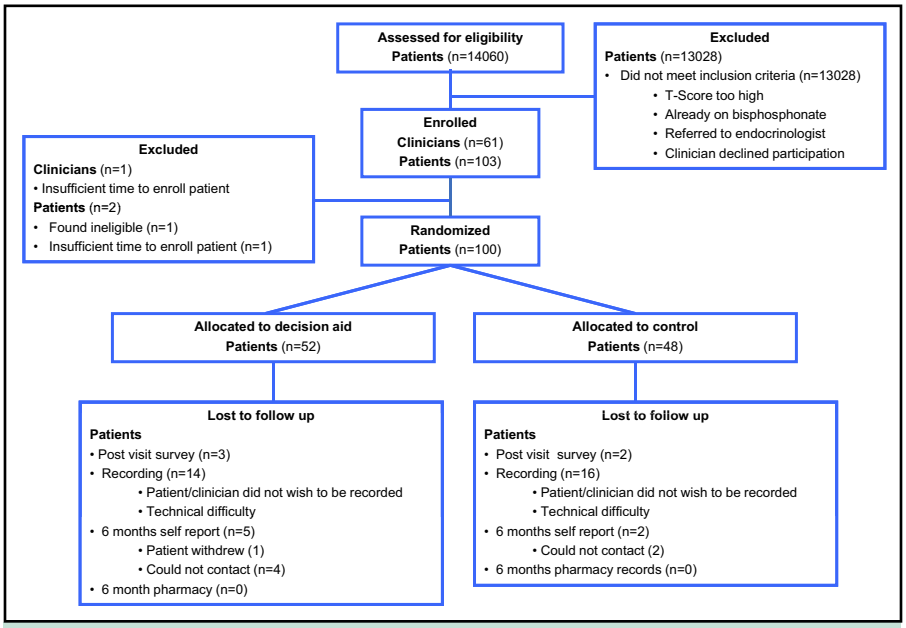

Figure 2 Flow of participants through the trial.

RESULTS

From August 2007 to July 2008, we randomized 100 patients into the study (Figure 2). All patients were followed for 6 months after the visit date, except for 7 who were lost to follow-up (decision aid, n = 5; control, n = 2). Table 1 describes the patients by study arm. Although 13 clinicians enrolled more than 1 patient, only 5 enrolled more than 2. Of the 70 patients with video analysis, the median (range)

Table 1 Baseline Characteristics of Trial Participants

	Decision Aid	Usual Care
Primary care clinicians	N = 39	N = 33
Patients	N = 52	N = 48
Annual income in US$1000, median (interquartile range)	50 (25-90)	35 (25-70)
Achieved high school education or greater, n (%)	50 (96)	46 (96)
Self-reported health (100 on feeling thermometer = best possible health), median (range)	90 (50-100)	85 (40-100)
Osteoporosis risk factors		
Age, median (range)	67 y (51-84)	67 y (50-82)
Body mass index, median (range)	27.8 (18.4-41.8)	26 (17.1-46.5)
Past bone fracture, n (%)	23 (44)	22 (46)
Parent had fragility fracture/hip fracture, n (%)	17 (33)/6 (12)	14 (30)/6 (13)
Past use of corticosteroids, n (%)	9 (18)	12 (25)
Past or current smoker, n (%)	25 (48)	24 (50)
Past or current alcohol user, n (%)	31 (60)	30 (65)
T-score left hip femoral neck, median (range)	−1.80 (−3.7-−0.7)	−1.65 (−3.1-−0.9)
T-score right hip femoral neck, median (range)	−1.90 (−2.9-−0.8)	−1.60 (−3.3-−0.5)
T-score total spine, median (range)	−1.60 (−4.0-0.2)	−1.65 (−3.4-1.0)
10-y fracture risk		
Major fragility fracture, median (range)	19 (6.1-39)	16.5 (5.9-56)
Hip fracture, median (range)	2.05 (0.6-18)	2.50 (0.6-20)
Risk category, n (%)		
<10%	2 (3.9%)	4 (8.3%)
10%-30%	40 (76.9%)	29 (60.4%)
>30%	10 (19.2%)	15 (31.3%)

duration of osteoporosis discussions was 12.4 minutes (2.3-27.4) in the decision aid arm compared with 9.4 minutes (2.1-58) in the usual care arm ($P = .045$).

Contamination and Fidelity

The Appendix (online) describes the checklist and the results of the contamination and fidelity evaluation. Of 12 maximum points, encounters in the decision aid arm had a fidelity score of 8 (3-12), whereas encounters in the usual care arm had a contamination score of 1 (0-8). Usual care encounters of clinicians who had used the decision aid previously had a contamination score of 1 (0-6).

Satisfaction with Knowledge Transfer, Decisional Conflict, and Trust

Patients receiving the decision aid were satisfied with this mode of information transfer to the same extent as patients in usual care encounters (Table 2). Patients also reported similar levels of decisional conflict (which was, on average, very low) and trust in their clinician (which was, on average, very high).

Knowledge Transfer

Patients receiving the decision aid were able to answer approximately 2 more of 9 questions correctly than patients in the control group (Table 2). Patients in the decision aid arm also were more likely to correctly estimate their 10-year risk of fracture (24/49, 49% correct) and the expected risk reduction with bisphosphonates (21/29, 43% correct) compared with patients receiving usual care (12/43 [28%] and 7/43 [16%], respectively). Indeed, compared with usual care patients, those receiving the decision aid were approximately twice as likely to correctly identify their 10-year fracture risk (relative risk 1.8; 95% CI, 1.03-3.15) and approximately thrice as likely to correctly identify the estimated risk reduction with bisphosphonates (relative risk 2.69; 95% CI, 1.27-5.72).

Patient Involvement

Analysis of the video-recorded visits (38 decision aid visits and 32 usual care visits) revealed that patient involvement in clinical decision-making was significantly more intense (Table 3), approximately double, in the decision aid arm than in the usual care arm as judged by the OPTION scale (interobserver agreement for the OPTION scale score was 0.97).

Clinicians' Views

Primary care clinicians considered that the quality of the decision-making process facilitated by the decision aid was superior to usual care (Table 4). They also expressed significantly greater satisfaction with the knowledge transfer process the decision aid facilitated than the usual care process.

Medication Starts, Adherence, and Persistence

Of the 100 patients in the trial, 45 stated on the baseline survey that they were going to start bisphosphonates, but 6 had no prescription in their pharmacy record and 2 received intravenous bisphosphonate. Another 7 patients answered "no" or delayed their decision to start treatment on the baseline survey, yet ended up with a prescription filled on their pharmacy records or, in the case of 1 patient, receiving intravenous bisphosphonate. For adherence analyses, we used data from the 42 patients with prescriptions on their pharmacy record. The distribution of prescriptions was similar across risk groups (Table 5) and study arms, with approximately half the patients receiving a prescription for oral bisphosphonates. At 6 months, no additional patients had decided to start bisphosphonates. However, 5 patients in the decision aid arm (side effects [2], cost [1], doubts about benefit [1], and "personal choice" [1]) and 3 patients in the usual care arm (side effects in all) had decided to stop bisphosphonate therapy.

Most patients exhibited optimal medication adherence and persistence at 6 months. Analyses of adherence or persistence did not show any significant effect of the decision aid on 6-month adherence to bisphosphonates among

Table 2 Satisfaction with Knowledge Transfer, Decisional Conflict, Trust, and Knowledge

	Decision Aid Median (Range) Mean	Usual Care Median (Range) Mean	Mean Difference (95% CI)	*P* Value*
Satisfaction with knowledge transfer				
Amount of information	7 (4-7) 6.6	7 (1-7) 6.3	0.22 (−0.28-0.73)	.798
Clarity of information	6 (2-7) 6	6 (1-7) 6	0.36 (−0.22-0.96)	.296
Helpfulness of the information	6 (2-7) 6	6 (1-7) 5.8	0.22 (−0.36-0.8)	.624
Would want other decisions	7 (1-7) 6.1	7 (2-7) 5.8	0.37 (−0.25-0.98)	.248
Recommend–others	7 (1-7) 6.4	7 (4-7) 6.2	0.18 (−0.28-0.65)	.435
Conflict, trust, and knowledge				
Decisional conflict scale	10.9 (0-51.6) 14.4	13.3 (0-58.3) 16.2	−1.84 (−7.8-4.1)	.725
Trust in physician scale	100 (69-100) 96.7	100 (75-100) 97.2	−0.45 (−3.2-2.30)	.462
Knowledge questionnaire				
DA specific (9 questions)	6 (0-9) 5.7	4 (0-8) 3.9	1.77 (0.77-2.77)	**.001**
Not in the DA (4 questions)	2 (0-4) 1.8	1.5 (0-4) 1.5	0.25 (−0.29-0.79)	.351

DA = decision aid.
*Wilcoxon rank-sum test; **bold type** reflects statistically significant results.

Table 3 Patient Involvement in Decision-making About Medications

	Decision Aid Median (Range) Mean	Usual Care Median (Range) Mean	Mean Difference (95% CI)	*P* Value of Difference in Means
OPTION scale on recorded visits (100-point scale)				
Provider draws attention to an identified problem as one that requires a decision-making process	2.5 (1-4) 2.5	2.0 (0-4) 1.8	0.67 (0.2-1.1)	**.005**
Provider states that there is > 1 way to deal with the identified problem	2.0 (0-4) 2.0	1.0 (0-3) 1.0	1.05 (0.6-1.5)	**<.001**
Provider assesses patient's preferred approach to receiving information to assist decision-making	1.0 (0-3) 1.6	0 (0-3) 0.5	1.01 (0.6-1.4)	**<.001**
Provider lists "options," which can include the choice of "no action"	1.0 (0-4) 2.3	1.0 (0-3.5) 1.1	1.19 (0.7-1.7)	**<.001**
Provider explains the pros and cons of options to the patient	1.0 (0-4) 2.4	1.0 (0-4) 1.2	1.27 (0.8-1.8)	**<.001**
Provider explores the patient's expectations about how the problem is to be managed	2.0 (0-4) 2.0	1.0 (0-3) 1.0	1.01 (0.6-1.4)	**<.001**
Provider explores the patient's concerns about how problems are to be managed	2.0 (0-4) 1.7	1 (0-3) 1.1	0.62 (0.2-1.1)	**.010**
Provider checks that the patient has understood the information	1.5 (0-3) 1.4	1.0 (0-3) 0.7	0.68 (0.3-1.1)	**.001**
Provider offers the patient explicit opportunities to ask questions during decision-making process	2.0 (0-4) 2.0	1.0 (0-4) 1.5	0.57 (0.1-1.1)	**.026**
Provider elicits the patient's preferred level of involvement in decision-making	2.0 (0-4) 1.8	1.0 (0-2) 0.7	1.16 (0.7-1.6)	**<.001**
Provider indicates the need for a decision-making stage	2.0 (0-4) 2.2	1.0 (0-4) 1.2	1.02 (0.5-1.5)	**<.001**
Provider indicates the need to review the decision	2.0 (0-4) 1.9	1 (0-3) 1.1	0.78 (0.2-1.3)	**.016**
Total observer OPTION score	48 (9-90) 49.8	27 (6-79) 27.3	22.5 (13.6-31.4)	**<.001**

Bold type reflects statistically significant results.

the patients receiving a prescription at the conclusion of the visit, although there was a significant trend toward improved adherence in patients receiving the decision aid when the analysis was dichotomized at 80% of days covered (Table 5).

DISCUSSION

Our Findings

In this trial, we found that the decision aid improved knowledge transfer and patient involvement in decision-making with adequate patient and clinician satisfaction, but with weak or no effect on medication start and adherence.

Limitations and Strengths

This was a small trial, rendered even smaller for the purposes of adherence analyses by the relatively low proportion of patients opting to take bisphosphonates. The decision aid itself seemed successful at improving knowledge transfer, but knowledge remained low in both groups. The study was conducted by personnel who participated in the development of the decision aid and among clinicians affiliated with an academic medical center. On the other hand, we conducted this work in otherwise usual primary care practices, with the expected time pressures and expertise of primary care clinicians regarding osteoporosis treatment. We used adequate randomization and allocation concealment and

Table 4 Primary Care Clinician Responses

	Decision Aid Median (Range) Mean	Usual Care Median (Range) Mean	Mean Difference (95% CI)	*P* Value
Perception of decision quality (7-point scale)				
Patient made an informed choice	5 (3-5) 4.5	4 (2-5) 4.0	0.52 (0.27-0.78)	**<.001**
Patient's decision shows what is important to the patient	4 (3-5) 4.2	4 (2-5) 4.0	0.27 (0.01-0.54)	.053
Provider expects patient to stick with decision	4 (3-5) 4.3	4 (3-5) 4.0	0.34 (0.07-0.60)	**.013**
Provider believes patient is satisfied with decision	4 (3-5) 4.3	4 (3-5) 4.1	0.25 (0.01-0.49)	**.029**
Satisfaction with knowledge transfer (7-point scale)				
Helpfulness of the information	6 (3-7) 5.8	5 (2-7) 5.2	0.64 (0.18-1.09)	**.006**
Would want other decisions	6 (4-7) 6.1	5 (1-7) 4.9	1.2 (0.73-1.67)	**<.001**
Recommend to others	6 (3-7) 5.9	5 (1-7) 4.8	1.09 (0.57-1.61)	**<.001**

Bold type reflects statistically significant results.

Table 5 Decision to Use Bisphosphonates and Adherence to Medications at 6 Months After Study Visit

	Decision Aid	Usual Care	*P* Value
Started bisphosphonates	N = 52	N = 48	
<10%, n (% in risk category in arm)	1 (50)	1 (25)	
10%-30%, n (% in risk category in arm)	18 (45)	13 (45)	
>30%, n (% in risk category in arm)	4 (40)	5 (33)	
Total, n (% in arm)	23 (44)	19 (40)	
Adherence: self-report*	N = 17	N = 19	
Did not miss a dose, n (%)	11 (65%)	12 (63%)	.92
Adherence: pharmacy records†	N = 23	N = 19	
Persistence: No. of days covered, median (range)	170 (30-180)	180 (28-180)	.38
Adherence: proportion of days covered (%), median (range)	100 (86.1-100)	98.2 (0-100)	.09
Adherence: pharmacy records†	N = 23	N = 19	
Adherence: >80% d covered, n (%)	23 (100%)	14 (74%)	**.009**

*Thirty-six patients with the 6-month phone survey and answered yes to currently taking a medication.
†Forty-two patients with prescriptions for bisphosphonates in the pharmacy data; **bold type** reflects statistically significant results.

blinding of data collectors and analysts, and kept the results unconfounded by contamination and poor fidelity. Video recording of the visits provided important practical information regarding the duration of the consultation with and without the decision aid, and about the impact the tool had on the ability of clinicians to engage patients in decision-making. Finally, to our knowledge, this is the first report of results from a randomized trial of a decision aid in osteoporosis treatment.

Implications for Policy, Practice, and Research

The use of decision aids to improve adherence to therapy is in its infancy, and it is yet unclear that these tools will have a profound or lasting influence on the component of adherence to therapy that relates to beliefs, knowledge, and attitude. In this context, the results of this small trial are encouraging and justify greater exploration of this tool in other populations, including those with limited health literacy.

The relative insensitivity of patients to their estimated risk of fracture, judged by the relatively similar rate of bisphosphonate uptake across risk groups and the relatively low uptake rate in the high risk group, suggests that the interplay of values and preferences that postmenopausal women have in relation to osteoporotic fracture prevention deserve further exploration. Is it possible that some of these patients require a greater risk of fracture than currently deemed cost-effective for bisphosphonates (>20% at 10 years) to justify treatment or that their perception of their own vulnerability to fractures remains unaffected by the risk presentation? In developing the decision aid, we had to remove the label "osteoporosis" because most of the at-risk women who participated in developing the tool rejected the notion that they could have a disease, in part because they embodied a much-promoted lifestyle: Most were nonsmoking, thin, and active women. Also, some women may perceive bone thinning as part of the natural aging process and accept fractures as the inevitable result. Further work in this area, which will include an in-depth analyses of the dialogues that took place in the video-recorded visits during this trial, is planned.

Shared decision-making has been touted as an appropriate tactic to translate evidence into practice in a patient-centered way. However, current guidelines do not seem to embrace this concept in a wholehearted fashion. Even advocates of shared decision-making would consider the decision to start bisphosphonates in at-risk patients to be a component of "effective healthcare" rather than "preference-sensitive care" amenable to patient involvement. It is our proposition that some effective treatments, particularly preventive treatments that require frequent patient self-administration, require adequate patient adherence to ensure the promised positive balance of benefits versus harms and costs. In these instances, patient involvement in decision-making may improve adherence and increase the value of healthcare, and in turn justify investments in shared decision-making. However, the extent to which this is true remains uncertain. Current efforts to promote patient involvement through legislation, tool development and certification, and definition of meaningful use of health information technology could be justified, at this time, mostly by the ethical imperative of patient autonomy and patient-centered care. Further research is still necessary to support the position of those who require evidence in support of utilitarian arguments (eg, or that it reduces costs or malpractice risks) to promote and implement shared decision-making. Those supporting utilitarian arguments in support of shared decision-making may find, however, the additional 3 minutes that using this decision aid added to primary care visits unacceptable.

CONCLUSIONS

Our decision aid, Osteoporosis Choice, improves the quality of clinical decisions about bisphosphonate therapy in postmenopausal women at risk of osteoporotic fractures by

improving knowledge transfer and patient involvement. However, medication start rates were similar across risk groups, and medication adherence results were mixed with a trend toward improved adherence in patients receiving the decision aid.

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Conflict of Interest: The authors of this article disclose no financial conflicts of interest pertinent to this trial. In particular, the decision aid described in this article is in the public domain and can be obtained from the authors without charge. The authors, their relatives, or other associates have not initiated any business to profit from this decision aid (or any other decision aid they have developed and studied) or the dissemination of the results of this trial, beyond the usual benefits of academic recognition. The authors or any member of the team who participated in the development or evaluation of the decision aid have not received financial support from pharmaceutical companies that market bisphosphonates or their competitors. The KER UNIT, a laboratory within the Mayo Clinic where the study was conceived, run, and analyzed, and this report was prepared, had explicit rules in place before, during, and at the time of writing this note against receiving any funding from for-profit pharmaceutical or device manufacturers.