

Helping Patients With Type 2 Diabetes Mellitus Make Treatment Decisions

Statin Choice Randomized Trial

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Background: Poor quality of information transfer about the benefits and risks of statin drug use may result in patients not making informed decisions that they can act on in a timely fashion.

Methods: The effect of a decision aid about statin drugs on treatment decision making in 98 patients with diabetes was determined in a cluster randomized trial of decision aid vs control pamphlet, with concealed allocation, blinding of participants to study goals, and adherence to the intention-to-treat principle. Twenty-one endocrinologists conducted specialty outpatient metabolic consultations. Patients in the intervention group received *Statin Choice*, a tailored decision aid that presents the estimated 10-year cardiovascular risk, the absolute risk reduction with use of statin drugs, and the disadvantages of using statin drugs. Patients in the control group received the institution's pamphlet about cholesterol management. We measured acceptability, knowledge about options and cardiovascular risk, and decisional conflict immediately after the visit, and adherence to pill taking was measured 3 months later.

Results: Patients favored using the decision aid (odds ratio [OR], 2.8; 95% confidence interval [CI], 1.2-6.9); patients who received the decision aid (n=52) knew more (difference, 2.4 of 9 points; 95% CI, 1.5-3.3), had better estimated cardiovascular risk (OR, 22.4; 95% CI, 5.9-85.6) and potential absolute risk reduction with statin drugs (OR, 6.7; 95% CI, 2.2-19.7), and had less decisional conflict (difference, -10.6; 95% CI, -15.4 to -5.9 on a 100-point scale) than did patients in the control group (n=46). Of 33 patients in the intervention group taking statin drugs at 3 months, 2 reported missing 1 dose or more in the last week compared with 6 of 29 patients in the control group taking statin drugs (OR, 3.4; 95% CI, 1.5-7.5).

Conclusions: A decision aid enhanced decision making about statin drugs and may have favorably affected drug adherence.

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BECAUSE PATIENTS WITH DIABETES are at increased cardiovascular risk¹ and because valid and consistent evidence from large randomized trials supports the efficacy of statin drugs in reducing this risk,^{2,3} current guidelines recommend statin drugs in all patients with diabetes.¹ Nevertheless, many studies have documented limited adherence to statin drug regimens.^{4,5}

Low statin use may result from a lack of adequate patient involvement in the decision to use the medication. *Decision aids*, tools that present tailored evidence-based estimates (ie, best available information for the group that the patient belongs to) of benefits and disadvantages (adverse effects and burden of treatment) of the available treatment options, can improve knowledge and involve-

ment in the decision. In this article, we define a good decision as an informed decision that patients act on in a timely fashion. Randomized trials have demonstrated that decision aids can be helpful in achieving this goal.⁶ Of the nearly 400 aids in the Cochrane inventory, there are none specifically designed for patients with diabetes who are considering statin use,⁶ and, to our knowledge, no randomized trials have evaluated decision aids addressing statin use in patients with diabetes.⁶

We designed and tested the *Statin Choice* decision aid to present the best available information about the patient's cardiovascular risk and the potential benefits and disadvantages of statin therapy. We conducted a randomized trial of this tool in a subspecialty setting to determine its acceptability to patients, effect on patient knowledge of the infor-

1 What is your risk of having a heart attack in the next 10 years?

Using information about your health we've estimated that you have a **15-30%** chance of having a heart attack sometime in the next 10 years. This table shows you how we estimated this risk.

In addition you are lowering your cardiovascular risk by regularly using **metformin and gemfibrozil (Lopid)**.

| Your risk | <15% | 15-30% | >30% |
|-----------------------|------------------|----------------|-------------|
| Gender | woman | man | man |
| Age | 60 or younger | 60-75 | 75 or older |
| Had diabetes for | less than 10 yrs | 10 or more yrs | |
| Have protein in urine | no | no | yes |
| Latest A1c | <6% | 6-7% | >7% |
| Usual blood pressure | <120 | 120-140 | >140 |
| Total/HDL cholesterol | <4 | 4-6 | >6 |
| Smoking | non-smoker | ex-smoker | smoker |

WHAT DOES THIS ESTIMATE MEAN?

It means that out of 100 people like you, about 20 will have a heart attack in the next 10 years, and about 80 will not.

Keep in mind that we do not know what will happen to you; if you were to have a heart attack we cannot tell when this will happen.

2 What benefit can you expect from taking statins compared to not taking statins?

NO STATIN

Our guess of what will happen to 100 people like you if they were to decide NOT to take statins; out of 100 people like you, about 20 will have a heart attack in the next 10 years, and about 80 will not.



YES STATIN

Our guess of what will happen to 100 people like you if they were to decide to take statins; out of 100 people like you, about 15 will have a heart attack in the next 10 years and about 85 will not. About 5 people will avoid a heart attack by taking statins; about 95 did not change their outcome by taking statins.



- had a heart attack
- avoided a heart attack
- didn't have a heart attack

ATTENTION!

If you were to decide to take statins, we will not know if you would be among those who would not benefit (either by having a heart attack or by having one despite taking statins regularly) or those who would benefit (by avoiding a heart attack by taking a statin.)

3 What downsides can you expect from taking statins compared to not taking statins?

- Statins need to be taken daily for years.
- Some statins may cost less to you depending on your drug plan.
- **Common side effects:** nausea, diarrhea, constipation (most patients can tolerate)
- **Muscle aching/stiffness:** 5 in 100 patients (some need to stop statins because of this)
- **Liver enzymes go up** (no pain, no permanent liver damage); 2 in 100 patients (some need to stop statins because of this)
- **Muscle and kidney damage:** 1 in 20,000 patients (requires patients to stop statins)

4 What do you want to do now?

- Take (or continue to take) statins
- Not take (or stop taking) statins
- Discuss with your clinician today
- Discuss with your clinician in the future
When? _____
- Discuss with others
Who? _____

Figure 1. Personalized *Statin Choice* decision aid for a hypothetical patient with an estimated 10-year cardiovascular risk of 20%. HDL indicates high-density lipoprotein. Reproduced with permission from the Mayo Foundation for Medical Education and Research. All rights reserved.

mation about the potential merits and demerits of the options, and decisional conflict.

METHODS

SETTING

The trial took place in the metabolic clinic at the Mayo Clinic, Rochester, Minn. This referral clinic provides one-off consultations for about 5 patients with diabetes and dyslipidemia per half-day. The Mayo Clinic Institutional Review Board approved the protocol.

PARTICIPANTS

Consenting endocrinologists (faculty and fellows) scheduled to staff the metabolic clinic participated in the trial. Eligible patients had type 2 diabetes mellitus, were referred to the clinic, had no contraindications to statin use, were able (had no major hearing, visual, or cognitive impairment or did not require translation) and willing to provide informed consent, and were available for follow-up at 3 months. The informed consent document kept participants and clinicians blinded to the study objectives.

INTERVENTIONS

The experimental intervention was the *Statin Choice* decision aid; the control intervention was a Mayo Clinic standard educational pamphlet about cholesterol management. The *Statin Choice* 1-page decision aid included the patient's name, cardio-

vascular risk factors, and 1 of 3 levels of baseline 10-year cardiovascular risk: 10% for patients with 10-year cardiovascular risk less than 15%,⁷ 20% for patients with estimated risk between 15% and 30%, and 50% for patients with estimated risk greater than 30%. The decision aid also showed the absolute risk reduction with statins and the potential disadvantages of taking statins (**Figure 1**). A question prompted patients to express whether they were ready to make a decision and, if so, whether they wanted to take or not take statins, to discuss the issues with their primary care clinician or another important person, or to delay the decision until some other time. A multiple-page pamphlet provided detail with visual links to the tailored 1-page version, facilitating patient review of the material after the visit. The decision aid was developed with extensive input from patients with diabetes from the community and clinicians, both endocrinologists and primary care clinicians, and was extensively pilot-tested with patients and clinicians who did not participate in the trial. The control intervention, the Mayo pamphlet, defined lipid disorders and provided dietary guidelines for control of cholesterol along with general statements encouraging exercise and smoking cessation.

ALLOCATION PROCEDURE

A computer-generated allocation sequence, unavailable to personnel enrolling patients, randomized providers to intervention (decision aid) or control groups, stratified by sex and status (fellow or faculty), and randomized patients to receive the intervention (decision aid or pamphlet) either from their clinician during the visit or from a researcher (A.J.W., V.M.M., or L.A.J.) before the visit (2 × 2 clustered factorial design).

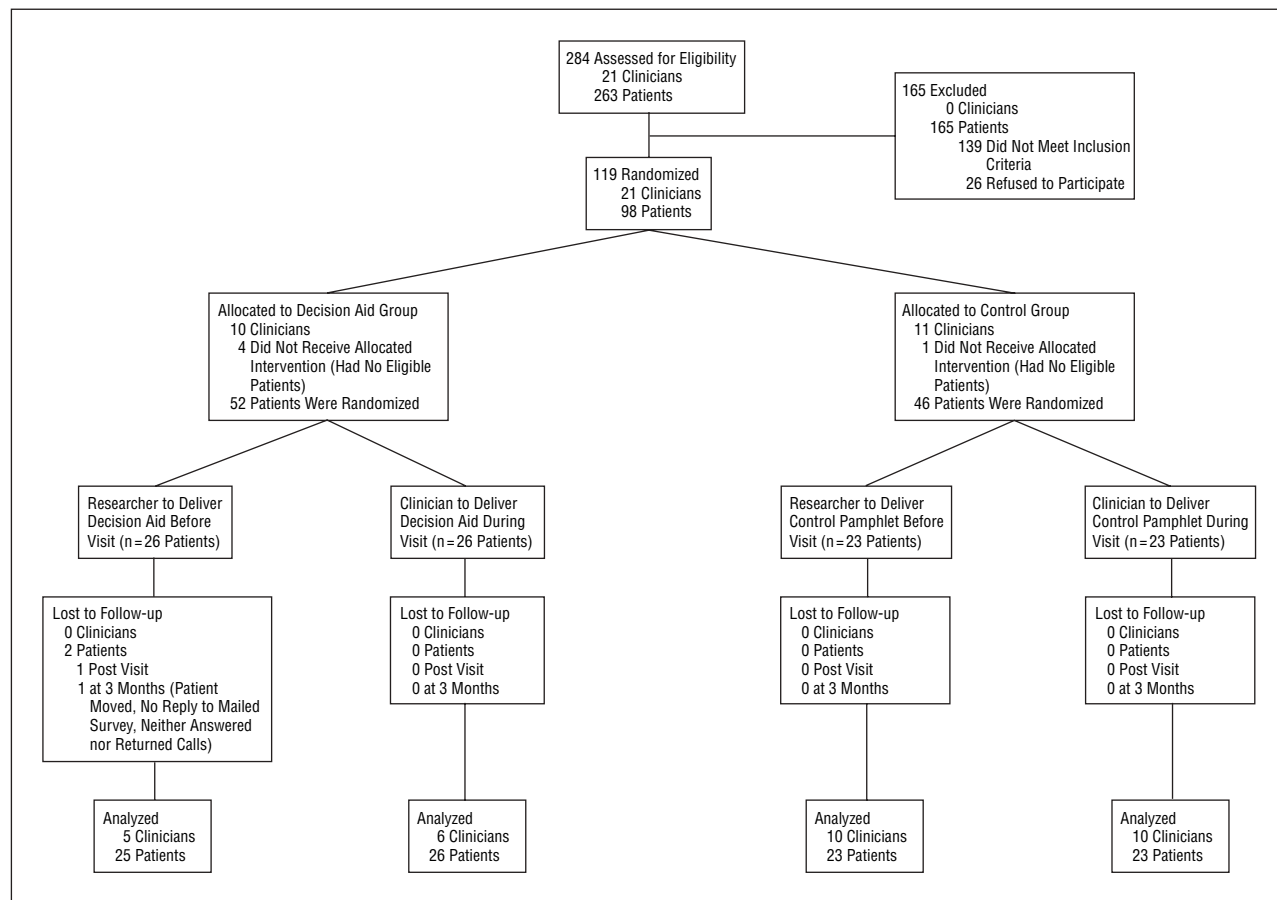


Figure 2. Flow of clinicians and patients through the *Statin Choice* trial.

OUTCOMES AND DATA COLLECTION

The primary objective of the *Statin Choice* trial was to estimate the extent to which that decision aid compared with usual care plus a standard pamphlet was acceptable to patients, could improve patient knowledge, and reduced decisional conflict. We also sought to preliminarily explore the effect of the use of the decision aid on action (ie, start of statin therapy) and adherence to statin use in patients with type 2 diabetes mellitus.

Patients completed a self-administered written questionnaire immediately after the visit. This questionnaire included 7-point Likert-type scales to explore patient perceptions of the amount, clarity, and helpfulness of the information, willingness to recommend the way statins were discussed with others, and desirability of using the process of sharing information in future decisions. We converted the mean of all answers to a 1- to 7-point acceptability summary scale. We compared scale scores of 6 or higher (endorsing the decision aid) with scores lower than 6.

The questionnaire also included 14 knowledge questions to assess patient understanding of the relative merits of using or not using statins. Nine of these questions were addressed in the decision aid; 5 were not. We also used the 16-item Decisional Conflict Scale⁸ to evaluate participant confidence about their knowledge of the information received and the resulting decisional efficacy and satisfaction on a 100-point scale. At 3 months, we mailed surveys to patients and telephoned non-respondents to determine whether they were taking statins and, using a single-question,⁹ whether they had missed any doses in the last week.

STATISTICAL ANALYSIS

The present study, an explanatory trial of *Statin Choice* in patients with diabetes, was designed to provide evidence of efficacy and help plan a multicenter pragmatic trial with the end points being statin drug starts and persistent drug use. Thus, one of our objectives for the present trial was to estimate statin starts. To support the conduct of the pragmatic trial, we sought to assess whether the results of this trial were consistent with an 18% absolute increase in the rate of initiation of statin therapy (ie, 80% confidence interval [CI] around the point estimate of the difference in rates includes 18%); also, we wanted to exclude a difference in favor of the intervention if the point estimate favored the control treatment arm. The assumptions for sample size calculation included the following: a control event rate 65% (peak of sample size needed); α level of .20; power of 80%; and intraclass correlation between 0.05 and 0.15 (range for process variables in usual care¹⁰). This estimation yielded a minimum sample of 7 patients per provider and 5 providers per treatment arm and a maximum sample of 9 patients per provider and 10 providers per treatment arm. Our goal was 7 patients per provider and 7 providers per treatment arm. To be able to complete the study, however, we had to enroll patients already receiving statin therapy. This restricted the sample not taking statins at baseline but allowed the estimation of the effect of the intervention on persistence and on decisional outcomes.

Data analysts and statisticians blinded to allocation used generalized estimating equations to estimate the association between intervention and outcomes. These equations allowed us to consider clustering and to seek interactions between the

2 factorial comparisons in our trial. A secondary analysis adjusted these estimations by patient characteristics potentially relevant to adherence to statins (sex, cardiovascular risk, and number of medications). We present estimates of association using either odds ratios (ORs) or mean differences in scores and their 95% CIs.

RESULTS

Between April 22, 2005, and July 18, 2005, 124 eligible patients were referred to the metabolic clinic; 98 patients (79%) gave informed consent and were randomized to the decision aid group (n=52) or the control group (n=46) (**Figure 2**). **Table 1** gives their baseline characteristics. Ninety-seven (99%) of the 98 participants provided complete postvisit questionnaire data and 3-month data.

ACCEPTABILITY

The decision aid proved superior in terms of amount and helpfulness of the information (**Table 2**). While 74% of participants would recommend (score of 6 or 7) the decision aid to others considering the statin choice (vs 53% of control patients, who recommended the pamphlet; OR, 2.6; 95% CI, 0.8-8.0), 68% would want to receive similar support for future decisions (vs 58% of control patients; OR, 1.5; 95% CI, 0.6-3.8). Overall, patients were more likely to find the decision aid vs the pamphlet highly acceptable (OR, 2.8; 95% CI, 1.2-6.9).

KNOWLEDGE OF INFORMATION ABOUT OPTIONS, CARDIOVASCULAR RISK, AND DECISIONAL CONFLICT

Participants receiving either the decision aid or the control pamphlet scored similarly on the 5 questions irrelevant to the statin choice (**Figure 3A**). Patients allocated to receive the interventions from their clinicians during the visit achieved better knowledge scores when using the decision aid than when using the control pamphlet; this effect was significantly greater than the effect of the decision aid vs the control pamphlet in patients allocated to receive the interventions from the researchers before the visit ($P_{\text{interaction}} = .02$; **Figure 3A**). Patients allocated to receive the interventions from the clinicians during the visit were most accurate when reporting the relevant cardiovascular risk without statins when using the decision aid than when using the control pamphlet; this effect was significantly greater than the effect of the decision aid vs the control pamphlet in patients allocated to receive the interventions from the researchers ($P_{\text{interaction}} = .03$; **Figure 3B**). Participants receiving the decision aid were more likely to accurately estimate the potential absolute risk reduction afforded by statin use than participants receiving the control pamphlet (OR, 6.7; 95% CI, 2.2-19.7; **Figure 3B**).

Compared with the control group, the decision aid group had significantly less postvisit decisional conflict (**Figure 3C**). Similar to the knowledge results, participants using the decision aid thought they were better informed about the options than did participants using the

Table 1. Patient Baseline Characteristics*

| Demographic Data | Decision Aid Group (n = 52) | Control Group (n = 46) |
|---|-----------------------------|------------------------|
| Age, mean (SD), y | 64 (12) | 66 (8) |
| Female sex | 16 (31) | 26 (57) |
| High school education completed | 51 (98) | 39 (87) |
| Cardiovascular risk | | |
| Current smoker | 2 (4) | 2 (4) |
| Diagnosis of coronary artery disease | 26 (50) | 20 (43) |
| Systolic blood pressure, mean (SD), mm Hg | 140 (17) | 144 (24) |
| UKPDS estimated 10-year cardiovascular risk | | |
| <15% | 6 (12) | 15 (33) |
| 15-30% | 16 (31) | 7 (15) |
| >30% | 30 (58) | 24 (52) |
| Diabetes | | |
| Glycosylated hemoglobin, median (IQR) | 7.6 (6.5-8.4) | 6.4 (5.9-6.8) |
| ≥10 Years since diabetes diagnosis | 20 (38) | 16 (35) |
| Polypharmacy | | |
| Total medications, mean (SD) | 9 (4) | 11 (5) |
| Statin data | | |
| Taking a statin | 29 (56) | 27 (59) |
| LDL cholesterol, median (IQR) | 80 (76-115) | 87 (74-110) |

Abbreviations: IQR, interquartile range; LDL, low-density lipoprotein; UKPDS, United Kingdom Prospective Diabetes Study.

*Data are given as number (percentage) unless otherwise indicated.

control pamphlet, particularly when the clinician delivered the interventions during the visit ($P_{\text{interaction}} = .04$). The effective decision subscale was significantly improved from a mean (SD) of 22.1 (16.9) to 12.3 (14.1), a mean difference of 10 points (95% CI, 5-15). Results after adjusting for sex, cardiovascular risk, and number of medications at baseline were similar (data not shown). At 3 months, participants in the decision aid arm continued to have less decisional conflict than those in the control arm, but these differences were no longer statistically significant.

STATIN THERAPY STARTS

Among participants not receiving statin therapy at baseline, 7 (30%) of 23 in the decision aid group (6 of whom received the decision aid from their clinician during the visit) and 4 (21%) of 19 in the control group decided to start statin therapy immediately after the visit. Eight of these starts occurred among participants with 10-year cardiovascular risk greater than 15%. Of the 3 starts in the group with cardiovascular risk less than 15%, 2 occurred in the control group. At 3 months, 9 (39%) of 23 participants in the intervention group and 6 (32%) of 19 participants in the control group had started statin therapy (OR, 1.5; 95% CI, 0.3-6.8). Two of 4 patients with interim starts received *Statin Choice* from the clinician during the visit. Clinicians recommended that 2 control patients with estimated 10-year cardiovascular risk greater than 30% stop statin therapy after attributing to statin use bilateral leg pain in one patient and mild liver enzyme level elevation in the other.

Table 2. Acceptability and Willingness to Recommend the Decision Aid to Others*

| Variable | Participants Responding 6 or 7 of 7 (Favoring DA) | | | | OR (95% CI) for DA vs Control |
|----------------------------|---|---------------|-------------------|--------------------|----------------------------------|
| | DA Clinician | DA Researcher | Control Clinician | Control Researcher | |
| Amount of information | 23 (88) | 23 (92) | 16 (70) | 17 (74) | 3.4 (1.7-6.7) |
| Clarity of information | 19 (73) | 13 (52) | 12 (52) | 12 (52) | 1.6 (0.8-3.2) |
| Helpfulness of information | 18 (69) | 12 (48) | 8 (35) | 10 (43) | 2.3 (1.4-3.8) |
| Would recommend to others | 21 (84) | 16 (64) | 13 (57) | 11 (50) | 2.6 (0.8-8.0) |
| Would want other DAs | 18 (72) | 16 (64) | 14 (61) | 12 (55) | 1.5 (0.6-3.8) |
| Overall acceptability | 20 (77) | 14 (56) | 9 (39) | 10 (43) | 2.8 (1.2-6.9) |

Abbreviations: CI, confidence interval; DA, decision aid; OR, odds ratio.

*Data are given as number (percentage) unless otherwise indicated.

3-MONTH USE

At 3 months, 33 (63%) of the 52 participants in the decision aid treatment arm and 29 (63%) of the 46 participants in the control treatment arm reported taking statins (OR, 1.4; 95% CI, 0.8-2.4). Overall, there was no difference in adherence to patient choice at 3 months (analysis adjusted by sex, cardiovascular risk, and number of medications; OR, 1.9; 95% CI, 0.4-9.8). Of those patients taking statins at 3 months, 2 of 33 participants in the decision aid group reported missing 1 dose or more in the last week compared with 6 of 29 participants in the control group (OR for adherence, 3.4; 95% CI, 1.5-7.5).

COMMENT

STATEMENT OF PRINCIPAL FINDINGS

Patients found the *Statin Choice* decision aid acceptable and would recommend it. Compared with usual care in our setting, use of this decision aid improved the accuracy of patients' estimate of cardiovascular risk without statin therapy, improved their knowledge about statins and the potential relative merits of statin therapy, and improved the accuracy of their estimate of absolute cardiovascular risk reduction with statin therapy. These effects were generally greater when a clinician rather than a researcher reviewed *Statin Choice* with the patient. Furthermore, use of the decision aid significantly reduced decisional conflict and improved the score of the effective decision subscale. Preliminarily, *Statin Choice* use resulted in most of the starts of statin therapy in the trial among patients with 10-year cardiovascular risk greater than 15%, was not associated with stopping statin therapy, and was associated with apparently greater statin adherence at 3 months.

STUDY LIMITATIONS AND STRENGTHS

Enrollment of patients already receiving statin therapy and limited statin uptake decreased the precision of our results; we used a self-reported measure of medication adherence without verification and we conducted our study in one referral clinic with well-educated patients.

While the United Kingdom Prospective Diabetes Study risk calculator is based on individuals without known cardiovascular disease, risk assessments for enrolled patients were calculated using the paper version,⁷ which was validated against a population that included patients with and without known cardiovascular disease. As a result of these limitations, our results should best be interpreted as preliminary and requiring verification.

The study was randomized, maintained allocation concealment and adequate blinding wherever possible, and completed follow-up without crossovers. Design of the study included clustering to avoid contamination. Adjustment for observed imbalances in important predictors of outcomes at baseline did not affect the results. That patients seeing specialists using the decision aid received better decision support than patients who had an equally focused visit with specialists without the decision aid suggests a large effect of the decision aid on decisional quality. The effect of the decision aid seemed greater when it was delivered by a clinician vs a researcher. These strengths suggest that, despite our study's limitations, the findings are well worth following up in future studies.

STRENGTHS AND WEAKNESSES IN RELATION TO OTHER TRIALS

A systematic review of randomized trials included trials of 31 decision aids, none of which were related to diabetes or cardiovascular risk reduction.⁶ In contrast to most of the decision aids included in that review, our decision aid was designed for clinicians to use during a visit. Our decision aid achieved similar improvements in knowledge and lowering of decisional conflict to the pooled estimates in the systematic review. Nevertheless, *Statin Choice* seems to be more effective in helping patients quantify the expected potential benefits of treatment.

Other decision aids designed to help patients and clinicians make decisions about cardiovascular risk are available.¹¹⁻¹³ A recently published randomized trial of 75 participants at various levels of cardiovascular risk found that a tailored computerized decision aid addressing coronary heart disease prevention increased the likelihood of patient-clinician discussions about coronary risk reduction and of patients making plans to address that risk.¹²

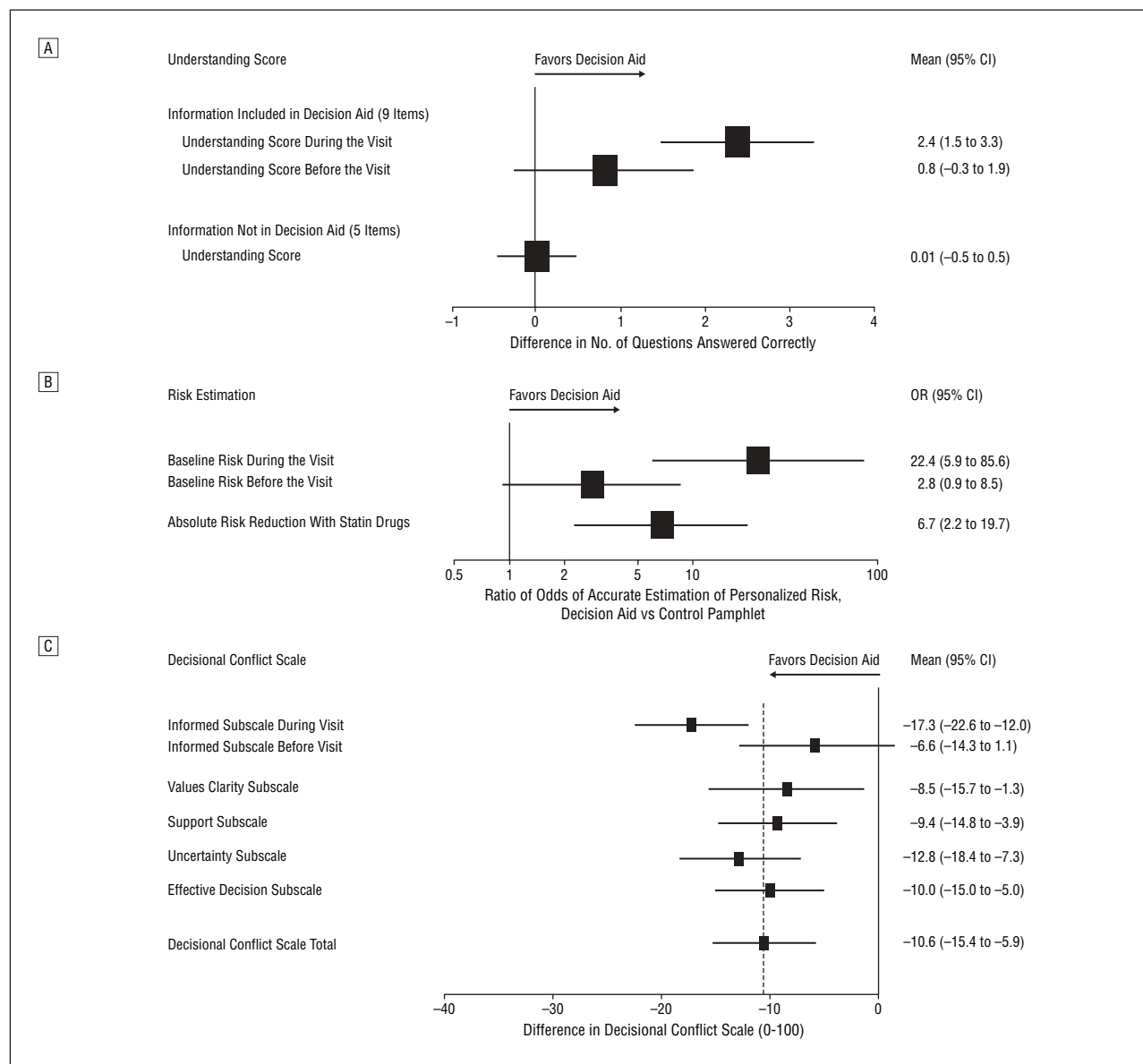


Figure 3. Knowledge, risk estimation, and decisional conflict scale. A, Mean difference (boxes) in number of questions answered correctly between decision aid and control groups and 95% confidence interval (CI) (horizontal lines). There was significant interaction between the knowledge score for the 9 questions for which the decision aid (*Statin Choice*) provided information and the mode of delivery of the decision aid ($P=.02$). B, Odds ratio (OR) (boxes) of accurate estimation of tailored baseline risk and absolute risk reduction with statin therapy between decision aid and control groups. There was significant interaction between accurate estimation of baseline risk and the mode of delivery of the decision aid ($P=.03$). Horizontal lines indicate 95% CI. C, Mean differences (boxes) in the Decisional Conflict Scale and subscales between decision aid and control groups (larger negative differences indicated lower decisional conflict with the decision aid) and their 95% CI (horizontal lines). There was significant interaction between the informed subscale score and the mode of delivery of the decision aid ($P=.04$).

One before-and-after study in 16 patients found that their decision aid booklet with a personal worksheet was acceptable. The patients were able to improve their knowledge, correctly identify their cardiovascular risk category, and decrease their decisional conflict.¹³ Our results are consistent with these studies.

Debate continues over inclusion of values clarification exercises in decision aids.¹⁴ Although the development of our decision aid predates the publication of the International Patient Decision Aids Standards,¹⁵ it satisfies most of the standards with the exception of the presentation of a values clarification exercise. Despite omission of an explicit values clarification exercise, the decision aid group

had significantly better scores in the values clarification subscale of decisional conflict, indicating that the decision aid facilitated values clarification implicitly. Whether a values clarification exercise should be a necessary feature of all decision aids requires further exploration.

UNANSWERED QUESTIONS AND FUTURE RESEARCH

Elements in the agenda for future research include evaluation of the role of decision aids in chronic conditions requiring decision revisions over time, testing *Statin Choice* in primary care and with less educated patients, use of

multiple measures of adherence to medication regimen, estimation of the costs and burdens (eg, time) of implementing decision aids in practice, use of decision aids as tools to educate physicians-in-training to better enhance patient-clinician communication and decision making, and development of decisional quality as an outcome of clinical trials and as a measure for quality of care.

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Author Contributions: Dr Montori had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Weymiller, Montori, Gafni, Bryant, and Smith. *Acquisition of data:* Weymiller, Montori, and Jones. *Analysis and interpretation of data:* Weymiller, Montori, Gafni, Guyatt, Bryant, Christianson, Mullan, and Smith. *Drafting of the manuscript:* Weymiller, Montori, Guyatt, Bryant, and Christianson. *Critical revision of the manuscript for important intellectual content:* Weymiller, Montori, Jones, Gafni, Bryant, Mullan, and Smith. *Statistical analysis:* Montori, Bryant, and Christianson. *Obtained funding:* Montori and Smith. *Administrative, technical, and material support:* Weymiller, Montori, and Guyatt. *Study supervision:* Montori and Smith; *Methodological skills in this area (Gafni).*

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