Decision Aids for Localized Prostate Cancer Treatment Choice: Systematic Review and Meta-Analysis

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Patients who are diagnosed with localized prostate cancer need to make critical treatment decisions that are sensitive to their values and preferences. The role of decision aids in facilitating these decisions is unknown. The authors conducted a systematic review of randomized trials of decision aids for localized prostate cancer. Teams of 2 reviewers independently identified, selected, and abstracted data from 14 eligible trials (n = 3377 men), of which 10 were conducted in North America. Of these, 11 trials compared decision aids with usual care, and 3 trials compared decision aids with other decision aids. Two trials suggested a modest positive impact on decisional regret. Results across studies varied widely for decisional conflict (4 studies), satisfaction with decision (2 studies), and knowledge (2 studies). No impact on treatment choices was observed (6 studies). In conclusion, scant evidence at high risk of bias suggests the variable impact of existing decision aids on a limited set of decisional processes and outcomes. Because current decision aids provide information but do not directly facilitate shared decision making, subsequent efforts would benefit from user-centered design of decision aids that promote shared decision making. **CA Cancer J Clin 2015;65:239–251. © 2015 American Cancer Society.**

Keywords: decision making, decision support techniques, patient education as topic, patient participation, patient preference, patient satisfaction, prostatic neoplasms

Introduction

Prostate cancer is very common, accounting for more than 40% of all cancers among men in the United States.[1] Radical prostatectomy and external-beam radiotherapy have similar oncologic outcomes and may modestly improve survival in selected patients.[2-5] However, this survival benefit comes at the price of impaired urinary, sexual, and bowel-related quality of life.[6-8] The long natural history of prostate cancer also makes active surveillance a reasonable treatment approach, especially for patients with low-risk disease.[9-13] Similarly, watchful waiting may also be appropriate for patients who have

Additional Supporting Information may be found in the online version of this article.

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low-risk to intermediate-risk disease and limited life expectancy.[10] These deferred treatment strategies are generally well tolerated but may cause increased anxiety and decreased health-related quality of life in some patients.[10,14-16]

In an effort to improve the efficacy/morbidity profile, surgical innovation has focused on evolving laparoscopic and robotic techniques. Similarly, innovation in radiotherapy has focused on delivering higher doses of radiation to more tightly defined anatomic regions through 3-dimensional conformal radiation therapy, intensity-modulated radiation therapy, low-dose-rate and high-dose-rate brachytherapy, and stereotactic radiosurgery, with or without androgen-deprivation therapy. Although the reported benefit and risk profile of each approach varies, there is no single optimal choice, and patients often face more than one reasonable alternative.[13,17]

Given the variety of treatments with no clear best choice, decisions for prostate cancer are highly preference-sensitive and require shared decision making to ensure that decisions are consistent with each patient's preferences.[18,19] Shared decision making is characterized by intentional and cooperative communication between patient and clinician in which knowledge, values, and preferences are shared and a process of common deliberation leads to a treatment decision.[20,21]

Depending on the decision and context, shared decision making can increase patient knowledge, decrease decisional conflict, facilitate reaching a decision, and increase active participation in the decision-making process.[22-25] Consequently, a consensus that shared decision making is integral for prostate cancer screening and treatment has emerged.[10,26,27] Decision aids may facilitate this shared decision making by providing a common understanding of the risks and benefits associated with treatment choices, tailored, when possible, to each patient's circumstance.[28] In this systematic review, we summarize and critically appraise the randomized control trials (RCTs) that have addressed the impact of decision aids on decisional outcomes (including decisional conflict and regret), patients' treatment choices, health outcomes, and health care use in the context of prostate cancer.

Materials and Methods

Data Sources and Searches

We developed our search strategy in collaboration with an experienced research librarian (N.B.). The searches were performed on August 26, 2014 in MEDLINE (from 1946 to the present), EMBASE (from 1974 to August 25, 2014), PsychINFO (from 1806 to week 3 of August 2014), Evidence-Based Medicine (EBM) Reviews-Cochrane Central Register of Controlled Trials (CENTRAL) (July 2014), EBM Reviews-Cochrane Database of Systematic Reviews (from 2005 to July 2014), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (from 1984 to the present) without search limits and adapted for each electronic database. Supporting Table 1 (see online supporting information) provides the search strategy.

Study Selection

We included RCTs of a decision aid intervention for localized prostate cancer without language restrictions. We used a broad definition of decision aid as an intervention designed to help patients make choices regarding treatment of localized prostate cancer. Our definition is similar to, but broader in scope than, the definition used in a recent Cochrane review of decision aids.[22] We did not exclude studies based on the format of the decision aid (booklet, audiotape, online, or other) or the framework used. We excluded RCTs that included patients with metastatic or locally advanced disease. We included one study[29] that had a very small proportion (1.4%) of patients with locally advanced prostate cancer.

Independently and in duplicate, we applied standardized and piloted data forms to screen the titles and abstracts of each report for initial eligibility and to screen the full texts for final eligibility. A third clinician-methodologist adjudicator resolved disagreements regarding eligibility.

Data Extraction

We abstracted data in duplicate, and a third clinician-methodologist verified extraction and resolved disagreements. We sent our consensus data extraction to the original authors of each article for confirmation or correction. When needed, we also asked authors to clarify details regarding missing or unclear information.

Outcomes and Study Characteristics

We considered outcomes categorized into the following 4 groups: 1) shared decision-making outcomes, 2) treatment choice, 3) health outcomes, and 4) health care utilization (Table 1). We also collected information on several other characteristics of the articles and their study populations.

Risk of Bias of the Studies and the Quality of Decision Support Technologies

We assessed the risk of bias independently and in duplicate by using a modified version of the Cochrane Collaboration risk of bias tool.[42] We evaluated each trial according to 4 criteria: randomization-sequence generation, randomization concealment, blinding of data collectors, and blinding of outcome assessors, and each criterion was judged to have either a high risk or a low risk of bias. If a study was determined to have a high risk of bias for any one criterion, then it was considered to have a high risk of bias overall.

We evaluated, in duplicate, the quality of available decision aids using the International Patient Decision Aid Standards instrument short-form (IPDASi-SF).[43] For treatment decision aids, the IPDASi-SF has 16 items

TABLE 1. Outcomes Considered

OUTCOMES	INSTRUMENTS USED FOR ASSESSMENT	STUDIES USING THE INSTRUMENT
Shared decision-making outcomes		
Decisional conflict	Decisional Conflict Scale	Feldman-Stewart 2006,[30] Davison 2007,[31] Taylor 2010,[32] Berry 2013,[33] Feldman-Stewart 2012,[34] Hacking 2013,[35] Chabrera 2014[36]
	Decisional Conflict Scale-Revised	Chambers 2013[37]
Decisional regret	Decisional Regret Scale	Mishel 2009,[38] Feldman-Stewart 2012,[34] Hacking 2013[35]
Satisfaction with decision	Satisfaction With Decision Scale	Feldman-Stewart 2006,[30] Chabrera 2014[36]
	5-Point Likert scale developed by authors	Davison 2007[31]
Knowledge	Prostate Cancer Knowledge Scale	Mishel 2009[38]
	Author-developed questionnaire	Chabrera 2014[36]
Preparation for decision making	Preparation for Decision Making Scale	Feldman-Stewart 2006,[30] 2012[34]
Coping skills	Stanford Inventory of Cancer Patient Adjustment	Feldman-Stewart 2006[30]
	Problem Solving Subscale of Self-Control Schedule	Mishel 2009[38]
	Ways of Coping Inventory for Cancer Patients	Chabrera 2014[36]
Quality of communication	Medical Communication Competence Scale	Mishel 2009[38]
Patient participation in shared decision making during the consultation	None	
Actual decision/treatment choice	RP vs XRT vs BT vs AS/WW	Berry 2013,[33] Diefenbach 2012[39]
	RP vs XRT vs BT	Davison 2007,[31] van Tol-Geerdink 2013[40]
	RP vs XRT vs AS/WW	Davison & Degner 1997,[41] Hacking 2013[35]
Health outcomes		
Quality of life	Satisfaction With Life	Chambers 2013[37]
	Cantril's Ladder	Mishel 2009[38]
Emotional health	State-Trait Anxiety Inventory	Feldman-Stewart 2006,[30] Berry 2013,[33] Davison & Degner 1997[41]
	Profile of Mood States	Mishel 2009[38]
	Mental Adjustment to Cancer Scale	Hacking 2013[35]
	Impact Events Scale-Revised	Diefenbach 2012,[39] Chambers 2013[37]
Prostate cancer-specific mortality	None	
Overall mortality	None	
Erectile dysfunction	None	
Urinary incontinence	None	
Health care utilization		
Consultation time	None	
Cost	None	

Abbreviations: AS/WW, active surveillance/watchful waiting; BT, brachytherapy; RP, radical prostatectomy; XRT, external radiation therapy.

addressing 7 dimensions (information, probabilities, values, development, disclosure, decision support technologies evaluation, and evidence) corresponding to theoretical elements derived from a systematic review of the evidence addressing effective formats for communicating outcome probabilities to patients.[43]

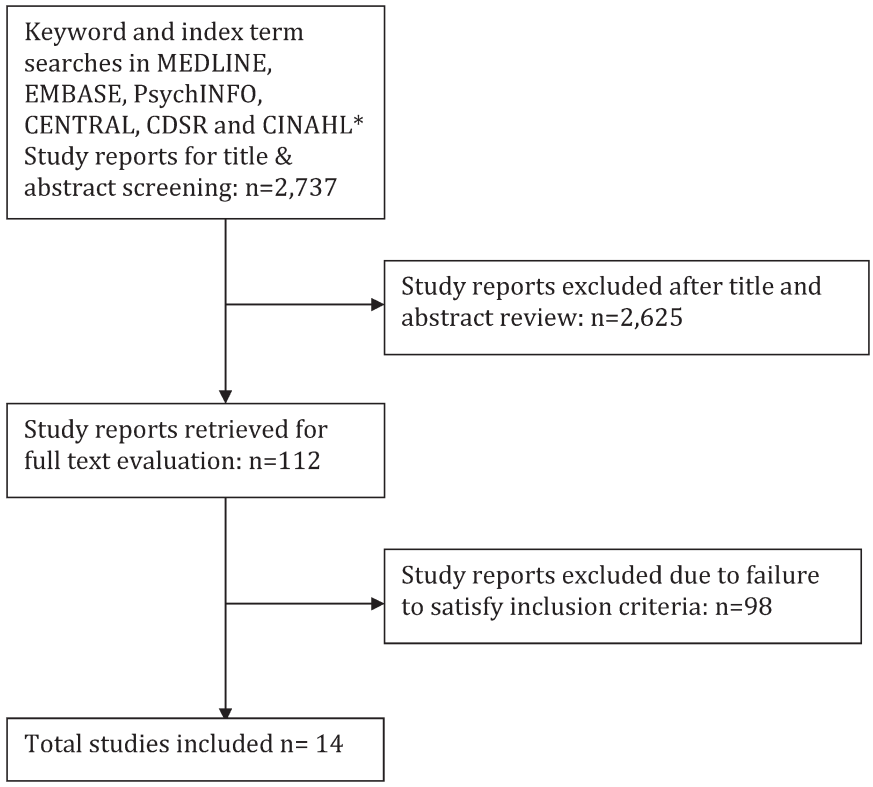

FIGURE 1. Flowchart Outlining the Literature Search and Article Evaluation Process. CENTRAL indicates Evidence-Based Medicine Reviews, Cochrane Central Register of Controlled Trials; CINAHL, Cumulative Index to Nursing and Allied Health Literature; CSDR, *Cochrane Database of Systematic Reviews*.

Statistical Analysis

For continuous outcomes, we standardized scores ranging from 0 to 100,[44,45] and we summarized the data as means and standard deviations. The treatment effect between the decision aids and usual care was measured by the standardized mean differences and the associated 95% confidence intervals. For categorical outcomes, we summarized the distribution in frequency and percentage. For binary outcomes, we expressed treatment effects as relative risks and 95% confidence intervals. We conducted a meta-analysis when data for a particular outcome were available from at least 2 RCTs. We pooled the results across studies based on the DerSimonian-Laird random-effects inverse variance method. In addition, we tested the association between the treatment and the distribution of therapy choice adjusted by studies using the Cochran-Mantel-Haenszel method.

Regarding the treatment choice, we considered the following binary outcomes. First, we assessed the impact of a decision aid on the choice of immediate versus deferred treatment. We defined immediate treatment as the choice of radical prostatectomy, external-beam radiation therapy, or brachytherapy; and we defined deferred treatment as watchful waiting or active surveillance. Because none of the studies defined watchful waiting or active surveillance, it was not feasible to perform analyses separately for these management strategies; therefore, we treated them as equivalent in our analyses.

Second, we considered the intervention's impact on less aggressive treatment versus more aggressive treatment. We defined less aggressive treatment as the receipt of brachytherapy, watchful waiting, or active surveillance; and we defined more aggressive treatment as the receipt of radical prostatectomy or external-beam radiation. Finally, we compared the choice between the 2 most commonly used management options for localized prostate cancer: radical prostatectomy versus radiation therapy.

We did not assess for the presence of publication bias with a funnel plot, because too few studies were included in our meta-analysis.[46] We assessed heterogeneity using the I^2 statistic.[47]

Results

Literature Search and General Characteristics of Included RCTs

We identified 2737 reports from 6 databases. Screening titles, abstracts, and full texts yielded 14 eligible RCTs (Fig. 1).[29-41,48] We excluded one trial in which a substantial proportion of patients did not have localized prostate cancer (34% had "intracapsular" prostate cancer, 46% had "locally advanced" prostate cancer, and 20% had "distant" prostate cancer).[49] Three studies (21%) confirmed the accuracy of our consensus data extraction,[31,41,48] 8 studies (57%) corrected some errors and/or added additional

TABLE 2. General Characteristics of Included Randomized Controlled Trials

			CONTROL ARM			INTERVENTION ARM			RECRUITMENT	
REFERENCE	COUNTRY	NO. OF PATIENTS RANDOMIZED	COMPARATOR	NO. OF PATIENTS	AGE, Y[a]	INTERVENTION	NO. OF PATIENTS	AGE, Y[a]	FIRST YEAR	LAST YEAR
Davison & Degner 1997[41]	Canada	60	Usual care	30	70	Interview preparing for consultation	30	66	1995	1995
Feldman-Stewart 2006[30]	Canada	NR	AZ booklet	NR	NR	CCE information booklet	NR	NR	2001	2002
Davison 2007[31]	Canada	324	Generic information (videotape)[a]	162	NR	Written information printout based on information preferences (individualized)	162	NR	NR	NR
Hack 2007[29]	Canada	425	Usual care	211	68	Audio recording of clinical encounter	214	67	2001	2001
Mishel 2009[38]	United States	256	Usual Care	74	61	a) Communication strategy intervention via DVD and 4 telephone calls; b) Patient and primary support person receive intervention	a) 93; b) 89	a) 63; b) 63	NR	NR
Taylor 2010[32]	United States	132	Information CD	66	NR	Information CD + decision tool	66	NR	2002	2004
Berry 2011[33,50]	United States	494	Usual care	228	62	Tailored internet aid	266	63	2007	2009
Diefenbach 2012[39]	United States	72	Usual care	19	64	Internet/CD-ROM-based education and decision program (with or without tailoring)	53	61	2005	2007
Feldman-Stewart 2012[34]	Canada	156	Decision aid interview with general questions	75	NR	Decision aid interview with Values clarification exercise	81	NR	NR	NR
van Tol-Geerdink 2013[40]	Netherlands	240	Usual care	77	64	Semi-structured interview providing information	163	64	2008	2011
Chambers 2013[37]	Australia	740	Usual care	368	63	Telephone delivered psychosocial intervention	372	63	NR	NR
Hacking 2013[35]	United Kingdom	123	Usual care	60	67	Preparing of personalized consultation plan	63	65	2009	2010
Marcus 2013[48]	United States	NR	Usual care	NR	NR	Web-based multimedia education and decision program	NR	NR	2008	2010
Chabrera 2014[36]	Spain	147	Usual care	74	69	Booklet with information, interview preparation material, values clarification exercise	73	69	2011	2013

Abbreviations: AZ, AstraZeneca (London, UK); CCE, Division of Cancer Care and Epidemiology, (Cancer Research Institute, Queens University, Kingston, Ontario, Canada); NR, not reported. [a]Patients were recruited from the Prostate Education and Research Center located within Vancouver General Hospital. Usual care at this center includes watching an information video.

information,[29,30,34-37,39,40] and 3 groups (21%) did not respond to our requests.[32,33,38] Ten RCTs were conducted in North America, and the remaining studies were conducted in Europe (The Netherlands, Spain, United Kingdom) and Australia (Table 2).[29-41,48] Ten reports (71%) appeared within the past 5 years. Patients included in the trials were recruited from a variety of settings, primarily urology clinics (n = 4), an oncology clinic (n = 1), or multidisciplinary or multiple settings (n = 7). One study recruited from a dedicated prostate cancer research and education center,[31] and another study recruited from the National Cancer Institute (NCI) federally funded public-access Cancer Information Service.[48]

In total, 3377 men participated in the included trials. The mean age of participants ranged from 61 to 69 years (the maximum and minimum ages reported across all trials were

TABLE 3. Risk of Bias Using a Modified Version of the Cochrane Collaboration Risk of Bias Tool

REFERENCE	WAS ALLOCATION SEQUENCE RANDOMLY GENERATED?	WAS ALLOCATION ADEQUATELY CONCEALED?	WERE DATA COLLECTORS BLINDED?	WERE OUTCOME ASSESSORS BLINDED?	RISK OF BIAS
Davison & Degner 1997[41]	+	–	–	–	High
Feldman-Stewart 2006[30]	+	–	–	–	High
Davison 2007[31]	+	+	–	–	High
Hack 2007[29]	+	–	–	–	High
Mishel 2009[38]	+	–	–	–	High
Taylor 2010[32]	+	–	–	–	High
Berry 2011[33,50]	+	–	+	+	High
Diefenbach 2012[39]	+	–	–	–	High
Feldman-Stewart 2012[34]	+	–	–	–	High
van Tol-Geerdink 2013[40]	+	–	–	–	High
Chambers 2013[37]	+	+	+	+	Low
Hacking 2013[35]	+	–	–	–	High
Marcus 2013[48]	+	–	–	–	High
Chabrera 2014[36]	+	–	–	–	High

45 years and 86 years, respectively). Patient demographics varied considerably by study in terms of higher education (range, 19%-70%) and active involvement in the workforce (range, 17%-63%). The majority of patients reported being married or in long-term relationships (range, 79%-93%) and were white or Caucasian (range, 55%-100%).

Risk of Bias

Of the 14 RCTs, 13 were at high risk of bias, and one was at low risk of bias (Table 3). All trials adequately randomized patients, and only 2 trials (14%) reported adequate concealment[31,37] or blinding of data collectors and outcome assessors.[33,37,50] No trial reported whether data analysts were blinded.

Decision Aids

Ten authors (71%) provided the decision aid used in their study,[30,32-37,39,40,48] three (21%) reported that the decision aid was no longer accessible and/or had been destroyed,[29,31,41] and one (7%) was unable to provide access to the decision aid used in the study.[38] Decision aids varied considerably in their underlying theoretical framework, form, and method of delivery. Eleven (79%) of the 14 RCTs reported the use of a theoretical framework in the development of their intervention, with the Ottawa Decision Support Framework[51] being the most common (5 of 11 RCTs; 45%) (Table 4). Most decision aids (9 of 14 decision aids; 64%) used multiple media to convey information (n = 7).[31-33,35,38-41,48] The types of media used included personal interviews (n = 5),[34,35,37,40,41] printed material (n = 11),[29-31,33,35,36,38-41,48] audio recordings (n = 3),[29,35,38] videos (n = 4),[38,39,48,50] and interactive computer-based tools (n = 4).[32,39,48,50] Six decision aids (43%) aimed at providing information somewhat tailored to the patient's knowledge-seeking preferences[31,34,35,37,39,48] and sought to improve communication with physicians by helping the patient generate information-seeking questions for their subsequent clinical encounter.[32,35,36,38,41,48] Most decision aids were primarily designed for use by patients mainly outside of the clinical encounter; in one study, patients were explicitly invited to bring the results from the tool for discussion during the clinical encounter.[35]

We assessed the quality of 9 of the 10 decision aids that we were able to access (Table 5) (one decision aid was primarily a verbal tool).[35] All decision aids met many of the IPDAS-SF criteria. Decision aids reported well the options available (at least one of each: surgical, radiation therapy, and deferred treatment option) as well as positive and negative features (9 of 9 decision aids; 100%) but presented event rates less frequently (5 of 9 decision aids; 56%) and did not typically make direct comparison of the possible probabilities (4 of 9 decision aids; 44%). Decision aids had been typically tested with patients (8 of 9 decision aids; 89%), and the development process typically included finding out patients' needs (6 of 9 decision aids; 67%).

Effect of Decision Aids on Outcomes

Decisional Conflict, Decisional Regret, Satisfaction With Decision, and Knowledge

Authors used a variety of instruments to measure shared decision-making outcomes (Table 1). In studies that compared decision aids with usual care, we observed large

TABLE 4. Theoretical Framework Delivery and Timing of Evaluation of Decision Aids

	SAMPLE	DECISION AID		FOLLOW-UP			
REFERENCE	SOURCE OF SAMPLE	THEORETICAL FRAMEWORK	METHOD OF ADMINISTRATION	TIME POINT 1	TIME POINT 2	TIME POINT 3	TIME POINT 4
Davison & Degner1997[41]	Urology	Self-efficacy theory	Research staff	5 Weeks	N/A	N/A	N/A
Feldman-Stewart 2006[30]	Cancer center	N/A	Self-administered	"After reading booklet"	N/A	N/A	N/A
Davison 2007[31]	Prostate research and education center	Ottawa Decision Support Framework	Nurse	4 Weeks	N/A	N/A	N/A
Hack 2007[29]	Radiation oncology	N/A	Nurse	12 Weeks	N/A	N/A	N/A
Mishel 2009[38]	Cancer center	Uncertainty in illness theory	Nurse	4 Weeks	3 Months	N/A	N/A
Taylor 2010[32]	Urology, radiation oncology, medical oncology	N/A	Research staff	1 Month	N/A	N/A	N/A
Berry 2011[33,50]	Urology, oncology, multidisciplinary	Ottawa Decision Support Framework	Self-administered	1 Month	6 Months	N/A	N/A
Diefenbach 2012[39]	NR	Self-regulation theory	Self-administered	"Immediately after intervention"	N/A	N/A	N/A
Feldman-Stewart 2012[34]	Cancer clinic	Differentiation and consolidation theory	Research staff	0 Days (after reading)	After decision made	3 Months	12-18 Months
van Tol-Geerdink 2013[40]	Urology	Ottawa Decision Support Framework	Research staff	Postdecision, pretreatment	N/A	N/A	N/A
Chambers 2013[37]	Urology	Ottawa Decision Support Framework	Nurse by telephone	2 Months	6 Months	12 Months	24 Months
Hacking 2013[35]	Urology	SCOPED	Research staff	Postconsultation planning (time)	Postconsultation planning (time)	6 Months postconsultation	N/A
Marcus 2013[48]	Cancer information service	(Several)	Self-administered	2 Months	9 Months	N/A	N/A
Chabrera 2014[36]	Urology, radiation oncology, medical oncology	Ottawa Decision Support Framework	Self-administered	3 Months	N/A	N/A	N/A

Abbreviations: N/A, not applicable; SCOPED, acronym for "situation, choices, objectives, people, evaluation, decisions."

heterogeneity for decisional conflict,[31,35-37] satisfaction with decision,[31,36] and knowledge[36,38] (Fig. 2). For decisional conflict, one relatively small trial reported an extremely large effect,[36] another small trial reported a much smaller effect,[35] and 2 large trials suggested no effect whatsoever[31,37] (Fig. 2). For both satisfaction with decision and knowledge, the smaller trial once again showed very large effects,[36] whereas larger trials suggested possible marginal effects.[31,38] For decisional regret, the pooled estimate from 2 trials with consistent results suggested small effect with a confidence interval that included no effect (Fig. 2).

Two studies that compared decision aids reported no differences in decisional conflict.[30,34] A study that tested the addition of an explicit value-clarification exercise with or without the decision aid suggested decreased regret at one year when used in conjunction with a decision aid.[34]

Preparation for Decision Making, Satisfaction With Communication, and Coping

Table 1 presents the instruments used to measure preparation for decision making, satisfaction with communication, and coping. Three studies reported on the impact of decision aids on preparation for decision making,[30,33,34] two of which compared alternative decision aids.[32,48] Feldman-Stewart et al compared a drug company-derived and investigator-derived decision aids and observed a small improvement in preparation for decision making with the investigator-derived decision aid.[30] In a second trial, values-clarification exercises (presenting information tailored to patient preferences) integrated into a decision aid improved preparation for decision making over the decision aid alone.[34] Berry et al also identified that, compared with usual care, using a decision aid designed to provide patient-

TABLE 5. The International Patient Decision Aid Standards Instrument "Short Form" (IPDASi-SF) Ratings

	PRIMARY PUBLICATION								
VARIABLE	FELDMAN-STEWART 2006[30]	TAYLOR 2010[32]	BERRY 2011[33,50]	DIEFENBACH 2012[39]	FELDMAN-STEWART 2012[34]	VAN TOL-GEERDINK 2012[40]	CHAMBERS 2013[37]	MARCUS 2013[48]	CHABRERA 2014[36]
Production year[a]	2013	2001	2013	NR	2014	NR	2010	2008	NR
Information									
Options available	+	+	+	+	+	+	+	+	+
Positive features	+	+	+	+	+	+	+	+	+
Negative features	+	+	+	+	+	+	+	+	+
Fair comparison	+	+	−	+	+	−	+	+	+
Probabilities									
Reference class	+	+	+	−	+	+	+	−	+
Event rates	+	+	+	−	+	+	−	−	−
Compare probabilities	+	−	−	−	+	+	+	−	−
Values									
Personal importance	−	+	+	−	+	+	+	+	+
Development									
Patients' needs	+	+	+	−	+	−	−	+	+
Impartial review	+	+	+	+	+	−	−	+	+
Tested with patients	+	+	+	+	+	−	+	+	+
Disclosure									
Information about funding	+	+	+	+	+	+	+	+	+
DST evaluation									
Knowledge	−	+	−	+	−	−	−	+	+
Improved decision quality	−	−	+	−	+	−	−	−	+
Evidence									
Citations to studies	+	+	−	−	+	+	+	−	−
Production date	+	+	+	−	+	+	+	+	−
Total	13	14	12	8	15	10	11	12	11

Abbreviations: DST, decision support technologies; NR, not reported. [a]"Production year" refers to the year of decision aid production or to the year of the most updated decision aid version available.

specific information and coach the patient on how to share these issues with their physician improved preparation for decision making.[50]

Two RCTs addressed satisfaction with communication[29,38] using instruments that measured substantially different constructs and, thus, did not warrant pooling. Hack et al reported that patients who used a decision aid perceived that they had received more information about treatment alternatives, but this did not improve satisfaction with communication.[29] Mishel et al observed that the use of decision aids increased scores on the patient-provider communication scale overall and the domain related to quantity of knowledge provided by the physician.[38]

Three RCTs addressed the impact of decision aids on various aspects of coping skills.[30,36,38] Mishel et al reported that a multifaceted decision aid improved uncertainty management and problem solving compared with usual care.[30] Chabrera et al reported that patients receiving a decision aid made more extensive use of a variety of coping mechanisms at 3 months postintervention.[36] One other investigation found no difference in coping between drug company and clinician-derived decision aids using the Stanford Inventory of Cancer Patient Adjustment.[30]

Effect of Decision Aids on Decision/Treatment Selection

Six studies (43%)[31,33,35,39-41] measured the impact of decision aids on treatment selection (Table 1). Consistent results suggested no difference in deferred versus immediate treatment choice between decision aids and usual care[33-35,41] (Fig. 3). In part because a relatively small number of patients chose deferred treatment, the confidence

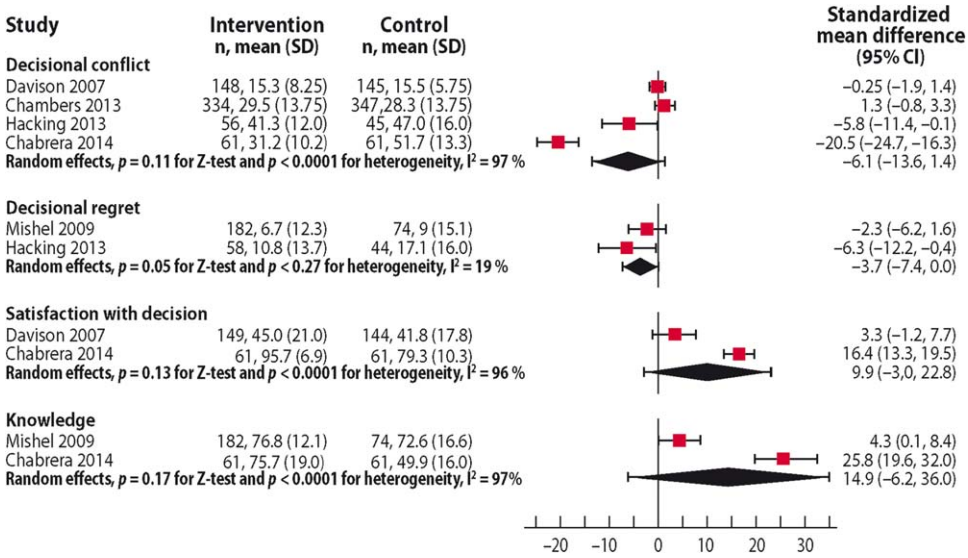

FIGURE 2. Forest Plot of Shared Decision-Making Outcomes for Trials That Compared Decision Aids With Usual Care. CI indicates confidence interval; I^2, test of heterogeneity; SD, standard deviation.

intervals around the relative effect were wide (ranging from a 42% relative risk reduction to a 74% relative risk increase).

More variable results also suggested no impact of decision aids versus usual care in choice of less aggressive versus more aggressive treatment (Fig. 3). The relatively small sample size and inconsistent estimates once again resulted in wide confidence intervals (ranging from a 22% relative risk reduction to a 89% relative risk increase).

Six RCTs were available for comparing the selection of radical prostatectomy versus radiation therapy (versus other).[31,33,35,39-41] We observed no difference in distributions between decision aid use and usual care ($P = .22$). Of the patients who received usual care, 55% chose surgery, and 24% chose external-beam radiation; whereas, among those who received a decision aid, the corresponding estimates were 51% and 23%.

Health Outcomes and Health Care Use

Although 6 of 14 RCTs (43%)[29,32,33,37,38,40] reported methodology that included some measure of health-related quality of life, only 3 studies reported results on those outcomes (Table 1).[32,37,38] All 3 trials failed to demonstrate an impact on quality of life. Six trials reported on the impact of decision aids on emotional health using a variety of instruments.[29,32,34,35,38,41] Five trials did not find a benefit to decision aid on levels of anxiety,[30,35,41] depression,[35,41] mood disturbance,[38] or subjective well being.[37] One trial

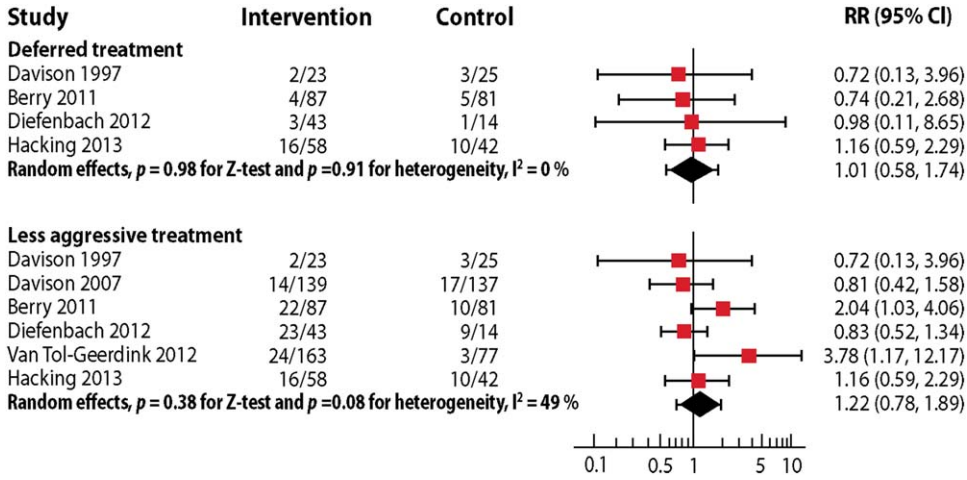

FIGURE 3. Forest Plot of Treatment Choice for Trials That Compared Decision Aids With Usual Care. Immediate treatment was defined as radical prostatectomy, external-beam radiation therapy, or brachytherapy; deferred treatment was defined as watchful waiting or active surveillance; less aggressive treatment was defined as brachytherapy, watchful waiting, or active surveillance; and more aggressive treatment was defined as radical prostatectomy or external-beam radiation therapy. CI indicates confidence interval; I^2, test of heterogeneity; RR, relative risk.

suggested that an interactive computer-based intervention reduced the emotional impact of decision making compared with usual care, as measured by the impact of events scale.[39]

We identified no study that reported on the impact of decision aids on prostate cancer-specific mortality or overall mortality, erectile dysfunction, urinary incontinence, or health care use outcomes, such as consultation time or cost.

Four studies reported some measure of acceptability of implementing the decision aid. Taylor et al described the use and acceptability of an interactive computer-based decision aid favorably from the patient's perspective.[32] Other trials also provided a similar narrative description of high acceptability of decision aids among patients.[30,33,39]

Discussion

Main Findings

Randomized trials of decision aids, most at high risk of bias, have measured outcomes inconsistently and have shown inconsistent effects on decisional outcomes and no effect on choice. For instance, of 11 trials that compared decision aids with usual care, one trial demonstrated large positive effects on decisional conflict, satisfaction with the decision, and knowledge; whereas 3 studies, one study, and one other study did not (see Fig. 2). Other isolated positive findings from comparisons of decision aids with standard care included a perception of increased information (2 studies), and improved uncertainty management and problem solving (one study). A single study comparing different decision aids suggested that a values-clarification exercise may reduce regret at one year and improve preparation for decision making. Six studies that examined the decisions patients made showed that distributions in the use of different treatment options were similar regardless of use of the decision aid. Although the 4 studies that addressed the issue indicated that the aids were feasible and acceptable to patients, studies did not report the impact on health outcomes or health care utilization outcomes.

Decision aids varied widely in format but were consistent in providing information rather than facilitating shared decision making through use in the patient-clinician encounter. We evaluated the quality of available decision aids according to international consensus criteria using IPDAS-SF instrument criteria.[43] Most decision aids met the majority of IPDAS-SF criteria. Decision aids reported positive and negative features of the alternative interventions well, but a common limitation was that they did not usually allow direct comparison of event rates (possible with 44% of decision aids). We did not formally evaluate oncologic information provided by the decision aids, because contemporary understanding of the appropriate management of prostate cancer is continually evolving. Indeed, the decision aids lacked a mechanism by which the information content would remain current going forward.

Strengths and Limitations

Strengths of our study include the comprehensive search, the duplicate assessment of eligibility and data abstraction, the development of a taxonomy of outcomes to help with understanding results, and the appraisal of risk of bias. Our work has also benefited from extensive communication with the authors of included studies. This has led to more complete data than what would have been available from the original publications alone. Whenever possible, we conducted meta-analyses to increase the precision of estimates. In the presence of large heterogeneity (in 3 of our pooled analyses), we did not put undue emphasis on pooled estimates.

Limitations of our review are largely the weaknesses of the eligible studies and their decision aids. Sample sizes in general were modest, and the risk of bias was high in all but one study. The inconsistency in the domains measured and the instruments used, as well as the variability in results across studies, precluded any strong inferences.

"Usual care" likely varied between centers; and, for the most part, this was not evaluable. In one study,[31] patients were recruited from a prostate cancer education and research center in which patients undergoing usual care likely received more extensive preparation than at other sites. Similarly, knowledge content and approach likely varied over time, but insufficient numbers of studies were available to stratify by time period. Many decision aids used in the studies were developed on the basis of outdated therapeutic options and may differ substantially in several ways from those decision aids used in current clinical practice, potentially limiting the generalizability of the results. Finally, the studies included did not define active surveillance or watchful waiting and did not distinguish between them. Therefore, we combined active surveillance and watchful waiting as "deferred treatment."

Relation to Prior Work

A recently updated Cochrane systematic review[22] of more than 100 RCTs that tested decision aids for a wide array of medical conditions demonstrated increased knowledge, lower decisional conflict, and improved communication. The review documented that decision aids in general resulted in more conservative treatment choices: a 21% decrease in major elective, invasive surgery was reported among patients who were exposed to a decision aid.

These results contrast with our findings of no impact of the decision aids on treatment choices. However, most of these RCTs were from the United States and had very low

rates of active surveillance/watchful waiting. This may not be representative of current practice in the United States. A recent US study demonstrated that the rate of noncurative initial management increased in patients at low risk from 21% to 32% using the Surveillance, Epidemiology, and End Results database and from 13% to 20% in National Cancer Database information.[13]

In 2009, Lin et al published in *CA: A Cancer Journal for Clinicians* a review of observational studies and 3 RCTs addressing decision aids of prostate cancer.[52] Those authors concluded that the use of decision aids improved knowledge, encouraged more active patient involvement in decision making, and decreased levels of anxiety and distress.

Given the higher risk of bias associated with observational studies, we focused exclusively on randomized trials.[53] Our more comprehensive search strategy identified 2 additional RCTs of decision aids that were reported before the publication by Lin et al in March 2009[29,30] and a total of 14 RCTs that were published up to August 2014. Of the 3 RCTs that were included in the review by Lin and colleagues, one included patients with locally advanced and metastatic cancer,[49] which did not meet our inclusion criteria. Our more comprehensive search and more rigorous assessment of available studies does not support the optimistic conclusions of Lin et al regarding active patient involvement and improved emotional function.

Implications of Findings

Our results highlight the major limitations of studies that address prostate cancer treatment decisions aids. Three key limitations are the high risk of bias (typically because of problems in allocation concealment and blinding of data collectors/outcome assessors), the variability in constructs measured and instruments used, and the variability in results. Before we can obtain a clear idea of the impact of decision aids in prostate cancer, subsequent studies will have to address methodological issues and provide detailed information that may explain variability in results. There is an urgent need for a consensus in the decision aid investigative community regarding the constructs that warrant measurement and the optimal instruments for measuring those constructs. Finally, we suggest that future trials would benefit from measuring patient participation in shared decision making during the consultation, an outcome that has been neglected in the trials conducted to date.

We have also noted that decision aids for localized prostate cancer typically lack any update policy and, hence, rapidly become outdated.[54] Potential solutions to this problem include linking the production of decision aids to recent evidence-based summaries and clinical practice guidelines with a clear and trustworthy updating mechanism.[55,56] The emergence of new guideline authoring and publication platforms, allowing evidence to be structured and dynamically updated, offers promise for the production of electronic decision aids that would be modified as new evidence is published and appraised.[56,57]

Despite their considerable heterogeneity in the type of media used, most current tools essentially provide information about options and, thus, are focused mainly on patient education. In our comprehensive review, we identified only one decision aid tested in an RCT that was designed specifically for use within the clinical consultation.[35] Encounter decision aids may be more likely than information decision aids to result a shared decision-making conversation between patients and clinicians.[56,58-60] Going forward, such tools may contribute to a wider uptake of shared decision making at the point of care, an objective most interventions tested to date have failed to achieve.[61]

Conclusion

Optimal shared decision making about treatments for localized prostate cancer is paramount but challenging. Although the decision aids tested in the 14 eligible RCTs appeared feasible and acceptable to patients, studies failed to demonstrate important benefits. Furthermore, confidence in the available evidence is limited because of high risk of bias and inconsistency in results.

Finally, all but one of the studies addressed information rather than the use of encounter decision aids, providing information to patients rather than facilitating shared decision making in the patient-physician encounter. The best approach to ensuring optimal decision-making regarding prostate cancer treatment may be first to provide patients with an information decision aid and then, during the patient-physician interview, to use an encounter decision aid to facilitate a conversation[62] in which clinicians share information about the benefits, harms, and burden of alternatives and support patients in considering what matters most to them.[56] For patients with localized prostate cancer, optimal decision aid support and an understanding of the impact of decision aids must await further development and study. ■

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