A randomized controlled trial comparing two educational booklets on prostate cancer

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Purpose: *To compare the helpfulness of two educational aids or booklets on early-stage prostate cancer.*
Method: *Participating consecutive patients and a family member, in three centres, received one of two booklets, one produced by AstraZeneca (AZ), the other produced by us (CCE); the patient and family shared a booklet but were separate study participants. The primary outcome was the Purpose-based Information Assessment completed after participants read their booklet; they rated the importance (4-point Likert scale) of six potential purposes for the information: to help organize their thoughts, understand their situations, decide on treatment, plan, provide emotional support to others, and discuss issues. Each participant then rated how helpful their booklet was (4-point Likert scale) in addressing each purpose they had rated above the lowest importance category. Participants mailed in their responses.*
Results: *Complete data were received from 308 (81%) of those who consented to the study: 152 in the CCE group and 156 in the AZ group. The CCE booklet was read for a longer time [$\chi^2 = 28.61, p = 0.00$] but was easier to find information in [$\chi^2 = 7.6, p = 0.05$]. Although for each purpose, most readers rated each booklet in one of the top two (of four) helpfulness categories, the CCE booklet was rated more helpful for: organizing [$\chi^2 = 30.49, p = 0.00$], understanding [$\chi^2 = 12.07, p = .007$], deciding [$\chi^2 = 9.96, p = 0.02$] and planning [$\chi^2 = 18.67, p = 0.00$].*
Conclusions: *High helpfulness ratings of both booklets suggest that patients benefit from education aids while differences in the booklet ratings suggest that aids are not equally helpful. The CCE booklet, the more helpful booklet of this study, is a systematically developed education aid available to urologists in Canada.*

Key Words: prostate cancer, information needs, patient education, randomized controlled trial

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Introduction

Evidence suggests that many patients with prostate cancer want a lot of information about their condition and treatment options,[1-5] as do their families.[2,3,6] Although many physicians routinely provide written information or other educational aids (e.g., pamphlets, booklets, full books) to prostate cancer patients at the time of the cancer diagnosis disclosure, little evidence is available to support the effectiveness of such strategies. Moreover, there exists considerable variation in opinion about how educational aids should be assessed.[7-12] As a result, it is not easy for clinicians to anticipate when such aids will be most effective or to know which aids are most preferred by patients and their families.

In this study, we examined issues regarding the effectiveness of educational aids in the context of a randomized controlled trial that evaluated two aids (in this case, information booklets) provided to early-stage prostate cancer patients and their families in an ambulatory regional cancer centre. We designed the study to address two main themes: (1) to determine which of the two booklets better met the needs, and (2) to explore which needs were most germane to patients and their families, and, thus, most relevant to the evaluation of the material. The study explicitly included both patients and their family members, as evidence suggests that patients receive more effective support from their family members if the family members' information needs have been addressed.[13]

The study compared two information booklets. One booklet (developed by AstraZeneca, hereafter referred to as AZ), we refer to as a "standard" in that it was routinely provided to patients at two regional cancer centres in Ontario. Comparisons were made with a booklet created to answer the questions identified in our earlier studies as those that men with early-stage prostate cancer[1] and that their families[6] frequently want answered between the time of their diagnosis and when their treatment decisions are made. Detailed information about development of the CCE booklet, such as the language being kept to a Flesch-Kincaid grade 8 level, is available elsewhere.[9] We were interested in determining which of the booklets was more helpful to the patients and their families in addressing their particular purposes for wanting the information. We were also interested in determining which purposes were most relevant to readers. Because the CCE booklet was designed specifically for patients with low or intermediate risk disease, participants were eligible for the study only if they had such early-stage disease.

Materials and methods

Patients

Patients were eligible for the study if they had stage 1 or 2 disease, PSA < 20 and Gleason score < 8. In addition, they had to be judged by their attending oncologist as emotionally and cognitively capable of completing the task. Family members were eligible as long as they were at least 18 years old. In addition, each potential participant had to judge themselves as being able to read English. A patient did not have to consent to be part of the study for his family member to be eligible. "Family" was defined by the patient as anyone he felt was close support for him and could include friends. Ethics approval for the study was provided by the Queen's University Health Sciences and Affiliated Teaching Hospitals Review Board.

Procedures

Patients and family members were assigned at random to receive one booklet (the one we created, the CCE booklet, or the one created by AstraZeneca, the AZ booklet) after consenting to participate in the study at their first consultation in one of three cancer centres. Individual patients and their family were provided with only one copy of their booklet but filled out separate evaluations. Each participant was provided with his/her own envelope with two sets of evaluation forms (labeled BEFORE and AFTER) and two stamped, self-addressed envelopes. The BEFORE evaluation included a general question about the importance of getting information about prostate cancer and its treatments, and two demographic questions, one categorized their age and the other their highest level of formal education. In addition, participants rated how important each of six potential purposes was in their quest for information, with the option to add their own purposes. The BEFORE evaluation was to be completed and mailed to us before the participant read his/her booklet. The AFTER evaluation was to be completed and mailed to us after they read their booklet.

Outcomes

Our primary endpoint was the AFTER evaluation of the Purpose-based Information Assessment (PIA). The PIA asks the participant to rate the importance (using a 4-point Likert scale: "not important" to "very important") of various potential purposes they have for the information that they want. Then for each purpose that is important at any level *above* the lowest (not important), the participant rates (also using a 4-point Likert scale: "not helpful" to "very helpful") how helpful their booklet was in addressing that purpose. Validation of the PIA is available.[14] Based on our earlier research with both patients[1] and their family,[6] we proposed six purposes and provided space for readers to add others. The six purposes provided were: organizing their thoughts, understanding their situations, deciding on treatment, planning their futures, providing emotional support to others, and discussing the situation. In addition, the PIA asks some usage questions such as how long the booklet was read, how often sections were re-read, and how often readers discussed its content with others; responses to each question were ordinal using either 3 or 4 categories. Other AFTER evaluations for both patients and family included State-Trait Anxiety Inventory, State Form only,[15] and for patients only: the Stanford Inventory of Cancer Patient Adjustment,[16] for patients who decided they wanted to participate in decision making, the Decisional Conflict Scale[17] and the Preparation for Decision Making Scale.[18] For the purposes of this report, we are focusing primarily on the AFTER responses.

Statistics

Most comparisons between the groups involved comparing Likert scales which we treated as ordinal categories and tested with Chi-Square tests. T-tests were used to compare continuous variables between the two groups.

Results

Participants

Of 379 participants who consented to participate in the study from three cancer centres, we obtained full information (i.e., both BEFORE and AFTER evaluations) from a total of 180 patients and 128 family members for a total of 308 participants (81%); 152 participants (both patients and family) were assigned to the CCE group and 156 to the AZ group across the centres. An additional nine patients were not offered the study because their oncologist judged them to be emotionally incapable of completing the task, usually because they were still in a stage of being overwhelmed by the diagnosis. Of those who reported their age (n = 150 CCE and n = 147 AZ), the mean of the CCE group was slightly older (64 yr) than the AZ group (62 yr), [t = 3.0, p = .003]. There was no difference in highest level of formal education completed by the two groups: about 11% completed grade school as their highest level, about 42% completed high school, about 31% had some undergraduate/college education and about 16% had gone to graduate school [χ^2 = 4.12, p >.2].

Correlation between patient and family responses

We were first interested in determining the extent that patients' and their family members' responses were independent of one another, to determine if we could combine their responses as a single group and use statistical tests that assume independence of responses. Spearman's correlations were used to assess associations between their scores, separately for each booklet group and each purpose. The correlations between patient and their family's importance ratings of the six reasons for the CCE group ranged from 0.02 (decide) to .50 (providing support). Thus, patient responses accounted for 25% or less of the variance in their family members' responses. For the AZ group correlations ranged from -.02 (providing support) to .19 (discussing), thus, patient responses accounted for 4% or less of the variance in their family members' responses. To evaluate the relationship in helpfulness ratings for each purpose, we correlated the patient-family dyads in which both members rated the purpose at a level above "not important". The correlations for the CCE group ranged from 0.28 (understanding), accounting for 8% of the variance, to -.01 (discussing), accounting for less than 1% of the variance. The correlations for the AZ group ranged from .39 (organizing), accounting for 15% of the variance to -.001 (plan) accounting for less than 1% of the variance. The low amount of variance in the families' responses predicted by the patients' responses demonstrated that there was little relationship between the two, both among their importance ratings and among their helpfulness assessments. Thus, we subsequently treated patient and family responses as independent.

Usage

Participants in the two groups had their respective booklets for approximately the same length of time, with the largest subgroup using it for less than 1 week, the shortest category provided (CCE 40% versus AZ 51%), [χ^2 = 3.7, p >.1]. The two groups seem to have used the booklets in a similar manner, with no difference in how often sections were re-read (the largest percentage of each group re-read "some" sections, the second highest category: CCE 43% versus AZ 46%), made notes (the largest percentages reported "not at all": CCE 66% versus AZ 67%), or discussed the content with others (the largest percentages discussed it "some", the second highest category: CCE 38% versus AZ 41%), [all χ^2 < 3.2, p >.4].

Interestingly, the CCE booklet was read for a longer time than the AZ booklet with the largest percentage of each group reading it 1-3 hours (CCE 58% versus AZ 44%), [χ^2 = 28.6, p = 0.00] but participants had more trouble finding information they were looking for in the AZ booklet; the majority of each group rated it "not at all" hard to find (CCE 69% versus AZ 59%), [χ^2 =7.65, p = 0.05]. Importantly, more participants would recommend the CCE booklet than would recommend the AZ booklet, with the majority of each group recommending it "a lot" (CCE 85% versus AZ 66%), [χ^2 = 14.47, p = 0.001].

TABLE 1. **Distributions, within each group, of importance ratings for each purpose (%)**

Purpose	CCE				AZ			
	Not important	Somewhat important	Important	Very important	Not important	Somewhat important	Important	Very important
Organize	0	5	28	67	1	7	34	58
Understand	0	3	23	74	0	1	28	71
Decide	3	10	25	62	2	6	28	64
Plan	3	12	40	45	1	11	44	44
Provide support	6	21	39	34	6	14	41	39
Discuss	7	21	42	30	7	20	46	27

Importance ratings

Table 1 shows, for each purpose, the percentage of each group that rated the purpose at each level of importance. As the table shows, the distributions of importance ratings for each purpose are the same for the two booklets [all $\chi^2 < 3.3$]. The distributions show that organizing, understanding, and deciding are "very important" to the vast majority of participants. Planning and providing emotional support are "very important" to fewer participants but still almost one-half of each group. Discussing is "very important" to even fewer participants, although still about a quarter of each group. Finally, although every purpose is considered "important" or "very important" to at least three quarter of participants, each is also considered either "not important" or only "somewhat important" to others.

Additional purposes were added by 7 (2%) participants, 3 had the CCE booklet and 4 had the AZ: 2 added "to cope better" (both AZ), 3 added "to reduce anxiety" (2 CCE, 1 AZ), 1 added "to confirm what they read from other sources" (CCE), and 1 added "to help in asking questions" (AZ).

Helpfulness ratings

Table 2 shows, for each purpose, the helpfulness ratings of the participants who rated the purpose as more important than the lowest rating, "not important"; the table shows the six distributions of the helpfulness ratings for the two booklets. The CCE booklet was rated as significantly more helpful than the AZ booklet at serving the first four of the six purposes listed in the table: To help organize [$\chi^2 = 30.49$, p = 0.00], understand [$\chi^2 = 12.07$, p = .007], decide [$\chi^2 = 9.96$, p = 0.02] and plan [$\chi^2 = 18.67$, p = 0.00]. Although the trends for the other two purposes favored the CCE booklet, the differences were not reliable [both $\chi^2 < 5$].

Both booklets were rated as either very helpful or helpful in addressing each of the purposes that were added by individual participants. The one added purpose of participants in both booklet groups was "to reduce anxiety"; two had the CCE booklet for which one participant rated the booklet as very helpful, the other as only helpful while the one person who had the AZ booklet rated that booklet as only helpful.

TABLE 2. **Distributions, within each group, of helpfulness ratings for each purpose (%)**

Purpose	CCE				AZ			
	Not helpful	Somewhat helpful	Helpful	Very helpful	Not helpful	Somewhat helpful	Helpful	Very helpful
Organize	0	5	38	57	1	21	47	31
Understand	0	6	32	63	1	11	44	44
Decide	0	19	41	40	3	28	43	27
Plan	1	15	53	31	6	32	44	19
Provide support	6	21	47	26	8	28	43	20
Discuss	2	18	48	32	4	28	46	23

Additional outcomes

The CCE booklet was rated higher on the Satisfaction with Preparation for Decision Making scale than the AZ booklet (CCE 2.8 versus AZ 2.5), [t = 2.0, p = .047]. Although all means of the rest of the additional outcomes also appear to favor the CCE booklet, the differences were not statistically or clinically significant: the State-Trait Anxiety Inventory (CCE 41.4 versus AZ 41.6), Stanford Inventory of Cancer Patient Adjustment (CCE 7.6 versus AZ 7.5), and Decisional Conflict (CCE 3.35 versus AZ 3.4), [all t <1].

Discussion

This study was designed to compare how effectively each booklet served the purposes that early-stage prostate cancer patients and their families had for the information they required. The similarities and differences we observed between booklets have important general implications for the routine provision of educational aids in the urology or cancer centre clinic.

The observation that a high proportion of readers in both groups found their booklets to be helpful reinforces that patients do benefit from clinicians providing educational aids, and that routine provision of written information is, overall, desirable.

The observation that the two booklets were not equally helpful, however, demonstrates that clinicians should consider the quality and the effectiveness of the information they provide. For example, the CCE booklet is more effective at helping the patients and their families with understanding, organizing, deciding and planning. A methodological issue thus arises, namely, that no easily applied and validated evaluation strategy is available to clinicians. Our results further emphasize that the appropriate evaluation of such material is required to be multi-dimensional, since a single effectiveness outcome measure would not be able to demonstrate the differential benefits seen in this study. We note, however, that while our multi-dimensional evaluation provides us with more detailed information about the relative merits of the two booklets, it does not clarify exactly why the differences exist. For example, they could be related to the specific information provided, how it was provided, how easily it could be found or a combination of those reasons.

We note that we could have evaluated the two booklets by offering both to participants and then having the participant indicate which they preferred. We chose to not use such a study design because we wanted detail about the relative merits of each booklet in a manner that would not have evaluation of one booklet contaminated by experiencing the other booklet.

Although both booklets were considered helpful to the majority of patients for all purposes, we note that at least 20% of each group found their respective booklets to be only somewhat helpful at best for deciding, planning, providing emotional support and discussing issues. For those patients, it may be that the booklets, as educational aids, are not sufficient support. Recognizing that decision-making also requires patients to "sort out" their values, it may be that a decision aid could provide assistance over-and-above an educational aid.[19] Similarly, the booklets' limited helpfulness to some readers in planning, providing emotional support or discussing their situations may require interventions beyond information provision, such as individual counseling where required.

Conclusions

The results of this study indicate that clinicians should continue to provide patients with information, and that patients often find educational aids very helpful. Clinicians should also recognize, however, that some information aids are more helpful than others. The CCE booklet offers Canadian urologists a well-tested option for their patients with early-stage prostate cancer and their families. ☐

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