Special Feature

Does Use of the Adjuvant! Model Influence Use of Adjuvant Therapy Through Better Risk Communication?

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Key Words

Risk communication, shared decision-making, decision aids, Adjuvant!, breast cancer, patient education

Abstract

Adjuvant! is a model that provides recurrence and mortality risk predictions for patients with breast cancer considering adjuvant therapies. Although low-risk patients who saw Adjuvant! chose adjuvant therapy less frequently, whether this was because of educational or other aspects of the decision aid is unknown. The authors explored whether Adjuvant! affects choice of therapy through increased patient knowledge. A subset of data were analyzed from a cluster randomized trial in which oncology practices in 2 major United States cities were randomly assigned to use either Adjuvant! or an informational pamphlet to educate patients. Of 405 patients, 48 were low-risk, with 28 assigned to the decision aid and 20 to the pamphlet. Among the low-risk patients, using frequency tables and Fisher exact tests, the authors explored whether Adjuvant! was associated with more accurate patient estimates of survival; whether accuracy was associated with treatment choice; and whether, after controlling for accuracy, any remaining association was seen between Adjuvant! and treatment choice. Adjuvant! was associated with more accurate estimates of baseline prognosis compared with the pamphlet (57% vs. 25%; $P = .04$). Patients who had more accurate estimates of baseline prognosis were less likely to choose adjuvant therapy (62% vs. 89%; $P = .04$). After controlling for accuracy, no statistically significant association was found between the use of Adjuvant! and adjuvant therapy ($P = .59$ and $P = .11$ for inaccurate and accurate patients, respectively). Adjuvant! seems to influence patient choice through educational rather than other means of persuasion. However, many patients held inaccurate risk perceptions after viewing Adjuvant!. (*JNCCN* 2011;9:707–712)

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Patients with breast cancer who are at relatively low risk for recurrence or mortality after local therapy (surgery with or without radiation) face a "grey zone" decision about whether to undergo adjuvant therapy.[1] The choice of therapy involves balancing uncertain risks and side effects with uncertain benefits. Informed consent requires that patients understand potential risks and benefits.[2] Accordingly, oncologists present information regarding risks and benefits of adjuvant therapy, including its effects on 10-year survival and recurrence rates.[3]

Adjuvant! is a tool that provides personalized 10-year recurrence and mortality risk predictions for patients with breast cancer considering adjuvant therapies.[4–6] These estimates are based on patient and tumor characteristics under different therapy choices and have been validated against a large Canadian dataset.[7] One study suggests that 44% of community oncologists and 78% of research oncologists use printouts from the Adjuvant! Web site (adjuvantonline2.com) to estimate risks of recurrence or mortality.[8]

Previous research has shown that for low-risk patients, exposure to Adjuvant! is associated with less ad-

juvant therapy use.[9,10] These reports did not explore the mechanisms behind this association. Moreover, pilot studies of patients exposed to Adjuvant! suggest that only a minority of patients retain the estimates from Adjuvant!.[11–15] Therefore, whether Adjuvant! influences treatment choice through educating patients or other mechanisms is unknown.

The authors hypothesize that exposure to Adjuvant! is associated with increased accuracy of patient estimates of prognosis, and that patients with accurate estimates make different choices about therapy from those with inaccurate estimates. To test these hypotheses, the authors analyzed a subset of data from a randomized controlled trial of the effects of Adjuvant!,[9,10] focusing on low-risk patients because previous research showed that Adjuvant! affected therapy choice for these patients.[9] They chose to define low risk as a greater than 85% 10-year survival rate as predicted by Adjuvant!, which at the time represented a grey area for treatment. At intervention, patients with a greater than 10% recurrence rate would have been candidates for routine adjuvant therapy.[16,17] As the objective was to study risk communication and therapy choice, the authors believed that the threshold of a greater than 85% 10-year survival rate would include not only patients who would have been candidates for adjuvant therapy, but also those for whom forgoing adjuvant therapy would have been appropriate according to the guidelines at the time.

This study explored the following questions to assess the specific mechanism affecting treatment choice:

- Was Adjuvant! associated with more accurate patient estimates of prognosis compared with educational pamphlets?
- Was patient accuracy associated with use of adjuvant therapy?
- After controlling for accuracy, was residual association seen between Adjuvant! and use of therapy?

Figure 1 shows the relationships studied.

Patients and Methods

Patient Population

Patients were eligible for the original study if they were diagnosed with stage I through III breast cancer, had completed local therapy (surgery with or without radiation), were eligible for adjuvant therapy (chemotherapy, hormone therapy, or both), and did not have a history of breast cancer. A total of 432 patients participated in the study, and 405 provided complete data. The patients agreed to a study examining how patients and physicians communicate about health care decisions before their first meeting with their medical oncologist. The study was approved and reviewed by the institutional review boards at Case Western Reserve University and the University of Texas at San Antonio. For details about the original study, readers are referred to the primary publication.[9]

Study Design and Procedures

Physician practices were stratified by setting (community or academic) and then randomized to use Adjuvant! or the pamphlet. Patients in the Adjuvant! group were shown quantitative mortality and recurrence risk graphics, and a standard presentation to explain the graphics. Patients in the pamphlet group saw a pamphlet that discussed the different types of adjuvant therapy but did not contain quantitative risk estimates. Patients were expected to generate a numeric estimate based on whatever information they had available to them. In the pamphlet group, they were not primed with quantitative risk estimates. Overall, 58 oncologists in 14 oncology practices in Cleveland, Ohio and San Antonio, Texas participated during the study period (1998–2001). These practices included 9 community and 5 academic hospitals.

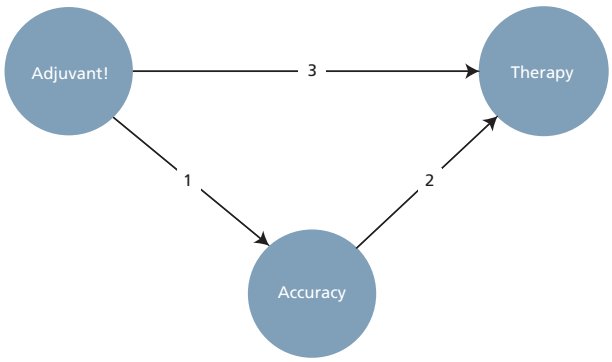

Figure 1 The arrows depict possible relationships. The numbers identify each of the research questions about these relationships: 1) Was Adjuvant! associated with more accurate patient estimates of prognosis compared to educational pamphlets? 2) Was patient accuracy associated with use of adjuvant therapy? 3) After controlling for accuracy, was any residual association seen between Adjuvant! and use of therapy?

Outcomes, Measures, and Instruments

The secondary analysis explored the association between 3 dichotomous variables: intervention (Adjuvant! or pamphlet); accuracy of patient estimates of survival (within 5% of the Adjuvant! estimate or not); and treatment chosen (adjuvant therapy or not). Specifically, as a measure of patient accuracy, the authors compared each patient's estimate of 10-year survival after local therapy alone versus the corresponding Adjuvant! estimate. Local therapy survival refers to survival after surgery with or without radiation (i.e., with no adjuvant therapy). The authors focused on this measure because it represents the baseline prognosis that all patients should understand as a matter of informed consent, and is an antecedent to understanding the effects of adding any therapy. A ±5% threshold for accuracy was used because this measure was previously found to be clinically relevant and to have desirable statistical properties.[11]

To measure patient estimates of survival, a research assistant administered a postintervention survey after the patient had been presented with the Adjuvant! intervention or the pamphlet control condition and completed the consultative visit with the medical oncologist. To generate Adjuvant! estimates and classify eventual treatment, the research assistant conferred with attending oncologists to confirm chart indications about the tumor size, grade, hormone receptor status, number of positive lymph nodes, comorbidity level, and whether the patient underwent chemotherapy, hormone therapy, both, or neither.

Interventions

In both the Adjuvant! and pamphlet groups, a physician first met with the patient to gather information about their cancer history and to conduct a physical examination. The patient then met with a health educator, who reviewed either a printout from Adjuvant! or a pamphlet. The pamphlet was based on common pamphlets in use, describing general information on adjuvant therapy, and did not contain numeric information. In the pamphlet arm, the health educator read the pamphlet aloud to the patient. In the Adjuvant! arm, the health educator used a standard script to review the results from Adjuvant! with the patient. Finally, the patient continued the consultation with the oncologist, who made a treatment recommendation.

Analysis Plan

Attention was focused on low-risk patients for 2 reasons: they were shown to have been most affected by the intervention, and recommendations about using adjuvant therapy are less clear for this population. For example, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) suggest that low-risk patients with positive estrogen receptor status arrive at a shared decision with their oncologists regarding use of hormone therapy.[1] Low-risk patients with negative estrogen receptor (ER) status may reasonably forego adjuvant therapy. An Adjuvant! estimate of 10-year survival greater than 85% was used to classify patients as low-risk.

To examine questions 1 and 2, the authors examined frequency tables and tested the corresponding null hypotheses using a Fisher's exact test, setting a 2-sided *P* value of 5% as the significance level.

To analyze question 3, the authors controlled for accuracy of the patient's estimate and then looked for any remaining influence of Adjuvant! on patient choice. This was done by first stratifying the sample on accuracy and then examining the relationship between exposure to Adjuvant! and use of therapy within the accurate and inaccurate group. Two frequency tables were constructed, one for each accuracy stratum, and the corresponding null hypotheses was tested using the same approach as described for questions 1 and 2. The rationale behind this analysis plan was to ascertain whether Adjuvant! had significant effects after controlling for accuracy. A significant effect in either or both accuracy strata would suggest that mechanisms other than education were involved, whereas a finding of no significance would indicate that the primary effect came through Adjuvant! being used as an educational tool.

Results

Patient Population

The low-risk group consisted of 48 patients with an Adjuvant!-predicted 10-year local therapy survival rate of greater than 85%. Twenty-eight of these patients had been randomized to the Adjuvant! arm and 20 to the pamphlet arm. Overall, 70% were postmenopausal and 80% were ER-positive. Patients had a broad range of education: 10% had not completed their high school education, 38% were high school graduates, 19% had some postsecondary education, and 33% had a bachelors or

graduate degree. No significant differences were seen among demographic variables, including age, income, education, race, marital status, or number of children.

Study Question 1

Adjuvant! was associated with more accurate patient estimates of baseline prognosis compared with usual care. In the low-risk group, 57% of the patients exposed to Adjuvant! and 25% of patients exposed to the pamphlet estimated their 10-year local therapy survival rate within 5% of the Adjuvant! estimate (P = .04, Fisher exact test, 2-sided; see Table 1).

Table 1 Relationship Between Intervention and Accuracy of Patient Estimates of 10-Year Survival

	Pamphlet	Adjuvant!
Accurate*	5 (25%)	16 (57%)†
Inaccurate	15 (75%)	12 (43%)
Total	20	28

*Defined as patient estimate of 10-year survival within 5% of Adjuvant! estimate.
†Difference between pamphlet and Adjuvant!: P = .04, 2-sided Fisher's exact test.

Table 2 Relationship Between Accuracy of Patient Estimates of 10-Year Survival and Use of Adjuvant Therapy

Therapy Choice	Inaccurate	Accurate*
Adjuvant therapy	24 (89%)	13 (62%)†
No additional therapy	3 (11%)	8 (38%)
Total	27	21

*Defined as patient estimate of 10-year survival within 5% of Adjuvant! estimate.
†Difference between inaccurate and accurate: P = .04, 2-sided Fisher's exact test.

Study Question 2

Increased patient accuracy among low-risk patients was associated with fewer choosing adjuvant therapy. Of 21 patients who were accurate, 8 chose to forego adjuvant therapy, compared with 3 of 27 patients whose prognostic estimates were inaccurate (P = .04, Fisher's exact test, 2-sided; see Table 2).

Study Question 3

Finally, an analysis was conducted to control for prognostic accuracy by stratifying the low-risk patients into separate accurate and inaccurate subsets. Before stratifying, a statistically significant difference was seen in the use of adjuvant therapy between the Adjuvant! and pamphlet groups. After stratifying, no difference was found. Specifically, of the patients who were inaccurate, 2 of 12 in the Adjuvant! group chose no additional therapy, compared with 1 of 15 in the control group (P = .57). Of the patients who were accurate, 8 of 16 chose no additional therapy in the Adjuvant! group, compared with 0 of 5 who chose no additional therapy in the pamphlet group (P = .11, Fisher exact test, 2-sided; see Table 3).

Discussion

The analyses conducted support the hypothesis that, among low-risk patients, Adjuvant! influences patient choice through increasing patient accuracy. Specifically, the authors found that Adjuvant! was associated with more accurate patient estimates of survival and that increased patient accuracy was associated with the decision to undergo adjuvant therapy. The authors also explored whether any residual association was seen after controlling for patient accuracy, but no statistically significant associations were seen. However, among accurate patients, the

Table 3 Relationship Between Use of Adjuvant! Model and Use of Adjuvant Therapy While Controlling for Accuracy of Patient Estimates of 10-Year Survival

	Inaccurate		Accurate*	
Therapy Choice	Adjuvant!	Pamphlet	Adjuvant!	Pamphlet
Adjuvant therapy	10 (83%)	14 (93%)†	8 (50%)	5 (100%)‡
No additional therapy	2 (17%)	1 (7%)	8 (50%)	0 (0%)
Total	12	15	16	5

*Defined as patient estimate of 10-year survival within 5% of Adjuvant! estimate.
†Difference between Adjuvant! and pamphlet: P = .57, 2-sided Fisher's exact test.
‡Difference between Adjuvant! and pamphlet: P = .11, 2-sided Fisher's exact test.

proportions were strikingly different: 8 of 16 (50%) chose to undergo additional therapy in the Adjuvant! group, compared with 5 of 5 (100%) in the pamphlet group. Although this was not statistically significant, this analysis should be replicated with a larger number of low-risk patients. Any significant residual association should stimulate researchers to search for other mechanisms through which the Adjuvant! presentation might be influencing the use of adjuvant therapy. If a larger study does not show a residual association, it would support the hypothesis that education is the primary mechanism through which Adjuvant! influences choice.

This study has other limitations. The choices of therapies today are more complex than they were when the study was conducted. The Adjuvant! predictions are known to be slightly inaccurate for certain population groups (< 35 y or with known additional adverse prognostic factors such as LVI).[7] Furthermore, new genomic profiling tools, such as Onco*type* DX, are available. This could make communication even more difficult today. Although the conclusions of this study were generated in the context of the Adjuvant! decision aid, they may be generalizable to risk communication for additional therapy choices and risk estimates based on more comprehensive patient information.

The results of this study are consistent with the overall literature on decision aids, showing that they do improve risk perceptions.[18] However, although the improvements in risk perceptions are statistically significant, these could be greater. In the Adjuvant! group, 57% of patients estimated their baseline survival to within 5% of the Adjuvant! predictions. This falls within the 35% accuracy found in a pilot study of Adjuvant![11,13] and the 60% accuracy found in a study of a different decision aid for breast cancer.[19]

One feature of this study must be highlighted as both a strength and limitation. The authors conducted a secondary analysis on a subset drawn from a larger primary dataset. This made efficient use of resources. However, the primary study data were collected between 1999 and 2001, meaning that these findings may be outdated. The rationale for conducting this analysis despite the time lag is that the Adjuvant! printouts are identical to those used now, and there is no reason to believe that patient information processing mechanisms have changed.

The authors conclude that Adjuvant! helps many, but not all, low-risk patients improve their understanding of risks and benefits of adjuvant therapies for breast cancer (57% vs. 25% accurate). Low-risk patients who are well informed about their baseline survival prospects use less adjuvant therapy than patients whose perceptions of baseline survival are inaccurate (62% vs. 89% used adjuvant therapy). Although Adjuvant! seems to influence choice through patient education, researchers should replicate this result with larger numbers of low-risk patients.

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