Development and pilot-testing of a Decision Aid for use among Chinese women facing breast cancer surgery

Angel H.Y. Au BA,* Wendy W.T. Lam PhD,† Miranda C.M. Chan MBBS,‡ Amy Y.M. Or MSc (Nursing),§ Ava Kwong MBBS,¶ Dacita Suen MBBS,** Annie L. Wong MSc (Nursing),†† Ilona Juraskova PhD,‡‡ Teresa W.T. Wong MSc* and Richard Fielding PhD§§

*Post-Graduate Research Student, †Assitant Professor, Centre for Psycho-Oncological Research & Training, School of Public Health, The University of Hong Kong, Hong Kong, China, ‡Consultant, §Breast Nurse Specialist, Department of Surgery, Breast Centre, Kwong Wah Hospital, Hong Kong, China, ¶Chief of Division of Breast Surgery, **Associate Consultant, Breast Centre, Tung Wah Hospital and Queen Mary Hospital, The University of Hong Kong, Hong Kong, China, ††Breast Nurse Specialist, Breast Centre, Tung Wah Hospital, Hong Kong, China, ‡‡Lecturer in Health Psychology, Centre for Medical Psychology and Evidence-based Decision-making (CeMPED), School of Psychology, The University of Sydney, Sydney, NSW, Australia and §§Professor, Centre for Psycho-Oncological Research & Training, School of Public Health, The University of Hong Kong, Hong Kong, China

Abstract

Background Women choosing breast cancer surgery encounter treatment decision-making (TDM) difficulties, which can cause psychological distress. Decision Aids (DAs) may facilitate TDM, but there are no DAs designed for Chinese populations. We developed a DA for Chinese women newly diagnosed with breast cancer, for use during the initial surgical consultation.

Aims Conduct a pilot study to assess the DA acceptability and utility among Chinese women diagnosed with breast cancer.

Methods Women preferred the DA in booklet format. A booklet was developed and revised and evaluated in two consecutive pilot studies (P1 and P2). On concluding their initial diagnostic consultation, 95 and 38 Chinese women newly diagnosed with breast cancer received the draft and revised draft DA booklet, respectively. Four-day post-consultation, women had questionnaires read out to them and to which they responded assessing attitudes towards the DA and their understanding of treatment options.

Results The original DA was read/partially read by 66/22% ($n = 84$) of women, whilst the revised version was read/partially read by 74/16% ($n = 35$), including subliterate women ($\chi^2 = 0.76$, $P = 0.679$). Knowledge scores varied with the extent the booklet was read (P1: $F = 12.68$, d.f. 2, $P < 0.001$; P2: $F = 3.744$, d.f. 2, $P = 0.034$). The revised, shorter version was graphically rich and resulted in improved perceived utility, [except for the 'treatment options' ($\chi^2 = 5.50$, $P = 0.019$) and 'TDM guidance' ($\chi^2 = 8.19$, $P = 0.004$) sections] without increasing anxiety ($F = 0.689$, $P = 0.408$; $F = 3.45$, $P = 0.073$).

Correspondence

Dr. Wendy WT Lam
Centre for Psycho-Oncological
Research & Training
School of Public Health
The University of Hong Kong
5.F, WMW Mong Block
Faculty of Medicine Building
21 Sassoon Road
Hong Kong
China
E-mail: wwtlam@hku.hk

Accepted for publication

25 October 2010

Keywords: breast cancer surgery, Chinese women, Decision Aid, pilot-testing

Conclusion The DA was perceived as acceptable and useful for most women. The DA effectiveness is currently being evaluated using a randomized controlled trial.

Introduction

Breast cancer is the second most common cancer worldwide,¹ and a major global health burden. Early surgical treatment can be highly effective, but the diagnosis and treatment of breast cancer profoundly impacts most women, causing multiple physical and psychosocial sequelae.^{2,3} Early adjustment to diagnosis and treatment is an important predictor for long-term quality of life,⁴ post-treatment adjustment,⁵ and may even improve 5-year recurrence and survival rates.⁶ Breast cancer management is complex, involving multiple medical, surgical and radiotherapeutic treatment options that produce a variety of possible outcomes. After diagnosis, women must make several difficult treatment decisions. Breast conserving therapy by minimizing body disfigurement is presumed to minimize psychosocial dysfunction. However, studies show that women having breast conserving therapy do not necessarily report better psychological outcomes than those having mastectomy.^{7–12} It is important that patient participation in treatment decision making (TDM) leads to a treatment choice congruent with the patient's values and preferences, which may be more important than the treatment itself in influencing longer-term adjustment.^{12–18} However, if not performed sensitively, responsibility for treatment outcomes may be directed on to patients,¹³ which can become problematic in the event of unsatisfactory outcomes.

Women experiencing TDM difficulties for breast cancer surgery report persistent psychological morbidity in the year following cancer diagnosis.^{12,19,20} However, women's individual preferences for TDM involvement vary,²¹ which makes providing good clinical care for such women challenging. Consequently, various informational and decision-support strategies such as Decision Aids (DAs) have been adopted to help to optimize women's TDM for breast

cancer surgery. DAs appear to benefit patients by improving the TDM process through reducing decisional conflict, improving knowledge and establishing more realistic outcome expectations.²² A recent systematic review on the effect of DAs on surgery knowledge and choice among women with breast cancer showed that women who used a DA knew more about breast cancer and relevant treatment options, had less decisional conflict, more often chose breast conserving therapy and reported greater satisfaction with the decision-making process.²³ However, published studies of DAs have been conducted mostly in Caucasian, English-speaking populations, and to our knowledge no DAs has been designed for Asian populations to date. The Chinese population is the largest ethnic group in the world and is experiencing increasing breast cancer rates, but there is currently no data on the acceptability, utility or efficacy of using DAs in TDM for breast cancer surgery among this population.

Hong Kong, with a population of approximately 7 million, 98% of whom are ethnic Chinese, is part of the Pearl Estuary conurbation of southern China. It has a mixed medical economy, comprising an affordable government taxation-funded western-style medical system of international standard. Private western and traditional Chinese medical services are also available. Education level varies from low among older adults to postgraduate among young adults. Median household income slightly exceeds US\$24 000 (€18 700) per annum. Population-wide breast screening is not warranted because of low population prevalence of breast cancer but walk-in and high-risk screening is available in well women clinics and risk information is widely disseminated. Dedicated breast clinics are available but most women are treated in surgical oncology departments where women generally make their surgical treatment decision after consultation.

To address the needs of this group, we therefore developed a DA for Chinese women facing TDM for breast cancer surgery. We report results of two Pilot studies assessing the acceptability and utility of this DA among Chinese women diagnosed with breast cancer prior to its evaluation in a randomized controlled trial.

Method

Development of the draft DA booklet

Various patient DAs have been developed, including audiotape–booklet combinations, booklet format and interactive computer pro-

grammes.²² As a first step, we conducted a survey among 80 Chinese women diagnosed with breast cancer to assess their preferred format for breast cancer treatment-related information. Most women expressed preference for a booklet format, which therefore was used. The content of the draft DA booklet was based on current clinical guidelines for surgical management of early stage breast cancer,²⁴ together with prior findings on breast cancer TDM among Chinese women.^{12,19,25} Guided by the International Patient Decision Aids Collaboration²⁶ criteria, the draft DA booklet (Fig. 1) comprised nine components: (i) information about early breast cancer, (ii) information about available treatment options, (iii) information about the main

Chapter 4

What are the main differences among the three treatment options?

	Breast conserving surgery followed by radiation therapy	Mastectomy	Mastectomy with immediate breast reconstruction surgery
What does the surgery remove?	Breast conserving surgery usually involves: <ul style="list-style-type: none"> the cancer and a small area of normal tissue around it (the surgical margin) of lymph nodes from the armpit 	Mastectomy usually involves: <ul style="list-style-type: none"> the entire breast (including the nipple) lymph nodes from the armpit 	Mastectomy with breast reconstruction usually involves: <ul style="list-style-type: none"> the entire breast (including the nipple) rebuilding a breast shape, using an implant or tissue from another part of your body.
Is this surgery suitable for me?	Suitable if <ul style="list-style-type: none"> the cancer is small, so that all the cancer and a surgical margin of normal tissue can be safely removed, <i>and</i> an acceptable appearance can be achieved for the remaining breast tissue. 	Suitable if: <ul style="list-style-type: none"> the area of cancer involved is large the cancer is in more than one area of your breast the cancer is under the nipple 	After mastectomy, reconstruction surgery can be done <ul style="list-style-type: none"> at the same time as the mastectomy operation <i>or</i> it can be done some time later.
What will my breast look like after the surgery?	You will be able to keep your breast, but the shape will look a bit different.	<ul style="list-style-type: none"> Your breast and nipple will be removed. You will have a flat chest on the side of your body where the breast was removed. Usually after the surgery, you need to use a breast prosthesis (a soft object shaped like your breast which fits into your bra) to give a fairly natural breast appearance when dressed. 	<ul style="list-style-type: none"> You will have a breast-like shape. Your breast will not look nor will it feel the same as it did before your surgery. You will have a natural body appearance when dressed.

Figure 1 Example of one page from the original draft Decision Aid booklet used in Pilot 1.

differences between the available treatment options including probabilities of outcomes associated with each choice, (iv) a review of benefits and costs of the available treatment options, (v) others' experiences, (vi) methods for clarifying patients' values and (vii) structured guidance in reaching a decision. The content and layout of the draft booklet were reviewed by a panel comprising three breast surgeons, two breast nurse specialists, a medical oncologist, a clinical psychologist, as well as five Chinese breast cancer survivors.

Pilot study 1

Participants and setting

After obtaining institutional ethical approval, a convenience sample of Chinese women identified in advance by clinic staff according to the following eligibility criteria was recruited from two Hong Kong government-funded breast clinics. Eligibility required confirmed early stage breast cancer suitable for surgical choice (mostly early stage 0-II breast cancer, which was known in advance by the clinic and would be revealed to the patient in their imminent consultation), adequate communication and comprehension ability and willingness to participate in the study. Recurrent breast cancer cases were ineligible.

When approached in the clinic by the research assistant, eligible women were awaiting their surgical consultation wherein their breast cancer diagnosis would be confirmed and treatment options discussed. (Prior to this consultation, women had made one previous clinic visit to investigate their breast abnormality.) Women who gave fully informed consent to participate in 'an evaluation study of an information booklet' were recruited. No mention of diagnosis was made at this stage. Consenting participants completed a baseline questionnaire assessing psychological distress (see Measures below). Women then went into their consultation where their diagnosis was disclosed. In most cases, three treatment options for early stage breast cancer were discussed: breast conserving therapy, modified radical mastectomy (MRM) and

MRM followed by immediate breast reconstruction, unless the patient's medical condition dictated otherwise. Women and usually their companion discussed treatment with the surgeon who answered patient's questions. Women were offered decisional delay of up to 7 days, to select their preferred surgical option. At the end of the consultation, the participating surgeons gave the draft DA booklet to eligible women who had consented to participate in the study. Immediately following this consultation, a trained research assistant accompanied the woman to a private room, where she briefly explained the purpose and layout of the DA booklet as well as its use for TDM to the participant, who was asked to read and use the booklet at home to facilitate TDM.

Four-to-seven days after the initial consultation, patients returned to the clinic for their next follow-up appointment. At this visit, participants completed a face-to-face follow-up questionnaire-based interview on the content, layout and acceptability of the DA, and measures of distress. Of 100 eligible women consecutively identified, 95 (95%) agreed to participate in Pilot study 1.

Measures

The acceptability of the draft DA booklet was assessed using a 31-item hybrid measure derived from those developed by Ottawa Health Decision Centre,²⁷ and by Juraskova *et al.*²⁸ Both measures were designed to assess general views on the presentation and content of information in DAs and, therefore, were considered suitable to adopt to evaluate DAs for other health conditions. The 31-item measure was chosen because it was carefully developed, robust, comprehensive and generic. It assessed the comprehensibility of components of the draft and revised versions of the DA booklet, its length, amount of information, balance in presentation of the treatment options, and overall suitability for decision making,^{27,28} using four- or five-option categorical responses per item, scored 1–4 or 1–5, respectively. Response options differed for different sections of the questionnaire: for the DA content, response options were 'Poor', 'Fair',

'Good', to 'Excellent'; for the DA utility, response options were 'Strongly Disagree', 'Disagree', 'Neutral', 'Agree' and 'Strongly Agree'. For the contribution to decision-making section, response options ranged from 'Not at all' through to 'A great deal'. Finally, evaluating importance of different decision-making influences had response options of 'Not important', 'Important', and 'Very important'.

The perceived utility of the draft DA booklet was assessed by the 10-item 'Preparation for Decision Making' measure developed by Ottawa Health Decision Centre.²⁹ We selected six items from the measure that were relevant to our study (Cronbach's alpha = 0.94 using Pilot 1 sample). We excluded the remaining four items, which assessed patients' opinion of DA effectiveness in facilitating consultation participation, as they were deemed irrelevant to the current study. Each item is rated on a five-point categorical scale ranging from 1 (not at all) to 5 (A great deal), giving a total score range from 6 to 30, with higher scores indicating greater perceived utility of the DA booklet in preparing the women to make treatment decision. Internal consistency for the six-item measure was 0.94 in the current study.

The above measures were translated into Chinese by a bilingual researcher. The translation was reviewed for clarity and wording by a professional teacher of Chinese. This Chinese version was independently back-translated into English and compared with the original by a native English speaker, and amendments were made to the Chinese wording where required. The process was reiterated until the two English versions corresponded semantically.

We assessed participants' breast cancer knowledge using a validated 10-item true/false response questionnaire of general information about breast cancer and its treatments and related benefits and harms.³⁰ Higher scores indicate better knowledge. Psychological distress was measured using the 14-item Hospital Anxiety and Depression Scale (HADS),³¹ comprising 2 seven-item subscales that measure anxiety and depression, respectively. Each item is rated on a four-point scale. Total scores for each subscale

range from 0 to 21, with higher scores indicating greater distress. Scores exceeding 10 on each subscale constitute case definition for psychological morbidity, scores of 8–10 indicate subclinical caseness and scores <8 represent non-cases. The HADS is widely used in cancer studies as it avoids contamination by physical symptoms and has good validity and reliability.³²

Demographic information, including age, education, marital status, occupation, household income, religion, and family history of breast cancer, was gathered. Excepting anxiety and depression, which were measured at both baseline and follow-up interviews, all other measures were administered once only during the follow-up interview.

Development of the revised DA booklet

Although the original draft DA booklet was well received (see Results section), women's feedback in Pilot study 1 indicated that revision of the DA booklet was needed. Several women found the original draft, comprising 36 A5 pages to be too lengthy ($n = 10$, 11%) and the information volume excessive ($n = 7$, 7%). Whilst the original version of the DA booklet was written for a grade 6 reading level, women with limited literacy skills did not read the booklet. Finally, women encountered difficulties comprehending the depiction of cancer recurrence risk magnitude. The original DA depicted this as a graphic showing a 10×10 matrix of 100 body silhouettes, each representing one person, a shaded proportion of five indicating the numbers of women out of 100 (i.e. 5%) with such a diagnosis who would experience recurrence. When questioned, women expressed preference for a pie-chart format to represent this risk proportion. We therefore surveyed another 40 women diagnosed with breast cancer and assessed their preference for communicating risk estimates via the 100 silhouettes or pie-chart risk formats. Most ($n = 29$, 73%) of these women preferred the pie-chart format.

We therefore revised the booklet (Fig. 2) based on the above feedback from Pilot study 1, reducing the content by 50% to 18 A5 pages and adopting a mostly graphical layout to replace

Treatment options for early breast cancer	
	Breast conserving surgery
Before Surgery
After Surgery
Main differences among three treatment options	
What does the surgery remove?	
• Cancer	✓
• Entire breast (including nipple)	✗
• Lymph node from armpit	✓
• Rebuilding breast	✗
How long will the operation take?	2 – 2.5 h

Mastectomy	Mastectomy with reconstruction

✓	✓
✓	✓
✓	✓
✗	✓
2 – 2.5 h	4 h-implant or 8 h-tissue flap

Figure 2 Example of the same page from the revised draft Decision Aid booklet used in Pilot 2.

large volumes of text to improve its utility for women with low literacy. We kept four of the seven components from the original version, including the following: (i) information about the main differences between the available treatment options including outcomes probabilities associated with each choice, (ii) a review of benefits and costs of the available treatment options, (iii) methods for clarifying patients' values and (iv) structured guidance in reaching a decision. Although only 57% of women had used the worksheet to clarify their values, we felt it was essential to retain these components in the revised DA booklet as helping patients clarify their values and provide guidance in reaching a decision represent key elements of DA tools. A pie chart replaced the 100 body silhouettes graphic to present risk estimate information.

Pilot study 2

We then conducted a second pilot study to test the revised version of the DA booklet (revised DA). The study eligibility, sampling, procedure

and measures used in Pilot study 2 were identical to those of Pilot study 1. We recruited a second group of 42 eligible women, 38 of whom took part in the Pilot study 2 (a response rate of 91%).

Data analysis

In both pilot studies, descriptive statistics delineated the acceptability of the two drafts of the DA booklet and women's knowledge about breast cancer and its treatment. Chi-square and *t*-tests were used to compare the two versions of the DA booklets by demographic characteristics and the acceptability and perceived utility of each. One-way analysis of variance (ANOVA) was used to compare women who read, partially read and did not read the DA booklet by knowledge about breast cancer. General linear models assessed change of psychological distress from baseline to follow-up interviews and tested whether the change of psychological distress was dependent of the usage of the DA booklet. All analyses were performed using SPSS v.17 (SPSS Hong Kong Ltd, Hong Kong).

Results

Sample characteristics

The 95 women in Pilot study 1 included more widowed and divorced women, who had a lower household income and lacked formal education, and who had a family history of breast carcinoma, compared to the 38 women in Pilot study 2 (Table S1). However, none of these differences between the two pilot study samples were statistically significant. Over 40% of the participants in both studies were given choices between breast conserving therapy, mastectomy, and mastectomy followed by immediate breast reconstruction. The remaining participants were offered a choice between breast conserving therapy and mastectomy (38%, 21%) or between mastectomy and mastectomy plus immediate breast reconstruction (21%, 37%). The median age of our samples matched that reported by the Hong Kong Cancer Statistics³³ for women with breast cancer. As no local data exist about the trends in the use of mastectomy and breast conserving therapy in Hong Kong, the representativeness of the study findings could not be estimated.

DA booklet utilization and acceptability

In both studies, most women had read (Pilot study 1: 66%, Pilot study 2: 74%) or partially read (22, 16%) the original (Pilot study 1) or revised (Pilot study 2) DA booklet (difference in reading $\chi^2 = 0.76$, $P = 0.679$). In Pilot study 1 (draft DA), 11 women (12%) did not read their DA because of low literacy skills ($n = 6$) or being too busy ($n = 5$). In Pilot study 2 (revised DA), four women (9%) did not read their DA because of the lack of interest ($n = 3$) or because they had already chosen the treatment option during the consultation ($n = 1$). Hence, we hereafter report only perceptions of both DA versions for women who had either read or partially read the booklet ($n = 84$ Pilot study 1; $n = 34$ Pilot study 2).

The utilization of the draft and revised DA booklets was assessed (Table S2). For the Pilot

study 1 draft consisting of seven components, the most commonly read sections were on (i) information about available treatment options including outcome probabilities associated with each choice (89%) and (ii) review of benefits and costs of the available treatment options (85%). The least commonly read components were the sections on (i) others' experiences (60%), (ii) methods for clarifying patients' values (50%), and (iii) structured guidance in reaching a decision (62%). For the Pilot study 2 revised DA booklet consisting of four components, the most commonly read components were the sections on (i) information about the main differences among the available treatment options including probabilities of outcomes associated with each choice (97%) and (ii) a review of benefits and costs of the available treatment options (91%); whilst the least commonly read component was the section on methods for clarifying patients' values together with structured guidance in reaching a decision (67%). Women also rated the quality of information in each component they had read. Whilst most rated the quality of information either good or excellent in both original and revised draft DA booklets, significantly more women rated the sections on 'Main differences between treatment options' ($\chi^2 = 5.50$, $P = 0.019$) and 'Structured guidance for decision making' ($\chi^2 = 8.19$, $P = 0.004$) in revised draft DA as poor/fair than those in the original draft DA booklet. The least 'liked' was a section on 'Structured guidance for decision making' (Table S2).

Overall, most women in both pilot studies found the length of their respective DA booklets to be 'just right' (89, 90%; $\chi^2 = 11.29$, $P = 0.004$) (despite the second booklet being about half the length of the first, responses disagreeing that the length was acceptable were present in the first, but absent in the second Pilot, hence the P value reported is significant), the amount of information also 'just right' (89, 88%; $\chi^2 = 3.77$, $P = 0.151$), and the presentation of the options balanced (98, 94%; $\chi^2 = 3.32$, $P = 0.344$). Most found their DA booklet useful when making their decision about breast cancer surgery (73, 77%; $\chi^2 = 0.19$,

$P = 0.667$). Both DA booklets were considered easy to understand (89, 81%; $\chi^2 = 5.39$, $P = 0.068$), the information therein not confusing (75, 78%; $\chi^2 = 2.14$, $P = 0.342$) and 'not anxiety provoking' (78, 88%; $\chi^2 = 0.19$, $P = 0.366$) (Table S3). Respondents liked the overall format of both draft DA booklets (75, 81%; $\chi^2 = 2.12$, $P = 0.341$) and most women felt the DA booklets improved their understanding of the information obtained from the surgeon (72, 94%; $\chi^2 = 3.63$, $P = 0.162$). Participants who had also obtained other information resources reported that the draft DA booklets provided information additional to that contained in the general breast cancer information booklet (88, 94%; $\chi^2 = 4.62$, $P = 0.10$). The acceptability of the two DA booklets was high and did not differ. (All statistical tests are of differences between the two Pilot studies' sample proportions).

Preparation for TDM

Mean scores (18.68, 17.61) for the 'Preparation for Decision Making' scale indicated women perceived both DA booklets to be somewhat useful in preparing them to make treatment decisions. The perceived utility of the DA booklet was comparable between the two pilot studies ($t = 0.91$, $P = 0.823$).

Knowledge about breast cancer and treatment

Mean breast cancer and treatment knowledge scores were 61% for both Pilot studies (Table 1). For each Pilot, we compared women's knowledge of breast cancer by how much they read (fully read, partially read, or did not read) their DA booklet. Knowledge scores varied with the extent the booklet was read (Pilot 1: $F = 12.68$, d.f. 2, $P < 0.001$; Pilot 2: $F = 3.744$, d.f. 2, $P = 0.034$). In Pilot study 1, women who fully read their draft DA booklet (mean 72%) had significantly higher knowledge scores compared to those who partially read (mean 47%, Bonferroni $P = 0.004$) or did not read it (mean 29%, Bonferroni $P < 0.001$). In Pilot study 2, women who fully read their revised DA booklet (mean

65%) had significantly higher knowledge scores compared to those who only partially read the booklet (mean 35%, Bonferroni $P = 0.044$), but there was no significant difference compared to those who did not read the booklet (73%).

Psychological distress

Women reported low levels of anxiety (Pilot study 1: median = 3, mean = 4.39, SD 4.23; Pilot study 2: median = 4, mean 4.46, SD 4.08) and depression (Pilot study 1: median 1, mean 2.4, SD 3.32; Pilot study 2: median 2, mean 2.6, SD 3.14). In Pilot study 1, 11% of the women met the case criterion score for anxiety, as did 4% for depression. In Pilot study 2, 6% of the women met the case criterion score for anxiety, as did 6% for depression. There was no significant change in scores for anxiety ($F = 0.689$, $P = 0.408$; $F = 3.45$, $P = 0.073$) or depression ($F = 0.092$, $P = 0.763$; $F = 0.206$, $P = 0.653$) from baseline to follow-up interview after adjustment for reading, for either version of the DA booklet.

Discussion

We believe this is the first DA developed for Chinese women faced with breast cancer surgery TDM. The DA, a self-administered take-home booklet, was designed as an adjunct to the surgical consultation when a breast cancer diagnosis is given and treatment options discussed. Whilst women who used the DA found it acceptable, the utilization of the draft DA booklet was suboptimal. In Pilot study 1 about 10% of women found the 36-page booklet to be too lengthy, and 6% found the volume of information to be excessive, with only two-thirds reading the whole booklet and 12% not reading it at all, either because of literacy issues or lack of time. We therefore revised the booklet to 18 A5 pages, reducing the content to avoid information overload, as well as replacing most of the text with pictorial information to extend its utility to women with low literacy skills. Whilst this led to only a minor increase in a number of women reading the booklet

Table 1 Women's knowledge about breast cancer and its surgical treatment

Items	Pilot study 1				Pilot study 2			
	Women read /partially read the DA booklet		Women did not read the DA booklet		Women read /partially read the DA booklet		Women did not read the DA booklet	
	Correct (%)	Incorrect (%)	Correct (%)	Incorrect (%)	Correct (%)	Incorrect (%)	Correct (%)	Incorrect (%)
Mastectomy is removal only of cancerous part	49 (58)	35 (42)	1 (9)	10 (91)	14 (41)	17 (50)	4 (100)	0 (0)
Radiation therapy (RT) is usually necessary after lumpectomy	70 (83)	14 (17)	6 (55)	5 (46)	26 (77)	5 (15)	4 (100)	0 (0)
After lumpectomy, there is a 50% chance that cancer will recur in the treated breast	41 (49)	43 (51)	2 (18)	9 (82)	9 (27)	22 (65)	0 (0)	4 (100)
Breast reconstruction is highly recommended after lumpectomy	62 (74)	22 (26)	3 (27)	8 (73)	24 (71)	7 (21)	4 (100)	0 (0)
Fatigue is an infrequent side-effect of RT	51 (61)	33 (39)	1 (9)	10 (91)	21 (62)	10 (29)	1 (25)	3 (75)
Frequently during RT, the treated area will look and feel like it has been sunburned	67 (80)	17 (20)	4 (36)	7 (64)	27 (79)	4 (12)	4 (100)	0 (0)
The usual schedule for RT is radiation once a day, 5 days a week, for 5–6 weeks as an outpatient	62 (74)	22 (26)	4 (36)	7 (64)	24 (71)	7 (21)	2 (50)	2 (50)
For women with stage I or II breast cancer, overall life expectancy is no different for those who have a lumpectomy than for those who have mastectomy	66 (79)	18 (21)	6 (55)	5 (46)	24 (71)	7 (21)	4 (100)	0 (0)
Every woman with breast cancer, regardless of the size or location of the tumour, has an option between having a mastectomy or a lumpectomy	32 (38)	52 (62)	0 (0)	11 (100)	11 (32)	20 (59)	2 (50)	2 (50)
Hair loss is not a common side-effect of RT	51 (61)	33 (39)	5 (46)	6 (55)	23 (68)	8 (24)	4 (100)	0 (0)

DA, Decision Aid.

(from 88 to 90%), there was a 37% relative decline in partial reading and 25% relative decline in numbers not reading the booklet at all. Whilst the small sample sizes make the absolute magnitude of changes insignificant, proportionately, these changes are of large magnitude and in the desirable direction, although at some inevitable cost in terms of

comprehensiveness and clarity. However, notably improved accessibility for a broader range of women justifies this trade-off and a 10% reduction in relative comprehensiveness and clarity for a 50% cut in length was considered a significant improvement.

Previous studies of DA development have addressed acceptability rather than utiliza-

tion.^{28,34–37} In our current study, most women did read the DA booklet, particularly information about available treatment options and their associated benefits and costs. Whilst previous studies showed that Chinese women prefer involvement in breast cancer TDM,²¹ we found that the practical components for clarifying patients' values and structured guidance in reaching a decision were used much less than anticipated. Despite being asked to use a worksheet to clarify their personal values regarding the pros and cons of each treatment option and then indicate their predisposition towards different treatment options, one in three women did not want to spend time completing the worksheet and ignored it. This suggests that the DA booklet is primarily being used by these women to enhance understanding of treatment options and their associated risks and benefits, rather than as a means to clarify personal values to make treatment decisions. This may reflect greater family involvement in TDM among Chinese communities.

Both versions of the DA booklet were acceptable to Chinese women facing decisions about breast cancer surgery. The DA content was not anxiety provoking, with the revised DA perceived as approximately 10% less anxiety provoking relative to the draft DA. Women who read the DA booklet had better breast cancer knowledge than those who only partially read or did not read the booklet. In Pilot study 2, however, breast cancer knowledge did not differ between those who read the revised DA booklet and those who did not. Women who did not read the revised DA booklet had the highest knowledge score, and this seems likely to reflect greater pre-existing knowledge, possibly from other sources. As we did not assess change of knowledge scores before and after the DA booklet, we could not evaluate whether the DA booklet leads to knowledge change. Nevertheless, most women reported the DA booklet enhanced their understanding of the information obtained from the surgeon, suggesting the DA booklet is a very useful adjunct following the consultation with the breast surgeon when treatment options are discussed. Notably, a

significant proportion of women still found the draft DA booklet to be unhelpful in the TDM process. Further research is needed to clarify why this is so.

At this point, it is worth considering what constitutes 'help' in making a decision. Perhaps an optimal DA would facilitate a rational decision with little difficulty. Whether TDM should ever be a purely rational decision is doubtful because breast cancer TDM involves significant loss, and a failure to incorporate or process the emotional aspects of this loss in the TDM process is likely to result in subsequent long-term emotional decrements.³⁸ More realistically, a DA could help patient decision making on a number of different levels. If the DA shifts women from a state where they do not or cannot face a decision of this magnitude, to one where they recognize that a decision must be made, then it is already helpful on one level. If the DA enables women to better determine what issues need to be considered and what information is pertinent through clarification of information, then this is a second level of help. A third level would be if the structure or content of the DA reduced the difficulties in decision making in some manner. Finally, a fourth and possibly most important level of help could be reached if women who use the DA showed reduced TDM-related distress or morbidity subsequent to the surgery; as this would indicate that they were more better able to calibrate their expectations of outcomes with reality, thereby minimizing unanticipated disappointment, which is associated with poorer psychosocial adjustment.^{19,20,38} This latter level is where the emotional impact of a DA is likely to be greatest, but it is probably the most difficult level to achieve using a simple information-based tool such as the DA used in the present study. A DA can therefore help patients on a number of levels, even when appearing simply to clarify information. The DA piloted here contributed to at least some of these decisional elements, and so it can be considered a true DA and not just an information source.

The limitations in these two studies include being cross-sectional and having very small

samples particularly for Pilot study 2. However, being a pilot evaluation of the basic acceptability and utility of this first Chinese breast cancer treatment DA then the sample size can be considered as sufficient. The use of statistical tests of difference to compare the two DA versions is fraught with difficulties. On the one hand, tests of significance are an expected part of academic papers even when the sample constraints argue against their use. Multiple tests of difference are prone to type one error and what amount to large differences (e.g. 22% difference in understanding or 37% reduction in partial reading) will not be significant in significance tests because of insufficient statistical power, despite being very large clinically meaningful effects. The findings we report must therefore be considered tentative. The revised DA booklet is currently being evaluated in a randomized controlled trial investigating the extent to which longer-term psychological outcomes can be improved by the use of this DA. Initial results from these two pilot studies indicate the DA booklet has good utility and may be a useful TDM adjunct for at least one in two Chinese women considering breast cancer surgery treatment options.

Acknowledgements

We thank all the women who participated in this study and the HKCF for their invaluable financial support.

Sources of funding

This work was funded by Hong Kong Cancer Fund 2007/2008.

Supporting Information

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

Table S1. Sample characteristics of Pilot study 1 ($n = 95$ patients) and 2 ($n = 38$ patients)

Table S2. Utilization of the DA booklet and women's view about the way the information presented on each section of the DA booklet

Table S3. Women's perceptions of the DA booklet

Please note: Wiley-Blackwell are not responsible for the content or functionality of any supporting materials supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author for the article.

References

- 1 World Health Organization International Agency for Research on Cancer (June 2003). *World Cancer Report*.
- 2 Portenoy RK, Thaler HT, Kornblith AB *et al.* Symptom prevalence, characteristics and distress in a cancer population. *Quality of Life Research*, 1994; **3**: 183–189.
- 3 Sarna L. Women with lung cancer: impact on quality of life. *Quality of Life Research*, 1993; **2**: 13–22.
- 4 Steginga S, Occhipinti S, Wilson K, Dunn J. Domains of distress: the experience of breast cancer in Australia. *Oncology Nursing Forum*, 1998; **25**: 1063–1070.
- 5 Fielding R, Lam WWT. Optimizing treatment decision-making and adjustment to breast cancer in Chinese women. Final Report to the Hong Kong Government Health Care Promotion Fund, 30th June, 2004.
- 6 Groenvold M, Petersen MA, Idler I, Bjorner JB, Fayers PM, Mouridsen HT. Psychological distress and fatigue predicted recurrence and survival in primary breast cancer patients. *Breast Cancer Research Treatment*, 2007; **105**: 209–219.
- 7 Fung KW, Lau Y, Fielding R, Or A, Yip AWC. The impact of mastectomy, breast-conserving treatment and immediate breast reconstruction on the quality of life of Chinese women. *Australian and New Zealand Journal of Surgery*, 2001; **71**: 202–206.
- 8 Irvine D, Brown B, Crooks D, Roberts J, Browne G. Psychosocial adjustment in women with breast cancer. *Cancer*, 1991; **67**: 1097–1117.
- 9 Moyer A. Psychosocial outcomes of breast-conserving surgery versus mastectomy: a meta-analytic review. *Health Psychology*, 1997; **16**: 284–298.
- 10 Royak-Schaler R. Psychological processes in breast cancer: a review of selected research. *Journal of Psychosocial Oncology*, 1991; **9**: 71–89.
- 11 van der Pompe G, Anotoni M, Visser A, Garssen B. Adjustment to breast cancer: the psychobiological effects of psychosocial interventions. *Patient Education and Counseling*, 1996; **28**: 209–219.
- 12 Lam WWT, Fielding R, Ho EYY. Predicting psychological morbidity in Chinese women after surgery for breast carcinoma. *Cancer*, 2005; **103**: 637–646.

- 13 Fallowfield LJ, Hall A, Maguire GP, Baum M. Psychological outcomes of different treatment policies in women with early breast cancer outside a clinical trial. *British Medical Journal*, 1990; **301**: 575–580.
- 14 Fallowfield LJ, Ford S, Lewis S. No news is not good news: information preferences of patients with cancer. *Psycho-oncology*, 1995; **4**: 197–202.
- 15 Fallowfield LJ, Hall A, Maguire GP, Baum M, Hern RPA. A question of choice: results of a prospective 3-year follow-up study of women with breast cancer. *Breast*, 1994; **3**: 202–208.
- 16 Levy SM, Herberman RB, Lee JK, Lippman ME, d'Angelo T. Breast conservation versus mastectomy: distress sequelae as a function of choice. *Journal of Clinical Oncology*, 1989; **7**: 367–375.
- 17 Morris J, Ingham R. Choice of surgery for early breast cancer: psychosocial considerations. *Social Science and Medicine*, 1988; **27**: 1257–1262.
- 18 Pozo C, Carver CS, Noriega V *et al.* Effects of mastectomy versus lumpectomy on emotional adjustment to breast cancer: a prospective study of the first year postsurgery. *Journal of Clinical Oncology*, 1992; **10**: 1292–1298.
- 19 Lam WWT, Fielding R, Chan M, Hung WK. Treatment decision difficulties and post-operative distress predict persistence of psychological morbidity in Chinese women following breast cancer surgery. *Psycho-oncology*, 2007; **16**: 904–912.
- 20 Lam WWT, Bonanno GA, Mancini AD *et al.* Trajectories of psychological distress among Chinese women diagnosed with breast cancer. *Psycho-oncology*, 2010; **19**: 1044–1051.
- 21 Lam WWT, Fielding R, Chan M, Chow L, Ho EYY. Patient participation and satisfaction with treatment decision making in Chinese women with breast cancer. *Breast Cancer Research & Treatment*, 2003; **80**: 2.
- 22 O'Connor AM, Stacey D, Entwistle V *et al.* Decision aids for people facing health treatment or screening decisions. *Cochrane Library*, Issue 2, 2004. Chichester, UK: John Wiley & Sons, Ltd, 2004.
- 23 Waliiee JF, Rogers MAM, Alderman AK. Decision aids and breast cancer: do they influence choice for surgery and knowledge of treatment options? *Journal of Clinical Oncology*, 2007; **25**: 1067–1073.
- 24 National Breast Cancer Centre, National Health and Medical Research Council. *Clinical Practice Guidelines for the Management of Early Breast Cancer*, 2nd edn. Canberra: National Breast Cancer Centre, 2001.
- 25 Lam WWT, Fielding R, Chan M, Chow L, Or A. Gambling with your life: the process of breast cancer treatment decision making in Chinese women. *Psycho-oncology*, 2005; **14**: 1–15.
- 26 Elwyn G, O'Connor A, Stacey D *et al.* Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *British Medical Journal*, 2006; **333**: 417.
- 27 O'Connor AM, Cranney A. Sample Tool: Acceptability (Osteoporosis therapy). ©1996 (updated 2002). Available at: <http://www.ohri.ca/decisionaid>, accessed 25 March 2008.
- 28 Juraskova I, Butow P, Lopez A *et al.* Improving informed consent: pilot of a decision aid for women invited to participate in a breast cancer prevention trial (IBIS-II DCIS). *Health Expectations*, 2008; **11**: 252–262.
- 29 Graham ID, O'Connor AM. Sample Tool: Preparation for Decision Making. ©1995 (updated 2005). Available at: <http://www.ohri.ca/decisionaid>, accessed 25 March 2008.
- 30 Ward S, Heidrich S, Wolberg W. Factors women take into account when deciding upon type of surgery for breast cancer. *Cancer Nursing*, 1989; **12**: 344–351.
- 31 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, 1983; **67**: 361–370.
- 32 Razavi C, Delvaux N, Fravacques C, Robaye E. Screening for adjustment disorders and major depression disorders in cancer patients. *British Journal of Psychiatry*, 1990; **156**: 79–83.
- 33 Hong Kong Cancer Stat 2006, Hong Kong Cancer Registry, Hospital Authority, 2008.
- 34 Stacey D, O'Connor AM, DeGrasse C, Verma S. Development and evaluation of a breast prevention decision aid for higher-risk women. *Health Expectations*, 2003; **6**: 3–18.
- 35 Swaka CA, Goel V, Mahut CA *et al.* Development of a patient decision aid for choice of surgical treatment for breast cancer. *Health Expectations*, 1998; **1**: 23–36.
- 36 Cranney A, O'Connor AM, Jacobsen MJ *et al.* Development and pilot testing of a decision aid for postmenopausal women with osteoporosis. *Patient Education and Counseling*, 2002; **47**: 245–255.
- 37 Kim J, Whitney A, Hayter S *et al.* Development and initial testing of a computer-based patient decision aid to promote colorectal cancer screening for primary care practice. *BMC Medical Informatics and Decision Making*, 2005; **5**: 36, doi: 10.1186/1472-6947-5-36.
- 38 Lam WWT, Fielding R. Is self-efficacy a predictor of short-term post-surgical adjustment among Chinese women with breast cancer? *Psycho-oncology*, 2007; **16**: 651–659, doi: 10.1002/pon.1116.