Title: A systematic review of decision aids for patients making a decision about treatment for early breast cancer

Running head: Breast cancer decision aid systematic review

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Word count: Abstract: 255

Body: 4552

Tables: 4

Figures: 1

Keywords: Breast neoplasms; decision aid; treatment; decision making; systematic review; chemotherapy; surgery; radiotherapy

Abstract

Objectives

Several complex treatment decisions may be offered to women with early stage breast cancer, about a range of treatments from different modalities including surgery, radiotherapy, and endocrine and chemotherapy. Decision aids can facilitate shared decision-making and improved decision-related outcomes. We aimed to systematically identify, describe and appraise the literature on treatment decision aids for women with early breast cancer, synthesise the data and identify breast cancer decisions that lack a decision aid.

Materials and Methods

A prospectively developed search strategy was applied to MEDLINE, the Cochrane databases, EMBASE, PsycINFO, Web of Science and abstract databases from major conferences. Data were extracted into a pre-piloted form. Quality and risk of bias were measured using Qualsyst criteria. Results were synthesised into narrative format.

Results

Thirty-three eligible articles were identified, evaluating 23 individual treatment decision aids, comprising 13 randomised controlled trial reports, seven non-randomised comparative studies, eight single-arm pre-post studies and five cross-sectional studies. The decisions addressed by these decision aids were: breast conserving surgery versus mastectomy (+/- reconstruction); use of chemotherapy and/or endocrine therapy; radiotherapy; and fertility preservation. Outcome measures were heterogeneous, precluding meta-analysis. Decisional conflict decreased, and knowledge and satisfaction increased, without any change in anxiety or depression, in most studies. No studies were identified that evaluated decision aids for neoadjuvant systemic therapy, or contralateral prophylactic mastectomy.

Conclusion

Decision aids are available and improved decision-related outcomes for many breast cancer treatment decisions including surgery, radiotherapy, and endocrine and chemotherapy. Decision aids for neoadjuvant systemic therapy and contralateral prophylactic mastectomy could not be found, and may be warranted.

Body

Introduction

Over the last 40 years, breast cancer survival rates in developed nations have improved by at least 30% due to earlier detection and better treatments (Jemal, Center et al. 2010). Along with these gains, an increasing array of treatment options have become available for patients and their doctors (Goldhirsch, Winer et al. 2013). While patient choice is integral to the shared decision-making model of modern medicine (Chewning, Bylund et al. 2012), this choice can be a burden on patients (Livaudais, Franco et al. 2013). Patient decision aids (DAs) have been developed for a range of health conditions including breast cancer. These have been successful in informing, involving and empowering patients to participate in decision-making, particularly in the cancer context (O'Brien, Whelan et al. 2009, Stacey, Legare et al. 2014).

DAs are suited to decisions that are preference-sensitive (i.e. there are legitimate options with different outcomes, which individuals may value differently). One example of such a decision is breast conserving surgery (BCS) versus mastectomy, which have equivalent survival outcomes in suitable patients, but differ in cosmesis and recurrence risks (Whelan, Levine et al. 1999). Women may also be asked to define the risk-benefit ratio at which they will accept treatment, which in the case of adjuvant chemotherapy, is variable and depends on individual values (Duric, Stockler et al. 2005).

Decisions about individual early stage breast cancer treatments do not take place in isolation, but often depend on other modalities. Over the past 20 years, the number of breast cancer treatment DAs has multiplied. However, these DAs generally target only *one* decision choice. It is not clear how these complement each other to provide women with complete coverage of all the relevant breast cancer decisions, nor whether there are any DAs which attempt to address more than one treatment decision.

Recent reviews of DAs for patient treatment and screening decisions across all health conditions (Stacey, Legare et al. 2014) and for cancer decisions (Trikalinos, Wieland et al. 2014) found good evidence that DAs increase knowledge and decrease decisional conflict, and moderate evidence that they increase active participation in decision-making and improve accuracy of risk perception. These reviews discuss individual DAs only briefly. Prior reviews have focussed on surgical decision-making in early stage breast cancer (Waljee, Rogers et al. 2007, Obeidat, Finnell et al. 2011), but other closely related DAs were not evaluated, such as for radiotherapy or systemic therapy. Therefore a review of DAs for early stage breast cancer, including all treatment options, was considered important to facilitate better access and integration of DAs across modalities.

We aimed to assess the effects of treatment DAs on decision-related outcomes in women making treatment decisions for early stage breast cancer. We also aimed to determine which breast cancer treatment decisions had an appropriately evaluated DA available and identify any gaps in the evidence.

Methods

This systematic review was designed and conducted according to the principles of the PRISMA statement for reporting of systematic reviews and meta-analyses (Moher, Liberati et al. 2009). The protocol was prospectively registered and is available on the Prospero register of systematic reviews

(www.crd.york.ac.uk/PROSPERO, CRD42014009474). By using broad search terms and including published papers and conference abstracts, the search strategy (Appendix A) was designed to be maximally inclusive. Studies were eligible if: (i) original research was reported; (ii) a comparative or non-comparative design was used; and (iii) patient outcome data were reported related to the use of a patient treatment DA for early stage breast cancer. A DA was defined as: a tool or technology, including paper-based, video, audio, electronic or multimedia; and containing information about two or more options and the associated relevant outcomes (Elwyn, O'Connor et al. 2006). Quantitative and qualitative papers were eligible. Studies of DAs for breast cancer prevention or metastatic breast cancer were excluded due to major differences in the treatment intent of these decisions compared with early stage breast cancer.

The following databases were searched: Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects, the Cochrane Database of Systematic Reviews, EMBASE, MEDLINE, PsycINFO, Web of Science, and the Ottawa Decision Aid Library Inventory (http://decisionaid.ohri.ca/index.html). Databases were searched from their inception to 25th February 2015. Conference abstracts from 2011-2015 were searched by hand: ASCO Meeting Library, the San Antonio Breast Cancer Symposium Library, European Breast Cancer Conference, European Society of Medical Oncology Annual Meeting. The EMBASE database includes abstracts from relevant conferences including the World Congress on Psycho-Oncology and the annual meeting of the Multinational Association of Supportive Care in Cancer. Reference lists were searched for additional papers not identified in the database search.

After removing duplicate results, titles and abstracts were screened to identify potentially eligible papers. The full text of potentially eligible papers was then reviewed to create a list of original research articles for inclusion in the review. Studies were rejected if they: did not report on patient outcomes; did not evaluate a treatment DA; were a review article without original research results; or were duplicate results, for example a conference abstract reporting on the same results as a published article.

A pre-piloted form was developed and used to extract data from eligible studies. Quality and risk of bias were assessed at a study level using the Qualsyst scoring system, which is designed for use on a variety of study types including randomised, non-randomised comparative, cohort and qualitative studies (Kmet, Lee et al. 2004). Qualsyst produces a score between zero and one, with a higher score indicating higher study quality and lower risk of bias. This scoring system was chosen to maintain consistency, with the expectation that qualitative and quantitative data would be included. Data extraction and quality scoring were performed independently by two authors, with duplicate extraction and scoring of 20% of papers. Differences in results were resolved through discussion.

Data points included: study type, study location, decision support type, decision being targeted, population characteristics, primary and secondary outcomes assessed and bias assessment. Data were synthesised using a narrative description, due to the heterogeneity of outcome measures. The term ‘decision aid (DA)’ will be used in this paper to describe tools, systems, technologies, interactive decision support and other terms used for decision support modalities. This paper will describe reported patient outcomes from DA use.

Results

After removing 394 duplicates, 1791 unique records were identified (Figure 1). Titles and abstracts were screened to identify 73 potentially eligible records. Full text review of these records resulted in inclusion of 33 eligible original research articles for analysis, in which 23 individual treatment DAs were evaluated (Table 1). Outcome measures were heterogeneous across studies, precluding meta-analysis. Seven additional DAs were identified on the Ottawa Decision Aid Library for which no corresponding literature was identified. These DAs have not been evaluated here.

Eleven DAs were developed for women deciding about surgical options such as mastectomy or BCS; nine were for adjuvant systemic therapy decisions such as chemotherapy and/or endocrine therapy; three were for radiotherapy decisions; three were for breast reconstruction and one targeted fertility preservation. Some DAs addressed more than one breast-cancer treatment decision, such as the DA by Vodermaier et al (Vodermaier, Caspari et al. 2011) for both surgery and adjuvant chemotherapy, and the DA by Wong for adjuvant endocrine therapy and radiotherapy (Wong, D'Alimonte et al. 2012).

Fifteen studies were led by researchers from the USA, seven from Canada, five from Australia, two from the United Kingdom, two from Hong Kong and one each from Germany and The Netherlands. Ten were randomised controlled trials (RCTs), including four cluster randomised trials. Four papers reported on different data taken from a single cluster randomised trial evaluating Adjuvant!Online, resulting in a total of 13 publications reporting on RCTs. Seven studies used a non-randomised comparative design, eight were single arm pre-post studies, and five were cross-sectional cohort studies.

Study quality

Qualsyst scores for study quality ranged from 0.23 to 1.0 (possible range 0.0-1.0, Tables 2 and 3). RCTs typically had the highest Qualsyst scores, predominantly due to greater methodological rigour in study design, sampling method (e.g., population sampling), control for potential confounders, and greater detail in reporting of results, including estimates of variance. Studies that scored lower on Qualsyst items generally did not specify whether and how investigators and/or participants were blinded, defined outcomes poorly, did not use well-validated outcome measures and/or employed measure subscales or hybrid measures without justification.

Outcome measures

Treatment choice was the most frequently used outcome measure type (17 studies) (Irwin, Arnold et al. 1999, Molenaar, Sprangers et al. 2001, Lee, Chen et al. 2010), suggesting that it was considered important in determining whether a DA is effective. However, if patients are making truly value-based decisions, then treatment choice is not necessarily a primary consideration. The decisional conflict scale, developed by O'Connor specifically to evaluate DAs, was used in 13 studies (O'Connor 1995). This scale consists of five subscales: uncertainty, informed, values clarity, support and effective decision. The use of this scale suggests that indecision is another primary measure of the efficacy of DAs. Other relevant outcomes included knowledge (16 studies), satisfaction with decision-making and decisional regret. Knowledge items necessarily varied across studies with minimal standardization. The satisfaction with decision (eight studies) (Holmes-Rovner, Kroll et al. 1996), and decisional regret (Brehaut, O'Connor et al. 2003) scales measure how satisfied a person is with their decision before and after the consequences

of that decision have been experienced, respectively. Acceptability was reported in 14 studies, using a variety of non-standardized questionnaires. When assesssed, values-choice agreement was not generally measured using a standardized, validated instrument. Although anxiety and depression are not expected to be reduced through use of a DA, anxiety (eight studies) and depression (five studies) were used as safety measures to ensure that DAs did not negatively affect psychological wellbeing.

The decision aids

DA format

Nine DAs took the format of an interactive computer system. Three were in booklet form, two involved one-on-one consultations with patient advocates, one was an audiotape and workbook, one was video-based and seven used a decision board format.

Internet based formats varied widely. Jibaja-Weiss et al created an 'education entertainment' DA which used a novel strategy of a virtual jewellery box where patients could 'store' issues of importance, and soap opera style episodes with information about options and outcomes (Jibaja-Weiss, Volk et al. 2011). The BRECONDA (Breast Reconstruction ONline DA) contains written information and graphics, with links to animations and interviews with a breast reconstruction surgeon. (Sherman, Harcourt et al. 2013, Sherman, Harcourt et al. 2014). Adjuvant!Online provides an individualised risk estimate of breast cancer recurrence and mortality over the subsequent 10 years based on clinical and pathological factors, and gives an individual estimate of the benefits of adjuvant chemotherapy and/or endocrine therapy (Peele, Siminoff et al. 2005).

Patients who used interactive computer program DAs reported satisfaction with this method of delivery (Street, Voigt et al. 1995, Molenaar, Sprangers et al. 2001, Heller, Parker et al. 2008, Lee, Chen et al. 2010, Sivell, Edwards et al. 2012, Sherman, Harcourt et al. 2013, Sherman, Harcourt et al. 2014). Ethnically diverse and/or low literacy American women found a computer-based format universally acceptable (Dhage, Castaneda et al. 2013). However, a pilot study of a surgical DA for Chinese women found that these women preferred graphics over text, and paper-based over other formats (Au, Lam et al. 2011, Lam, Chan et al. 2013).

The decision board style DA is a board with four panels that are revealed sequentially: treatment choice, side effects, impact of treatment choice on the breast, and impact of treatment choice on survival (Levine, Gafni et al. 1992, Whelan, Levine et al. 1995, Whelan, Levine et al. 1999, Whelan, Sawka et al. 2003, Whelan, Levine et al. 2004). Harwood et al supplemented a decision board format with take home information (Harwood, Douglas et al. 2011) but did not find that this addition improved knowledge and decisional conflict over historical controls who had used a decision board only.

Goel et al developed an audiotape and workbook DA, and compared versions which did and did not include probability diagrams and a values clarification exercise (Goel, Sawka et al. 2001). There were no differences between these versions in decision-related outcome measures, which calls into question the benefit of these components; however this result awaits corroboration from other studies.

Belkora et al developed four videos targeting different decisions for early stage breast cancer (DCIS, breast surgery, reconstruction surgery, adjuvant systemic therapy), and one for advanced breast cancer, which were reported to be acceptable and useful (Belkora, Volz et al. 2012). The videos were sent to patients prior to their clinic visit, depending on an assessment over the telephone by a "Decision Services" staff member identifying the decision that would be addressed at that visit. Finally, Sheppard et al developed a culturally sensitive patient support intervention for Latina and African American women that used one-on-one decision support consultations of between 40 and 120 minutes in duration; these were acceptable to women but time intensive (Sheppard, Figueiredo et al. 2008, Sheppard, Williams et al. 2010).

Since very few studies have directly compared different DA formats, or asked patients to review a range of formats and express a preference, the optimal format for DAs remains unclear; it may well be that a variety of formats will be effective or that certain formats are effective for certain populations.

Clinician involvement in DA use

All DAs were offered to patients by clinical staff, but clinicians had variable involvement in their use. DA use ranged from predominantly within the consultation, to predominantly outside the consultation. Examples of DAs used predominantly within the consultation include Adjuvant!Online, which is designed for data input and interpretation by the clinician within a consultation with a printout of results available for the patient to take home for future reference (Siminoff, Gordon et al. 2006). The decision boards are also designed for use within the consultation, to introduce information to the patient sequentially rather than overwhelm them with all information at once (Levine, Gafni et al. 1992, Whelan, Levine et al. 1995, Whelan, Levine et al. 1999, Whelan, Sawka et al. 2003, Whelan, Levine et al. 2004). The disadvantage to this approach is that restricted consultation time limits the amount of time that patients have to absorb and digest information.

An alternative is for clinicians to identify patients for whom a DA might be useful and then to introduce it briefly before giving the patient access to it for use prior to a follow-up consultation where the decision will be made (Molenaar, Sprangers et al. 2001, Peate, Meiser et al. 2012, Sivell, Edwards et al. 2012, Sherman, Harcourt et al. 2013). A third option for clinician involvement is for patient suitability for a DA to be assessed prior to their clinic attendance, so that the patients can be sent and review the DA before they attend the consultation. Whilst patient satisfaction was not measured, knowledge increased and decisional conflict decreased in those who received a DA in the single study that used this last, novel approach (Belkora, Volz et al. 2012). Impacts on consultation time or clinician-related outcomes were poorly reported, so it is not clear how and whether these different approaches might impact on routine implementation of DAs within the healthcare system.

Decision aids for different treatment modalities

Several DAs evaluated surgical decision-making for women considering one or more of the options of BCS, mastectomy, (Whelan, Levine et al. 1999, Goel, Sawka et al. 2001, Molenaar, Sprangers et al. 2001, Whelan, Levine et al. 2004, Jibaja-Weiss, Volk et al. 2011, Sivell, Edwards et al. 2012, Dhage, Castaneda et al. 2013) and/or axillary surgery choice (Harwood, Douglas et al. 2011) and/or reconstruction (Au, Lam et al. 2011, Lam, Chan et al. 2013). The decision about reconstruction is distinct from management decisions for early breast cancer, because more time may be available for information-seeking and

consideration of options. Three DAs were developed to assist women deciding amongst breast reconstructive options, all of which employed computer-based technologies (Heller, Parker et al. 2008, Lee, Chen et al. 2010, Sherman, Harcourt et al. 2013, Sherman, Harcourt et al. 2014).

Numerous DAs targeted women's decisions for adjuvant systemic therapy, including two DAs for chemotherapy (Levine, Gafni et al. 1992, Whelan, Sawka et al. 2003, Sheppard, Figueiredo et al. 2008, Sheppard, Williams et al. 2010), one for the decision between doxorubicin/cyclophosphamide (AC) and cyclophosphamide/methotrexate/5FU (CMF) (Irwin, Arnold et al. 1999), and five studies evaluating a single DA for chemotherapy and/or hormone therapy (Peele, Siminoff et al. 2005, Siminoff, Gordon et al. 2006, Vickers, Elkin et al. 2009, Lipkus, Peters et al. 2010, Belkora, Hutton et al. 2011). Whilst the decision about AC versus CMF is now rarely offered, due to the emergence of more effective treatment regimens, the use of DAs is likely to be relevant to other decisions between currently offered adjuvant chemotherapy regimens.

Two studies evaluated the utility of a DA for women deciding on radiotherapy treatment options following BCS: one for women over the age of 70 (Wong, D'Alimonte et al. 2012), and one which included endocrine therapy along with the decision about radiotherapy (Whelan, Levine et al. 1995). Two studies examined a DA booklet for fertility-preservation decisions prior to adjuvant chemotherapy (Peate, Meiser et al. 2011, Peate, Meiser et al. 2012). Belkora et al report on sustained implementation of five separate video DAs in a single practice, using a pre-post design (Belkora, Volz et al. 2012).

DA efficacy

Twelve out of the 17 comparative studies reported a positive primary outcome, most commonly knowledge or decisional conflict score (Whelan, Levine et al. 1995, Whelan, Sawka et al. 2003, Whelan, Levine et al. 2004, Peele, Siminoff et al. 2005, Heller, Parker et al. 2008, Lee, Chen et al. 2010, Belkora, Hutton et al. 2011, Jibaja-Weiss, Volk et al. 2011, Vodermaier, Caspari et al. 2011, Peate, Meiser et al. 2012, Sivell, Edwards et al. 2012, Sherman, Harcourt et al. 2013). Two additional studies in this group reported positive secondary outcomes: Lam et al found that decisional conflict decreased with a DA (Lam, Chan et al. 2013), and Siminoff et al found that their DA altered adjuvant systemic therapy choices (Siminoff, Gordon et al. 2006).

Three out of the five studies did not demonstrate a significant difference in decision-related findings (Street, Voigt et al. 1995, Goel, Sawka et al. 2001, Vickers, Elkin et al. 2009). These studies included an interactive computer DA for women considering mastectomy or BCS with radiotherapy (Street, Voigt et al. 1995); an audiotape and workbook comparing mastectomy and BCS (Goel, Sawka et al. 2001); and a subgroup analysis that aimed to model the effects of the Adjuvant!Online resource on expected survival (Vickers, Elkin et al. 2009).

Treatment choice was altered by the DA in six out of the twelve comparative studies that reported it as an outcome measure. Changes included: a decrease in mastectomy uptake combined with immediate reconstruction (Lam, Chan et al. 2013); an increased mastectomy rate (Jibaja-Weiss, Volk et al. 2011); increased use of breast conserving surgery (Whelan, Levine et al. 2004); increased use of flap-based reconstruction surgery (Lee, Chen et al. 2010); lower use of adjuvant systemic therapy in lower risk patients (Peele, Siminoff et al. 2005); and a decrease in the use of adjuvant chemotherapy in those who were more accurate at estimating the survival benefit of chemotherapy (Belkora, Hutton et al. 2011).

Notably, the direction of treatment decision change in the mastectomy versus BCS studies were contradictory.

The following section describes features common to those studies where DAs were effective. Low baseline knowledge predicted a greater benefit. For decisions where information is not readily available, or for populations who have low health literacy, larger incremental reductions in decisional conflict were seen. This is exemplified by the fertility DA (Peate, Meiser et al. 2012), and the DAs for minority groups (Jibaja-Weiss, Volk et al. 2011, Belkora, Volz et al. 2012, Lam, Chan et al. 2013). Whilst knowledge scores were heavily dependent on the questions asked, Peate et al found a low mean knowledge score of 50% of questions correct in both groups at baseline, increasing more in the DA group over time (Peate, Meiser et al. 2012). However, in the Chinese patients targeted by Au et al, decisional conflict decreased, but knowledge did not increase (Lam, Chan et al. 2013).

DAs that were used within the consultation, such as the series of decision boards, reduced decisional conflict and increased knowledge (Levine, Gafni et al. 1992, Whelan, Levine et al. 1995, Whelan, Levine et al. 1999, Whelan, Sawka et al. 2003, Whelan, Levine et al. 2004). A predominantly 'in consultation' model is also used with Adjuvant!Online; an internet-based DA for women who are candidates for adjuvant therapy (i.e., chemotherapy and/or endocrine therapy) following surgery for early breast cancer. Patients who used this DA were more likely to base treatment decisions on actual recurrence risk rather than relying on lymph node status to decide whether to have chemotherapy (Peele, Siminoff et al. 2005, Siminoff, Gordon et al. 2006, Vickers, Elkin et al. 2009, Lipkus, Peters et al. 2010, Belkora, Hutton et al. 2011).

The DAs that were less effective also shared some common features. For a decision such as delayed breast reconstruction where there is often time for decision-making, a DA was less effective (Heller, Parker et al. 2008). Both the DA group and the control group were highly satisfied with the available information, their ability to make a decision and their satisfaction with choices (Heller, Parker et al. 2008).

The amount of information in the control group influenced the benefit seen. One study was unable to demonstrate a difference in decisional conflict, knowledge or decisional regret when testing the benefit of adding a values clarification exercise and risk/benefit diagrams to identical written information (Goel, Sawka et al. 2001).

In summary, the major factors in the success of a DA are: use within the consultation, use in a population with low prior knowledge or a lack of available information, and use when time for decision-making is limited. There was no clear correlation between format and effectiveness.

Gaps in the Literature

Multiple DAs have been developed for decisions about breast cancer surgery, endocrine therapy and chemotherapy (Table 4). One has been developed for fertility preservation, three for breast reconstruction surgery and three for radiotherapy. No DAs were found for neoadjuvant systemic therapy, scalp cooling to prevent chemotherapy-induced alopecia or for contralateral prophylactic mastectomy after a breast cancer diagnosis.

Study Recency

The majority of DAs did not list their date of most recent update. The exceptions were: 'A patchwork of life', which was updated in 2013 according to the Ottawa Decision Aid Inventory; and Adjuvant!Online, updated in 2005 (with an update planned for 2015). An estimate of recency was made by cross-referencing the time period that the DAs were developed and the publication dates of significant literature impacting on that decision. Evidence that mastectomy is equivalent to BCS and radiotherapy has not changed since the late 1990s (Fisher, Anderson et al. 2002), although improvements in radiotherapy technique are likely to reduce the associated toxicity (Darby, McGale et al. 2005). For decisions about systemic therapy, Adjuvant!Online is based on historical survival and recurrence data, which continues to improve (Youlden, Cramb et al. 2012). It does not include HER2 status, which has emerged as an important prognostic and predictive factor (Coates, Winer et al. 2015). Modern chemotherapy has superior efficacy to CMF, rendering the DA comparing AC to CMF obsolete (EBCTCG 2012). Standard chemotherapy options have changed since 2005, so DAs that have not been updated since then are likely to be out of date (Group, Peto et al. 2012). Data about fertility preservation options continue to evolve, therefore fertility DAs are unlikely to contain up to date data unless ongoing review and revision occurs (Kasum, von Wolff et al. 2015).

Discussion

Early breast cancer patients face a number of complex treatment decisions. Recognition of this has led to the development of DAs for surgical, endocrine therapy, chemotherapy, radiotherapy, reconstruction and fertility preservation treatment decisions. Despite the importance of examining the decision resources available to early breast cancer patients and of holistically presenting available options in these decision resources, the present study is the first review that describes breast cancer treatment DAs across multiple treatment modalities. Overall, the evidence suggests that DAs for early stage breast cancer treatment decisions increase knowledge about options, decrease decisional conflict and are acceptable to patients, without increasing anxiety. The effect on treatment decisions is variable.

These treatment DAs were delivered using a variety of media, including online web-based technologies, educational multimedia tools, decision-boards and paper-based information resources. These formats were effective and were considered acceptable by patients, but because they were not compared directly it is not possible to draw conclusions about the superiority of any one format. Anecdotally, the most widely used treatment DA for women with early breast cancer is Adjuvant!Online. Adjuvant!Online does not take the traditional format of description of options, outcome probabilities, positives, negatives and values clarification exercise proposed by the International Patient Decision Aid Standards (IPDAS) collaboration (Volk, Llewellyn-Thomas et al. 2013). Rather, it presents an individualised set of recurrence and survival probabilities which the clinician interprets and puts into context to facilitate a final decision. The popularity of this DA may be due to the information that it provides to both the clinician and the patient, on the probability of relapse and death with and without treatment based on individual clinicopathological factors. Treatment decisions were altered by this DA, with patients placing a greater emphasis on survival benefit, rather than using axillary lymph node positivity as a marker of sufficiently high risk to warrant the use of chemotherapy.

Decisions about early breast cancer treatment are not usually made in isolation, because one treatment modality may impact on another. For example, the decision between mastectomy and BCS also requires

consideration of radiotherapy treatment, which is more likely to be given after BCS. Elderly patients who decide not to have radiotherapy might have different opinions about systemic therapy compared with those who decide to have radiotherapy. Yet only three DA studies addressed decisions across multiple modalities. This may be helpful for women who are likely to consider several treatment modalities for their breast cancer treatment. The study by Belkora et al. used 5 separate DA videos which could be used on their own, or be combined with one another if required (Belkora, Volz et al. 2012). The study by Vodermaier et al. included information on both surgery and chemotherapy (Vodermaier, Caspari et al. 2011), while another DA addressed radiotherapy and endocrine therapy for women over the age of 70. Whilst these are steps towards an integrated approach, they do not represent a single multimodality breast cancer DA. Thus there is a clear need for DAs addressing multiple treatment options to comprehensively assist women in this complex clinical scenario. Moreover, there are clear gaps in the literature in the treatment options addressed, with no DA available to assist women deciding on neoadjuvant systemic therapy and contralateral prophylactic mastectomy, despite evidence that these are challenging decisions (Hawley, Jagsi et al. 2014, Zdenkowski, Butow et al. 2015).

Several DAs were designed specifically for use by patients with low literacy or belonging to particular ethnic groups (Jibaja-Weiss, Volk et al. 2006, Sheppard, Figueiredo et al. 2008, Sheppard, Williams et al. 2010, Au, Lam et al. 2011, Jibaja-Weiss, Volk et al. 2011, Lam, Chan et al. 2013). Targeting these smaller populations allows use of more targeted information, but it also limits the dissemination of the DA to the size of that population. Another option is to apply the DA to a more general population, but ensure that it is approachable using a reading age of grade 8 or below (Stossel, Segar et al. 2012). A disadvantage to this approach may be difficulties in comprehensively addressing complex treatment options and subsequent impact on which patients are offered the DA in clinical practice.

The accessibility of DAs for patients is another salient issue. In order for patients to have the opportunity to access DAs as required, they should be made readily available from a central trusted source such as the Ottawa Decision Aid Inventory (ODAI, https://decisionaid.ohri.ca), with links from other relevant sites. The ODAI, however, appears designed for health professionals rather than patients. The ODAI contains an assessment of the quality of each DA, measured against the IPDAS criteria and provides an indication of whether evidence exists to support an improvement in knowledge and congruence between values and final decision. It does not have an assessment of the quality of the literature supporting those DAs, nor of the individual outcomes from the available literature. Eight breast cancer treatment DAs were listed on the ODAI at the time of writing. Only one, ‘A Patchwork of Life’, had supporting literature that enabled its inclusion in this review. The majority of the DAs identified in this review were not listed on the ODAI or other readily accessible central locations, limiting their widespread availability.

Online or computer-based, interactive DAs have the potential to be widely accessible and are able to be individualised to users’ needs. We found nine DAs of this type, with data to support acceptability of this mode of delivery (Street, Voigt et al. 1995, Molenaar, Sprangers et al. 2001, Siminoff, Gordon et al. 2006, Heller, Parker et al. 2008, Lee, Chen et al. 2010, Sivell, Edwards et al. 2012, Sherman, Harcourt et al. 2013, Sherman, Harcourt et al. 2014). These studies did not compare online delivery to other DA formats, so it is not possible to claim that any method of delivery is superior. Patients appear to have difficulty finding DAs on the internet, due to a lack of uniform labelling and the variety of hosting

locations (Morris, Drake et al. 2008). More evidence is therefore needed to evaluate the effectiveness of internet-based delivery of DAs to patients (Hoffman, Volk et al. 2013).

Finally, the content of DAs is crucial for success, both in terms of patient outcomes and implementation. A systematic review of DA content raised concerns about the completeness of information, balance and accuracy of DAs (Feldman-Stewart, Brennenstuhl et al. 2007). Feldman-Stewart et al found that potential benefits were emphasised more than harms in half of cases, and external consultation either was not conducted, or was heavily reliant on health professionals over patients and consumer advocates. Information within DAs may become out-dated as new treatment options become available. Several of the breast cancer DAs identified in the present review are likely to contain out-dated information. If the content is out of date, then the options and probabilities presented in the DA will lose relevancy. The consequence will be either a negative impact on usage or utility. Probabilities may change with new evidence, and choices that were once commonplace may not have the same clinical equipoise that they once did. For example, in the time since the paper by Irwin et al. was published (Irwin, Arnold et al. 1999), it has become evident that AC has superior efficacy to CMF, and is now commonly used with taxanes, rendering the DA obsolete. Ideally DAs would be available online as required, and updated regularly.

Conclusion

DAs for early stage breast cancer treatment decisions increase knowledge about options, decrease decisional conflict and are acceptable to patients, without increasing anxiety. Treatment decisions addressed included surgical, endocrine therapy, chemotherapy, radiotherapy, reconstruction and fertility-preservation decisions. Contralateral prophylactic mastectomy and neoadjuvant systemic therapy treatment options may be suited to a DA, however we were unable to identify a DA for these topics. We are currently evaluating a DA for women who have been offered neoadjuvant systemic therapy for operable breast cancer to fill this gap. A more integrated approach to breast cancer DAs across all modalities may lead to greater implementation and more effective shared decision-making.

Tables

Table 1. Included studies of patient decision-aids for treatment of early stage breast cancer

Author, year, location	Decision; type of decision support	Comparator	Study type	Population	Number of participants	Outcome(s), result	Qualsyst score
Surgery							
(Au, Lam et al. 2011) Hong Kong	BCS, mastectomy, reconstruction; Booklet – information, outcome probabilities, values clarification	Revised DA	Single arm cohort comparison of original DA with revision	Operable EBC stage 0-II, BCS candidate, Hong Kong public clinic	Original DA: 95 Revised DA: 38	Acceptability: No difference between groups at 4-7 days post DA Utility: No difference between groups Anxiety/depression: No difference between baseline and 4-7 day visit	0.59
(Lam, Chan et al. 2013) Hong Kong	As above	Standard information booklet	RCT	As above	DA: 138 Control: 138	Treatment decision-making difficulty at 1 week: no difference. DCS: 15.8 (DA) v 19.9 (control) (p=0.016). Knowledge: no difference. Decisional regret: at 1 month, no difference; 4, 10 months, greater regret in controls. Choice of surgery: non-significant difference, BCS 43% (DA) vs 51%, p=0.131. Anxiety/depression: no difference.	0.89
(Dhage, Castaneda et al. 2013) USA	Mastectomy vs BCS; Surgical Decision Support System: medical interpretation and	Nil	Pre-post cohort	Newly diagnosed breast cancer patients, single centre, low English	DA: 70 (39 completed all assessments)	Preparation for decision-making: 100% felt prepared prior to surgery. DCS: decreased over time (non-significant). Satisfaction with	0.23

	computer-based animations			proficiency and/or ethnically diverse		DA: 100% satisfaction prior to surgery.	
(Goel, Sawka et al. 2001) USA	Mastectomy vs BCS. Audiotape and workbook.	Pamphlet containing identical information but no numbers, graphics or values clarification	Cluster RCT (randomised by surgeon)	EBC, suitable for BCS or mastectomy, surgeon within 150km of Toronto, Canada.	57 Surgeons DA: 86 Control: 50	DCS 48-72 hours post DA: no difference, 1.98 DA vs 2.08 control (p=0.22), no difference in subscales. Knowledge: no difference (p=0.43). Anxiety: no difference (p=nr). Decisional regret: no difference on any item (p=0.32-0.93)	0.64
(Harwood, Douglas et al. 2011) Australia	Mastectomy vs BCS; ALND vs SLNB; decision following positive SLNB. Decision boards, supplementary information, take home booklet.	Nil	Prospective cohort with historical controls	EBC, choice of BCS or mastectomy, and/or ALND or SLNB, single centre.	DA: 11 Control: 28	Surgical choice: no difference (p=0.7 for breast and p=0.1 for lymph node surgery). DA: Knowledge (23.9/35), modified DCS (1.3/5) and satisfaction with the DA (4.7/5).	0.59
(Jibaja-Weiss, Volk et al. 2006) USA	Mastectomy vs BCS for low literacy patients. 'A patchwork of life' computer DA focussing on values clarification.	Nil	Pre-post cohort pilot study	Stage I-IIIA EBC, surgical candidate, English or Spanish speaker.	DA: 51	Use of jewellery box to identify issues related to their decision: 59% used it to flag a median of 4 issues. DCS uncertainty subscale: 3.10 pre, 1.98 post (p<0.001). DCS unclear about values: 3.19 pre, 0.80 post (p<0.001).	0.68
(Jibaja-Weiss, Volk et al. 2011) USA	As above.	Usual care.	RCT	As above.	DA: 51 Control: 49	Surgical choice: DA group more likely control group to opt for mastectomy than BCS than (60% vs 40%, p=0.018).	0.57

						Knowledge: no difference at baseline, better in DA group after DA, no difference at 1 year. Satisfaction with decision-making: no difference. DCS: DA group higher Informed subscale post DA.	
(Molenaar, Sprangers et al. 2001) The Netherlands	Mastectomy vs BCS. Interactive CD-ROM.	Usual care.	Quasi-experimental, longitudinal, pre/post.	EBC stage I-II, candidate for mastectomy or BCS.	DA: 92 Control: 88	Choice of treatment: DA 75% chose BCS vs control 68% chose BCS (p=0.29). Satisfaction: Overall positive effect of DA. Generic and breast quality of life: DA group higher score.	0.86
(Sivell, Edwards et al. 2012) United Kingdom	Mastectomy vs BCS. Online interactive DA.	Nil.	Observational cohort study, pre/post.	EBC, eligible for mastectomy or BCS.	DA: 62	Readiness to decide: pre 65.9, post 76.6 (<0.001). Knowledge: pre 8.3, post 8.5 (p=0.2). Intention for mastectomy: no change.	0.68
(Street, Voigt et al. 1995) USA	Mastectomy vs BCS. Interactive computer program.	Brochure.	RCT	EBC stage I-II	DA: 30 Control: 30	Choice of BCS: DA 76%, control 58% (not significant). Optimism: no difference. Knowledge: no difference between groups, significant improvement over time.	0.61
(Whelan, Levine et al. 1999) Canada	Mastectomy vs BCS. Decision board.	Nil	Single arm cohort	EBC stage I-II	DA: 175	SDM: Make final decision (51%), share decision with surgeon (36%). Comprehension: 84% correct. Satisfaction: information (97%), decision-making process (97%).	0.64

						Chose BCS + radiotherapy: 73%.	
(Whelan, Levine et al. 2004) Canada	As above	Usual care.	Cluster RCT (randomised by surgeon, matched for age and gender)	EBC stage I-II prior to surgical treatment	Surgeons: 20 DA: 94 Control: 107	Knowledge: DA 66.9, control 58.7 (p<0.0001). Post consult DCS: DA 1.4, control 1.62 (p=0.02). Decisional satisfaction: DA 4.5, control 4.32 (p=0.05). Chose BCS: DA 94%, control 76% (p=0.03). Anxiety/depression: no difference.	0.75
Breast Reconstruction surgery							
(Heller, Parker et al. 2008) USA	Reconstruction surgery. Interactive digital system.	Standard patient education only.	RCT	EBC, candidate for breast reconstruction	DA: 66 Control: 67	Knowledge: DA group knowledge increased to a greater extent than control (p=0.02). Satisfied with mode of delivery: DA group 97% vs control 86% (p=0.03). Pleased with choice: DA 95% vs control 83%. Anxiety: no difference between groups, decrease over time.	0.57
(Lee, Chen et al. 2010) USA	Reconstruction surgery. Computer-based learning module.	Usual care.	Non-randomised comparative cohort.	Immediate or delayed breast reconstruction after mastectomy for EBC.	DA: 216 Control: 120	Patient involvement in decision: greater in the DA group (p<0.001). Surgical choice: DA group more likely to choose autologous flap surgery. Satisfaction with information: Mostly/very -	0.36

						DA 91% vs control 85% (p<0.001). General satisfaction: no difference.	
(Sherman, Harcourt et al. 2014) Australia	Reconstruction surgery. Online interactive DA (BRECONDA).	Nil	Mixed-methods pilot study.	EBC or DCIS, scheduled for mastectomy, eligible for reconstruction.	DA: 28	Acceptability: mean 4.1/5. Usefulness: mean 3.97/5. Ease of use: mean 4.58/5. Sufficient information: mean 3.89/5.	0.57
(Sherman, Harcourt et al. 2013) Australia	As above.	General educational pamphlet.	RCT (conference abstract)	Women diagnosed with breast cancer, planned for or post-mastectomy.	Pre-mastectomy: 31 Post-mastectomy: 107 (number per arm NR)	Reconstruction patients (16 DA, 10 control) DCS: DA 27.3, control 34.6 (p=0.015). Satisfaction with information: DA 4.02, control 3.74 (p=0.03). Knowledge: no difference.	0.29
Systemic therapy							
(Peele, Siminoff et al. 2005) USA	Adjuvant endocrine therapy and/or chemotherapy. Adjuvant!Online – online prognostic/predictive calculator	Pamphlet containing non-numeric information	Cluster RCT (randomised by study site)	EBC, completed primary surgical interventions, candidate for AT	14 Sites DA: 226 Control: 160	Decision to receive AT in low tumour severity group: 58% DA v 87% controls (p<0.01). Logistic regression: DA group less likely to choose AT with low severity tumour, more likely to choose AT with high severity tumour	0.79
(Siminoff, Gordon et al. 2006) USA	As above	As above	As above	As above	14 Sites DA: 234 Control: 171	Decision not to receive AT: Pts who refused AT were more likely node negative and smaller tumours, older, lower income, treated in academic centres. Acceptability and utility of DA v control: DA more helpful,	0.79

						and more influential on decision. No difference in ease of understanding or comfort with information.	
(Vickers, Elkin et al. 2009) USA	As above	As above	As above	As above	14 sites DA: 226 Control: 160	Expected benefit required to receive AT: 3% (n=12) refused AT despite a large loss in survival. Numbers too small to fit a statistical model. Qualitative analysis: AT refusers tend to be women with ER+ EBC who opt for chemotherapy but not AET.	0.71
(Lipkus, Peters et al. 2010) USA	As above	Nil	2-stage pre-post prospective cohort	Single academic centre, EBC, T1-3, N0-2, ER+	Pilot 1: 60 (Adjuvant! alone) Pilot 2: 45 (Pre-consultation video and Adjuvant!)	Treatment expectations: more numerate patients more likely to correlate AET/CT with better survival. Comparison between high and low numeracy: higher numeracy more likely to match Adjuvant! with self-estimate of survival.	0.73
(Belkora, Hutton et al. 2011) USA	As above	Pamphlet	Subset analysis of Peele participants	EBC stage I-III, low risk (>85% 10-year survival estimate).	DA: 28 Control: 20	Survival benefit accuracy: 57% DA, 25% control (p=0.04). Treatment choice as a function of prognostic accuracy: 62% of those who were accurate chose AT compared with 89% of those who were inaccurate (p=0.04).	0.46

(Feldman, Stanford et al. 2002) United Kingdom	Chemotherapy. Prognostic table based on age and Nottingham Prognostic Index	Usual care	Retrospective cohort with historical control group	EBC, treated with surgery, candidate for AT, <70yrs.	DA: 288 Control: 301	Chemotherapy uptake: Increase with DA in patients with 4% survival advantage (42% vs 64%, p=nr). Descriptive data about referrals: 2% chemotherapy survival benefit, 48% referred to oncologist; 4% benefit, 91% referred. Node positivity was weighted lower for decision when DA used.	0.41
(Irwin, Arnold et al. 1999) Canada	Adjuvant chemotherapy (AC vs CMF). Decision Board.	Nil	Single arm cohort	Premenopausal node positive EBC treated with surgery referred for medical oncology opinion.	DA: 46	Information recall: all >80%. Helpfulness of DA: Quite/very helpful 98%. Difficulty of the decision: Quite/very difficult 32%. Treatment decision: 50% AC, 46% CMF, 4% no treatment.	0.69
(Levine, Gafni et al. 1992) Canada	Adjuvant chemotherapy vs no chemotherapy. Decision board.	Nil	Pre-post in 3 parts.	Pilot: EBC Stage I-II, completed chemotherapy. Study 1: healthy volunteers. Study 2: Consecutive high risk node negative EBC.	Pilot: 6 Study 1: 30 Study 2: 37	Pilot: 100% acceptability. Study 1: Chemotherapy (yes/no) with 5% absolute recurrence benefit – 57% yes, 43% no. Study 2: 97% easy/very easy to understand; 87% helpful/very helpful for decision.	0.28
(Sheppard, Figueiredo et al. 2008) USA	Adjuvant chemotherapy. Patient navigators for Latinas.	Nil	Phase 1: qualitative. Phase 2: Pilot of intervention pre/post.	1: Latina with EBC and advocates. 2: Latina with EBC, 4-20 weeks after definitive surgery.	1: 22 2: 15	1: Enablers for SDM: respect, personality, family, patient-provider communication. 2: High satisfaction with intervention: better communication, information and SDM.	0.40 (Qual) 0.5 (Quant)

(Sheppard, Williams et al. 2010) USA	Adjuvant chemotherapy. Survivor coaches for African American women.	Nil	1: DA development. 2: Qualitative evaluation.	1: Patients in active treatment (14), advocates (10), care providers (10). 2: As above (12), plus newly diagnosed EBC (8).	1: 34 2: 20	Community/clinician opinion of intervention: readability/content/format outstanding (66.7%), excellent (33.3%). Patients: High satisfaction (100%). Enablers: patient-provider communication, need for better communication.	0.6
(Whelan, Sawka et al. 2003) Canada	Adjuvant chemotherapy. Decision board.	Usual care	RCT	EBC, node negative, completed primary surgery, candidate for chemotherapy.	DA: 82 Control: 93	Knowledge: DA 80, control 71 ($p<0.001$). Satisfaction with decision-making: DA mean scores higher over time ($p=0.032$) Anxiety: no difference. Change to active role in decision making: DA 10%, control 2% $p=0.033$).	0.82
Radiotherapy							
(Whelan, Levine et al. 1995) Canada	Radiotherapy after BCS. Decision board.	C1: Consult C2: Consult + checklist	Non-randomised sequential cohort	EBC post BCS, tumour <5cm, node negative.	DA: 30 C1: 23 C2: 29	SDM: Offered choice - DA 97%, C1/C2: 70% (p0.02); Radiotherapy recommended – DA 20%, C1/C2 92% ($p<0.0001$). DA Acceptability: easy to understand (100%), helped make a decision (81%), recommend for use (93%). Knowledge: no difference overall.	0.59
(Wong, D'Alimonte et al. 2012)	Adjuvant radiotherapy for women >70 years.	Nil	Cohort 1: Pilot 2: Pre/post	EBC, >70 years of age, ER/PR positive, post	1: 12 2: 38	1: Acceptability - helpful and informative (100%).	0.64

Canada	Booklet DA.			lumpectomy, planned for radiotherapy.		2: DCS – mean pre/post change -7.18 (p=0.028). Knowledge and clarity of risks/benefits increased. No change in cancer-related distress (IES).	
Other							
(Belkora, Volz et al. 2012) USA	DCIS, surgery, reconstruction, AT, treatment of metastatic disease; 5 Video DAs addressing individual decisions.	Nil	Pre-post prospective cohort	Newly diagnosed patients with DCIS or breast cancer (stage 0-IV), single institution.	DA: 439	Knowledge change: mean score across 4 DAs, 45% correct pre, and 74% correct post DA (p<0.001). DCS: mean decreased of 0.52 units (p<0.001). Low baseline knowledge predicted greater change in knowledge. Higher DCS and Hispanic race predicted greater decrease in DCS.	0.68
(Vodermaier, Caspari et al. 2011) Germany	Mastectomy vs BCS, chemotherapy for ER+ EBC. Adapted decision board.	Brochure	RCT	Operable EBC, age 18-75, German language.	DA: 55 Control: 56	DCS: DA group had lower scores at each time point and over time (p=0.047). Anxiety, depression, quality of life, body image: no difference between groups over time.	0.68
(Peate, Meiser et al. 2011) Australia	Fertility after breast cancer diagnosis. DA booklet.	Nil	Single-arm pilot.	EBC diagnosed within 6-60 months prior, age 18-40 years, premenopausal at diagnosis.	DA: 17	Acceptability: 44% very helpful for fertility decision. Content: 94% very/quite relevant, 88% right amount of information, 100% clear and easy to read, 100% satisfied with balance.	0.36

(Peate, Meiser et al. 2012) Australia	As above.	Usual care	Non-randomised comparative pre-post.	EBC stage I-III, age 18-40, premenopausal, prior to adjuvant chemotherapy, desires fertility.	DA: 48 Control: 72	Knowledge: DA group higher score. DCS: DA group 14.7 vs control 29.3 (p=0.02) at 12 months. Decisional regret: DA group 45.8 vs control 49.1 (p=0.03) at 12 months. Informed choice: no difference. Anxiety/depression: no difference.	1

AET: adjuvant endocrine therapy; ALND: axillary lymph node dissection; AT: adjuvant therapy; BCS: breast conserving surgery; CT: chemotherapy; DA: decision aid; DCIS: ductal carcinoma in situ; DCS: decisional conflict score; EBC: early breast cancer; ER+: estrogen receptor positive; IES: impact of events scale; N/a: not applicable; nr: not reported; RCT: randomised controlled trial; SDM: shared decision-making; SLNB: sentinel lymph node dissection.

Table 2. Qualsyst scores: Quantitative studies

	1.Question fully described	2.Design evident and appropriate	3.Group selection method (N/A)	4.Participant characteristics described (N/A)	5.If randomised, was procedure reported (N/A)	6.If blinded to investigators, was it reported (N/A)	7.If blinded to participants, was it reported (N/A)	8.Outcome well defined and robust to measurement/misclassification bias (N/A)	9.Sample size appropriate (N/A)	10.Analytic methods described and appropriate (N/A)	11.Some estimate of variance reported for results (N/A)	12.Controlled for confounding (N/A)	13.Results reported in sufficient detail	14.Conclusions supported by the results	Total
(Au, Lam et al. 2011)	2	1	1	2	N/A	N/A	N/A	1	1	1	1	1	1	1	0.59
(Belkora, Hutton et al. 2011)	2	1	2	1	0	0	0	2	0	2	0	1	1	1	0.46
(Belkora, Volz et al. 2012)	2	1	1	1	N/A	N/A	N/A	1	2	2	0	1	2	2	0.68
(Dhage, Castaneda et al. 2013)	1	1	1	0	N/A	N/A	N/A	0	0	0	0	0	1	1	0.23
(Feldman, Stanford et al. 2002)	2	1	2	0	N/A	N/A	N/A	1	2	0	0	0	1	0	0.41
(Goel, Sawka et al. 2001)	2	2	2	1	2	0	0	2	1	2	1	1	1	1	0.64
(Harwood, Douglas et al. 2011)	2	0	1	1	N/A	N/A	N/A	2	0	1	2	1	2	1	0.59
(Heller, Parker et al. 2008)	1	2	1	1	2	0	0	1	1	2	1	1	2	1	0.57
(Irwin, Arnold et al. 1999)	2	1	1	2	N/A	N/A	N/A	0	N/A	2	N/A	N/A	2	1	0.69
(Jibaja-Weiss, Volk et al. 2006)	2	0	1	1	N/A	N/A	N/A	1	2	2	2	1	2	1	0.68
(Jibaja-Weiss, Volk et al. 2011)	1	2	1	1	2	0	0	1	2	2	0	1	2	1	0.57
(Lam, Chan et al. 2013)	2	2	1	2	2	2	0	2	2	2	2	2	2	2	0.89
(Lee, Chen et al. 2010)	1	1	1	1	0	0	0	0	2	1	0	0	1	2	0.36
(Levine, Gafni et al. 1992)	1	1	0	1	N/A	N/A	N/A	0	N/A	0	N/A	1	1	0	0.28

(Lipkus, Peters et al. 2010)	1	0	1	2	N/A	N/A	N/A	1	2	2	2	1	2	2	0.73
(Molenaar, Sprangers et al. 2001)	2	1	2	2	N/A	N/A	N/A	1	2	2	2	1	2	2	0.86
(Peate, Meiser et al. 2012)	2	2	2	2	N/A	N/A	N/A	2	2	2	2	2	2	2	1.00
(Peate, Meiser et al. 2011)	0	1	1	1	N/A	N/A	N/A	0	N/A	N/A	N/A	N/A	1	1	0.36
(Peele, Siminoff et al. 2005)	2	2	2	2	2	0	0	2	2	2	2	1	2	1	0.79
(Sheppard, Figueiredo et al. 2008)	1	1	1	2	N/A	N/A	N/A	0	N/A	1	N/A	N/A	1	1	0.50
(Sherman, Harcourt et al. 2014)	0	2	1	2	N/A	N/A	N/A	0	N/A	N/A	N/A	N/A	1	2	0.57
(Sherman, Harcourt et al. 2013)	1	1	0	0	1	0	0	0	1	1	0	1	1	1	0.29
(Siminoff, Gordon et al. 2006)	1	2	2	2	2	0	0	1	2	2	2	2	2	1	0.75
(Sivell, Edwards et al. 2012)	2	2	1	2	N/A	N/A	N/A	1	2	1	0	0	2	2	0.68
(Street, Voigt et al. 1995)	2	2	2	2	1	0	0	2	1	1	0	0	2	2	0.61
(Vickers, Elkin et al. 2009)	2	2	2	2	2	0	0	2	2	1	2	0	2	1	0.71
(Vodermaier, Caspari et al. 2011)	2	2	2	2	1	0	0	2	1	2	1	2	1	1	0.68
(Whelan, Levine et al. 1995)	1	1	2	1	N/A	N/A	N/A	0	2	1	0	1	2	2	0.59
(Whelan, Levine et al. 1999)	2	1	2	1	N/A	N/A	N/A	0	2	2	0	1	1	2	0.64
(Whelan, Levine et al. 2004)	1	2	2	1	2	0	0	2	2	2	2	1	2	2	0.75
(Whelan, Sawka et al. 2003)	2	2	2	2	2	0	0	2	2	2	2	2	1	2	0.82
(Wong, D'Alimonte et al. 2012)	1	1	1	2	N/A	N/A	N/A	1	2	1	2	0	2	1	0.64

Table 3. Qualsyst scores: Qualitative studies

	1.Question fully described	2.Design evident and appropriate	3.Context for study clear	4.Connection to theoretical framework/wider body of knowledge	5.Sampling strategy described, relevant and justified	6.Data collection described and systematic	7.Data analysis described and systematic	8.Use of verification procedures to establish credibility	9.Conclusions supported by results	10.Reflexivity of account	Total
(Sheppard, Williams et al. 2010)	2	2	2	2	1	1	1	0	1	0	0.6
(Sheppard, Figueiredo et al. 2008)	1	2	1	1	1	0	1	0	1	0	0.4

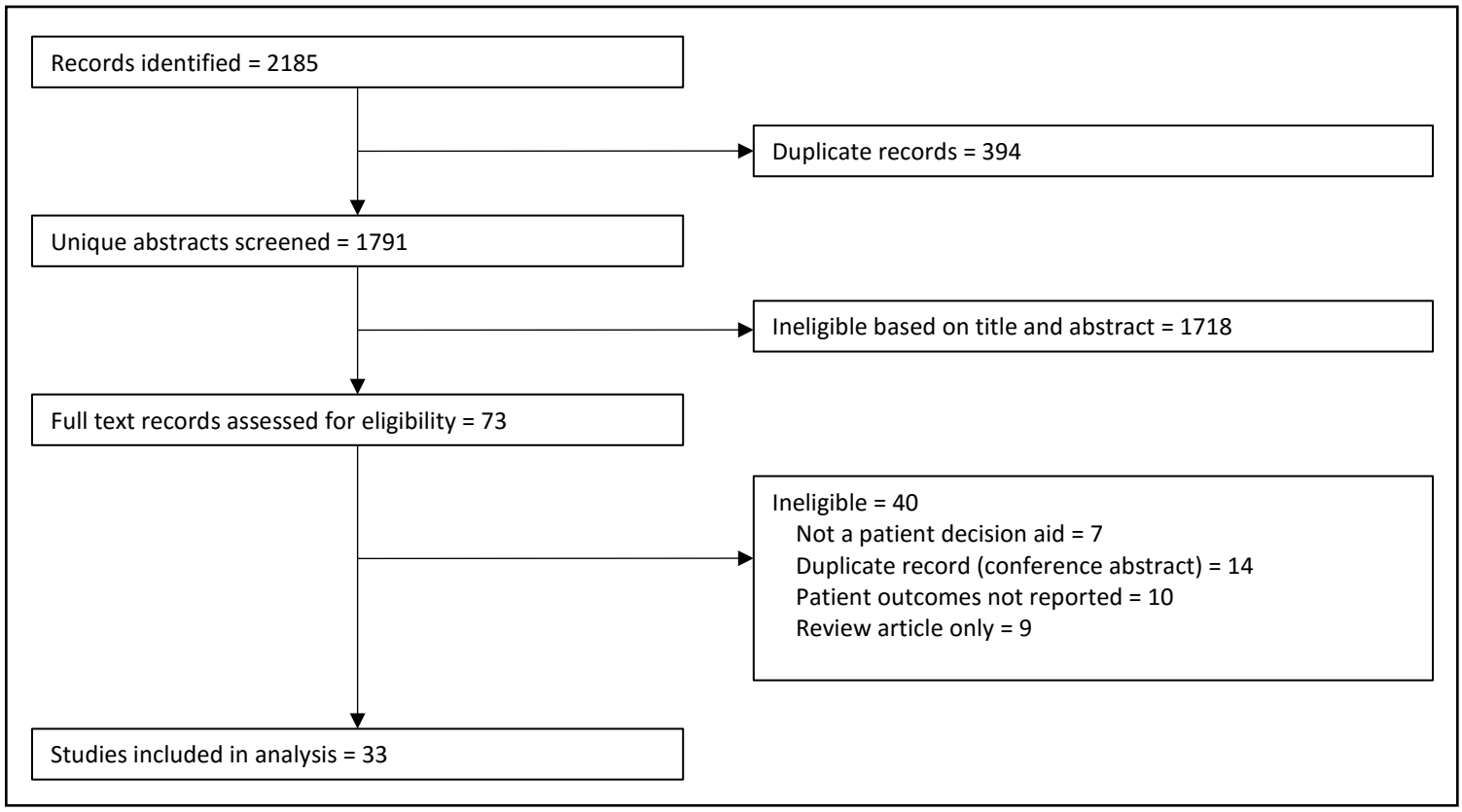
Table 4. Treatment options for early stage breast cancer in typical chronological order from left to right, and existing breast cancer treatment decision aids.

Fertility preservation	Neoadjuvant systemic therapy	Primary surgery	Adjuvant chemotherapy	Adjuvant radiotherapy	Adjuvant endocrine therapy	Breast reconstruction	Contralateral prophylactic mastectomy
(Peate, Meiser et al. 2012)		(Belkora, Volz et al. 2012)				(Lee, Chen et al. 2010)	
		(Vodermaier, Caspari et al. 2011)		(Wong, D'Alimonte et al. 2012)		(Heller, Parker et al. 2008)	
		Surgery decision board (Whelan, Levine et al. 2004)	Chemotherapy decision board (Whelan, Levine et al. 2004)			BRECONDA (Sherman, Harcourt et al. 2014)	
		A Patchwork of Life (Jibaja-Weiss, Volk et al. 2011)	Latina a Latina (Sheppard, Figueiredo et al. 2008)				
		(Street, Voigt et al. 1995)	Adjuvant!Online				
		(Dhage, Castaneda et al. 2013)	(Irwin, Arnold et al. 1999)				
		(Goel, Sawka et al. 2001)	(Levine, Gafni et al. 1992)				
		(Harwood, Douglas et al. 2011)	(Feldman, Stanford et al. 2002)				
		(Molenaar, Sprangers et al. 2001)	(Sheppard, Williams et al. 2010)				
		BresDex (Sivell, Edwards et al. 2012)					
		(Au, Lam et al. 2011)					

Decision aids are named where the name is known, otherwise the Author and year are given.

Figures

Figure 1. Systematic review flow diagram



APPENDIX A

Search strategy

1. exp Breast Neoplasms/
2. ((breast) adj6 (cancer$ or neoplasm* or carcinoma* or tumor* or tumour*)).tw.
3. 1 or 2
4. (advance$ or metasta$ or recurren$).mp. or exp Neoplasm Metastasis/
5. 3 not 4
6. exp Decision Support Systems, Clinical/
7. exp Decision Support Techniques/
8. exp Decision Making/
9. exp Decision Trees/
10. ((decision or decid*) adj6 (support* or aid* or tool* or instrument* or technolog* or system* or technique* or program* or algorithm* or process* or method* or intervention* or material*).tw.
11. (decision adj (board* or guide* or counsel*)).tw.
12. Interactive health communication.tw.
13. (interacti* adj (internet or online or graphic* or booklet*)).tw.
14. (interacti* adj6 tool*).tw.
15. (interacti* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw.
16. (decision mak* or choice behav*).tw
17. shared decision making.tw.
18. or/ 6-17
19. exp Drug Therapy/
20. exp General Surgery/
21. exp Radiotherapy/
22. exp Radiotherapy, Adjuvant/
23. 21 or 22
24. 19 or 20 or 23
25. 9 and 18 and 24
26. limit 25 to animals
27. 25 not 26
28. limit 27 to English language

Acknowledgements: We would like to thank Mr Jeremy Cullis, Librarian, University of Sydney, for assistance in developing the protocol and in collection of data.

Authorship

Conception and design: NZ, PB, FB
Collection and assembly of data: NZ, ST
Data analysis and interpretation: All authors
Manuscript writing: All authors
Final approval of manuscript: All authors

Conflict of interest statement: NZ and PB hold current grants funding studies to assess new decision aids for patients with breast cancer. These are not reviewed in the current paper.

Funding: This work was supported by the Breast Cancer Institute of Australia (BCIA), Sydney Catalyst and The Friends of the Mater Foundation. These funding bodies had no role in the design, conduct or analysis of this work.

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