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Review

Evaluating the content and development of decision aid tools for the management of menopause: A scoping review



Tasneem Siyam^a, Humirah Sultani^b, Sue Ross^c, Trish Chatterley^d, Nese Yuksel^{a,*}

- a Faculty of Pharmacy and Pharmaceutical Sciences, 3-171 Edmonton Clinic Health Academy (ECHA), University of Alberta, Edmonton, AB, T6G 1C9, Canada
- ^b Tom Baker Cancer Centre, 1331 29 Street NW, Calgary, AB T2N 4N2, Canada
- ^c Department of Obstetrics & Gynecology, Rm 5S131 Lois Hole Hospital/Robbins Pavilion Royal Alexandra Hospital 10240 Kingsway Ave, Edmonton, AB, T5H 3V9, Canada
- ^d John W. Scott Health Sciences Library, 2K3.28 Walter C. Mackenzie Health Sciences Centre, University of Alberta, Edmonton AB, T6G 2R7, Canada

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ABSTRACT

Objective: Decision-making during menopause (especially surgical menopause) can be complex given the variability in risk-benefit perceptions of menopausal treatments. Decision aid tools (DATs) help women participate in decision-making about options. Our objective is to identify and evaluate the content and development of DATs for managing menopause, with a special focus on surgical menopause.

Methods: We systematically searched electronic databases, including MEDLINE and EMBASE, from inception to March 2017 for relevant records. The principal inclusion criterion was that papers reported studies on DATs for managing menopause. Search terms were derived from two concepts: menopause and DATs. Data extracted were presented in written evidence tables and narrative summaries.

Results: Our search yielded 18,801 records. Of these, 26 records met our inclusion criteria, which gave rise to 12 DATs from peer-reviewed literature and 6 from grey literature. Seventeen DATs were focused on natural menopause and two targeted surgical menopause, both identified from grey literature. More than half were published before the Women's Health Initiative (WHI) publication and 70% before the release of the International Patient Decision Aid Standards (IPDAS). Very few studies reported the full development of the DAT involved, and less than half of DATs were informed by a needs assessment to identify the decisional needs of their target population. Most DATs focused on hormone therapy as a treatment option and did not provide a comprehensive overview of other options. None of the DATs reported the steps involved in finding, appraising and summarizing scientific content of the tool.

Conclusion: This review highlights several limitations in the content and development of DATs for managing menopause. No peer-reviewed DATs were identified for surgical menopause. A need for a complete, evidence-based DAT in the context of surgical menopause is identified.

1. Introduction

Decision-making at menopause can be complex given the variability in the risk-benefit perceptions of treatment options, such as hormone therapy (HT). The use of HT declined dramatically after the initial publication of the Women's Health Initiative (WHI) Estrogen-Progestin (EPT) trial showed an increased risk of coronary heart diseases (CHD), stroke, venous thromboembolism (VTE) and breast cancer with HT and raised concerns over its safety [1,2]. As participants in the WHI on average were in their 60 s and were not symptomatic, the same risks may not apply to younger symptomatic women [3]. Other treatment options are available for managing menopausal symptoms, however HT

is the most effective treatment. In light of the controversy with HT, menopausal women are often challenged by the value-laden nature of the decision to manage their menopausal symptoms. Women who go through early surgical menopause (\leq 45 years) are specifically challenged as they may experience severe symptoms associated with the abrupt decline in hormones and may have long-term health sequelae.

Decision aid tools (DATs) are patient-targeted interventions to help patients facing value-laden decisions. DATs are shown to be superior to standard measures in improving patients' knowledge, expectations about treatment outcomes, decision quality, shared decision-making, and decisional conflict [4–6]. DATs support shared decision-making and informed, value-based decisions when developed based on a

E-mail addresses: tsiyam@ualberta.ca (T. Siyam), humirah.sultani@ahs.ca (H. Sultani), Sue.Ross@albertaheatlhservices.ca (S. Ross), trish.chatterley@ualberta.ca (T. Chatterley), nese.yuksel@ualberta.ca (N. Yuksel).

^{*} Corresponding author.

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recognized quality criteria and valid evidence sources [7,8]. On the contrary, poorly developed DATs have the potential to cause harm and are less likely to advocate shared decision-making [9]. The International Patient Decision Aid Standards (IPDAS) provides a framework of evidence-based quality criteria that serves as a reference for developing and/or evaluating the quality of DATs [7].

In 2011, a systematic review of the effect of menopausal symptoms management decision aids reported several DATs created for managing menopause [10]. None of these DATs targeted surgical menopause. This review highlighted several inadequacies of identified DATs mostly related to the lack of completeness and currency of evidence on presented options [11-26]. However, this review did not include the grev literature, and focused only on trials evaluating the effectiveness of DATs in menopause. We decided to undertake a scoping review which would allow us to broadly examine the extent, range and nature of research activity associated with the development of DATs for menopause to identify gaps in existing literature, with no restrictions on the type and source of studies that can be incorporated (e.g. both peer-reviewed and grey literature) as opposed to a systematic review. The objectives of our scoping review were to identify and evaluate the development and content of DATs used for managing menopause in the published and unpublished literature, and specifically in the context of surgical menopause.

2. Methods

We conducted a scoping review based on the stages proposed by Arksey and O'Malley for performing scoping reviews [27]. The systematic approach involved in identifying, extracting and summarizing relevant scientific evidence in scoping reviews reduces the risk of introducing bias during any of these steps.

2.1. Eligibility criteria

Studies on the development and evaluation of DATs for managing natural or surgical menopause, with no restriction to the target population of women or treatment modalities discussed in the DAT were eligible for inclusion. Unpublished DATs for managing menopause, found in the grey literature also qualified for inclusion. We excluded: review papers; studies on DATs created for conditions other than menopause management; studies on determinants or predictors of decisions; and studies published in languages other than English.

2.2. Data sources

A systematic literature search was conducted by a librarian (TC) to identify all relevant published and unpublished studies. We searched electronic bibliographic databases including: Ovid MEDLINE (1946 to March 2017), Ovid EMBASE (1974 to March 2017), CINAHL (inception to March 2017), Ovid PsycINFO(1806 to March 2017), and HAPI (1985 to October 2015), to identify studies reporting the development of DATs for managing surgical or natural menopause (Additional file 1). Grey literature searches were conducted in SCOPUS, ProQuest Dissertations and Theses, and Google web from inception to March 2017. Search terms were searched as MeSH headings or keywords and were derived from two main concepts: menopause and DATs. We hand searched reference lists of relevant review papers and relevant articles for additional studies. We limited our search to English language and human.

2.3. Selection process

Search results from relevant sources were exported to one Refworks account and close duplicates were removed. Eligibility screening was completed independently by two reviewers (HS and LM) and disagreements were resolved by a third investigator (TS). Titles and abstracts were initially screened, followed by full-text review of articles to

confirm eligibility.

2.4. Data extraction and synthesis

Data extraction was completed by two independent reviewers (HS and LM) and discrepancies were resolved by a third reviewer (TS). Data extracted included: manuscript characteristics, population characteristics, DAT characteristics and data on DATs content and development evaluation in reference to the IPDAS quality checklist [7]. We chose the IPDAS checklist as a judging criteria because it is comprehensive, evidence-based and developed by an international collaboration of experts in the field of DATs. IPDAS has also been used as a quality reference in several systematic reviews [28,29] and is currently embraced as a DAT evaluation criteria by the Ottawa Health Research Institute (OHRI). The OHRI aims at educating the public about DATs and promotes their use in different health decision contexts [30]. The IPDAS criteria address three dimensions of quality: content, development and effectiveness. Since DAT effectiveness was previously addessed by Carpenter et al., our scoping review focuses on the content and development dimensions [10]. Each DAT was evaluated with respect to four content quality criteria including: 1) provides information about options in sufficient detail for decision making; 2) presents probabilities of outcomes in an unbiased and understandable way; 3) includes methods for clarifying and expressing values; and 4) includes structured guidance in deliberation and communication. Development was evaluated with respect to five development quality criteria: 1) presents information in a balanced manner; 2) has a systematic development process; 3) includes up to date scientific evidence that is cited in a reference section or technical document; 4) discloses conflicts of interest; and 5) uses plain language. Descriptive analysis was used to describe the evaluation of the content and development of DATs. Peer-reviewed and grey literature were discussed separately. To determine the qualifying and certifying potential of identified DATs we screened them against features of qualification and certification as proposed by Joseph-Williams et al. [30]. The proposed "qualifying" criteria for an intervention to qualify as a decision aid [31] included: describes health condition or problem for which index decision is required; explicitly states decision under consideration; describes the options available for the index decision; and describes the positive and negative features of each option. Additionally the following DAT "certified" criteria were proposed to prevent harm to a patient: shows the negative and positive features of options in equal detail; provides citations to the evidence selected; provides a production/publication date; provides an update policy; provides information about the levels of uncertainty around event or outcome probabilities; and provides the funding source used for development. Each DAT must meet all of the proposed criteria to be classified as "qualified" and "certified".

3. Results

The results of our search and screening process are included in Fig. 1. Our search yielded 18,801 records, of which 44 full-text records were retrieved and assessed for eligibility. Of these, 26 were included in the review. Twenty articles were located in the peer-reviewed literature which discussed 12 unique DATs. The remaining 6 records were found in the grey literature each representing a unique DAT.

Table 1A lists the main characteristics of peer-reviewed articles discussing DATs for managing menopause. Articles were mainly from the US (55%), and Canada (40%). The majority were evaluation studies (85%), of which 88% were randomized controlled trials (RCTs). Only 3 of the studies were on DAT development and included data on evaluation [14,32,33]. Over 50% were published before the WHI publication, and 70% published before the release of IPDAS. All studies focused on natural menopause. One study targeted menopausal women with disabilities [19]. The age range of women across studies was 40–75 years and the mean sample size was 177 (range 24–463)

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