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Review Article

A Scoping Review of the Application of **BREAST-O** in Surgical Research

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ABSTRACT

Background: Collection of patient-reported outcome (PRO) data can facilitate cost-effective, evidence-based, and patient-centered care. The BREAST-O has become the gold standard tool to measure PRO data in breast surgery. The last review of its application indicated that it was underutilized. Considering the evolution in breast surgery, the purpose of this study was to perform a scoping review of BREAST-Q application since 2015 and identify emerging trends and potential persistent gaps to guide patient-centered practice and future research in breast surgery.

Methods: We performed an electronic literature review to identify publications published in English that used the BREAST-Q to assess patient outcomes. We excluded validation studies, review papers, conference abstracts, discussions, comments, and/or responses to previously published papers.

Results: We identified 270 studies that met our inclusion criteria. Specific data was extracted to examine the evolution of the BREAST-Q application and examine clinical trends and research gaps.

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Discussion: Despite a significant increase in BREAST-Q studies, gaps in the understanding of the patient experience remain. The BREAST-Q is uniquely designed to measure quality of life and satisfaction with outcome and care. The prospective collection of center-specific data for every type of breast surgery will generate important information for the provision of patient-centered and evidence-based care.

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Introduction

Patient-reported outcomes (PROs) have become a critical metric in assessing the impact of medical and surgical interventions. PRO data can enhance patient engagement and promote an evidence-based, shared decision-making model.¹ The BREAST-Q is considered the gold standard PROM (Patient-Reported Outcome Measure) for breast surgery² and has 5 modules: augmentation, reduction/mastopexy, mastectomy, breast conserving therapy, and reconstruction. These measure quality of life (QOL) domains including physical, psychosocial, and sexual well-being and satisfaction with breasts, outcome, and care.³

A scoping review (2009-2015) indicated that the BREAST-Q was used mostly in retrospective reconstruction studies and examined limited breast surgery types and domains.⁴ Since 2015, the field of breast surgery has evolved. In breast reconstruction, prepectoral mastectomy reconstruction is regaining popularity, the use of acellular dermal matrixes (ADMs)/fat grafting is increasing, and the use of autologous breast reconstruction is expanding due to efficiency and new donor sites.⁵ Oncoplastic surgery (OPS) for immediate lumpectomy reconstruction is also gaining ground.⁶ Breast augmentation and breast reductions remain popular, but gender-affirming surgery is also emerging.⁷ More recently, a systematic review of study methodology identified significant shortcomings in the BREAST-Q literature.² The importance of long-term, prospective studies and understanding of preoperative data are critical components in interpreting BREAST-Q data and managing patient expectations.⁸

Thus, there is utility in re-examining the application of the BREAST-Q in clinical research. The purpose of this study was to perform a scoping review of BREAST-Q application since 2015 and identify emerging trends and potential persistent gaps to ultimately guide patient-centered practice and future research in breast surgery.

Methods

Search methodology

We followed the PRISMA guidelines for scoping reviews.⁹ We completed an electronic literature search of Embase and MEDLINE using OVID from January 2015 to November 2020. The search terms used were "Breast-Q" and "BreastQ."

Screening and inclusion/exclusion criteria

Two reviewers (NA and BM) independently reviewed the titles and abstracts of the articles identified, with differences in opinion managed by a third reviewer (GM). We included all primary research published in English that used the BREAST-Q to assess outcome (s) in breast surgery. Conference abstracts, editorials, commentaries, letters to the editor, review articles, protocol papers, and duplicates were excluded. Validation studies that compared the BREAST-Q to other patient-reported outcome



Figure 1. Inclusion and exclusion criteria applied to identify articles that used the BREAST-Q to measure outcome of breast surgery.



Figure 2. Number of BREAST-Q studies published per year.



Figure 3. Global distribution of BREAST-Q studies published (A) in 2015-2020 in total; (B) OPS & BCT; (C) Mastectomy Reconstruction; (D) Breast Reduction; (E) Breast Augmentation.

measures were included if they presented raw BREAST-Q data. We also performed a citation review of all included articles.

Our review timeline was January 2015 to December 2020. We also performed a review using the same methodology to identify BREAST-Q studies from December 2020 to February 2022. We identified 132 eligible abstracts in the additional time frame (Figure 2), and data from abstract analysis alone



Figure 4. Frequency of BREAST-Q modules per year. BCT, breast conserving therapy.

for these additional studies on frequency of module, type of surgery, and study design are included in Figures 4, 5, and 6, respectively.

Data extraction and analysis

The following data were extracted during full text review: country of origin, study design, study aim, sample size, follow-up duration, patient sociodemographic characteristics, BREAST-Q module utilized, domains and subdomains assessed, utilization of BREAST-Q pre- and/or postoperatively and key findings. Study design was categorized based on the timing of the administration of the BREAST-Q. The articles were organized based both on the type of module(s) used and the type(s) of breast surgery studied. Categories for types of surgery included breast augmentation, breast reduction, breast conserving therapy (BCT), OPS, mastectomy, mastectomy reconstruction, and "Other."

Results

The literature search resulted in 332 articles. Following the application of the inclusion and exclusion criteria and citation review, 270 articles were eligible for full text review (Figure 1).

Appendix A provides a list of the included studies, the data extracted, and key findings. The mean follow-up time was 900 days, the median was 564 days, and 81 studies (30%) did not report their response rate.

Since 2015, the number of BREAST-Q studies has increased significantly, from 49 to 270 (Figure 2). We identified studies from 27 countries, and 53% were conducted in North America. Although most breast reconstruction studies were from the United States and Canada, most breast augmentation studies were performed in China, and most breast reduction studies were from South America and Australia (Figure 3).

Regarding the distribution of modules, the reconstruction module was examined in most studies (195, 72.2%) followed by the breast conservation therapy (32, 11.9%), mastectomy (28, 10.4%), reduction/mastopexy (23, 8.6%), and augmentation modules (14, 5.4%) (Figure 4). With respect to type of surgery studied, mastectomy reconstruction was the most popular (177, 65.6%) followed by OPS and BCT (43, 15.9%). Breast augmentation and reduction studies represented 5.2% and 5.6% of the total number (Figure 5). Six studies compared BREAST-Q scores between mastectomy and mastectomy reconstruction (Figure 5). Fifteen studies in the "Other" category focused on congenital breast deformity, gender affirmation, and normative data collection (Figure 5).



Figure 5. Frequency and type of breast surgery assessed with BREAST-Q. BCT, breast conserving therapy; OPS, oncoplastic surgery.



Figure 6. Frequency of study design in reports of the BREAST-Q.

The distribution of study designs is shown in Figure 6. The dominant study types were cross-sectional and retrospective (54%), followed by prospective (31%), other (case-series, case control, 12%), and randomized controlled trials (RCTs) (3%).

Figure 7 outlines the BREAST-Q domains assessed: 96% of the studies reported satisfaction scores. Of these, 91% reported on satisfaction with breasts and 53% on satisfaction with outcome (Figure 7A). Scores for at least 1 of the 4 satisfaction with care domains were reported in 81% of studies, whereas all 4 were assessed in 12%. Satisfaction with surgeon was the most frequently reported (24%, Figure 7A).



Figure 7. Number of studies assessing A) Satisfaction and B) Quality of Life subdomains of the BREAST-Q.

Scores on QOL domains were reported in 92% of the studies. The most assessed QOL domain was psychosocial well-being (87%) followed by physical (chest) (83%) and sexual well-being (82%) (Figure 7B).

Discussion

Collection of PRO data facilitates cost-effective, evidence-based, and patient-centered care. Cohen et al⁴ concluded that the BREAST-Q was mostly utilized in cross-sectional, mastectomy reconstruction studies assessing only a fraction of the subdomains. Despite the increase in number of studies reporting on the BREAST-Q, the design, type, and domains assessed have not changed significantly.

The more than 5-fold increase in studies since 2015 demonstrates unequivocally that the BREAST-Q is the gold standard PROM tool in breast surgery. In 2021 alone, 132 studies utilized the BREAST-Q, thus our timeline is likely the last opportunity to perform a scoping review of its application. The global distribution in Figure 3 may reflect differences in the need for specific outcome data, insur-

ance coverage, and popularity of procedures. Considering the availability of the BREAST-Q in 30 languages, enhancing utilization of the tool globally would be an exciting avenue for future research inquiry.

The most common study design remains retrospective and cross-sectional. Only 31% of the studies were prospective and provided preoperative data. This trend continued in 2021 (Figure 6). Yet, several studies have emphasized the importance of preoperative data and how it can be affected by marital status, race, and personality.^{8,10,11} Preoperative data is necessary to put values into context and provide insight into patient eligibility, improve patient education, manage expectations, and identify patients that can benefit from support. There is also a paucity of normative values for all BREAST-Q modules to guide data interpretation.

Studies remain selective in the domains assessed, and not all domains have equal representation in the literature, thus leading to gaps in understanding. Satisfaction with breast and outcome remain the most popular (Figure 7A). Notably, many mastectomy reconstruction studies report satisfaction with outcome, indicating the use of version 1.0 of the reconstruction module. The newer, 2.0 version, available since 2017, does not include this subdomain as breast cancer patients found certain questions about repeating their experience not applicable. The modules are comparable, but version 2.0 is recommended. Satisfaction with care for all 4 components (surgeon, information, medical team, office staff) was only reported by 12% of the studies. Ho et al¹² showed that satisfaction with care can affect satisfaction with outcome. Builes-Ramirez et al¹³ reported that 40% of breast cancer patients are dissatisfied with the decision-making process, suggesting the BREAST-Q can give patients the opportunity to better reflect on their satisfaction with outcome and care. This data should ideally be breast center- and region-specific because the delivery of breast surgery is center-specific.¹³ The incorporation of the BREAST-Q in diverse centers, and the prospective collection of data with long-term follow-up, can help enhance patient-centered care.

In the following sections, we offer a qualitative assessment of our findings within the context of existing literature as it applies to commonly encountered clinical scenarios.

Considerations in breast reconstruction surgery

Should a patient consider mastectomy reconstruction?

Over 30% of breast cancer patients will undergo mastectomy and over 40% will go on to have reconstruction.¹⁴ Nearly half of these women report dissatisfaction with the decision-making progress and aesthetic outcome.¹³ We have identified many retrospective studies that attest to the positive impact of reconstruction, but the insight of women who do not undergo reconstruction is lacking. Baseline BREAST-Q scores of delayed mastectomy reconstruction patients are low,¹⁵ but this may represent a biased group of patients interested in reconstruction. Most mastectomy patients do not get reconstruction,¹⁴ and we identified no prospective studies that focused on these patients with adequate follow-up in the survivorship period. Chao et al¹⁶ carried out a prospective, multi-institutional study in Taiwan comparing BREAST-Q scores in mastectomy alone vs reconstruction patients and found a sharp decline in well-being scores in the first month for both groups. The low scores were stable for 9 months postoperatively for the mastectomy alone group, compared with the reconstruction group, which reported increased QOL after the first month. A decline in QOL early in the postoperative period may encourage women to consider reconstruction, whereas a gradual decline over a longer period may reassure women that they can consider delayed reconstruction if they desire.

We also identified only one cross-sectional but no prospective studies that reported results from the expectations part of the reconstruction module and concluded that delaying breast reconstruction may have a negative impact on patient's expectations of recovery.¹⁷ Expectations data can also aid the interpretation of postoperative scores, help identify gaps in patient education, and should be considered when the BREAST-Q is administered.

Overall, mastectomy reconstruction studies show that immediate and delayed reconstruction results in higher BREAST-Q scores compared with mastectomy alone, and therefore, women should at least consider it.¹⁸ Prospectively collected, long-term PROM data from mastectomy alone patients should also be represented in the preoperative consultation. Other important factors include:

Age

Nearly half of all newly diagnosed breast cancer is found in women aged \geq 65 years.¹⁹ The average age across the studies in our review was 48.4 years (*Appendices A, B*). Only 4 studies examined patients \geq 60 and found that age made no difference in BREAST-Q scores post reconstruction.¹⁹⁻²² Autologous reconstruction was associated with higher BREAST-Q well-being scores in women >65 compared with alloplastic reconstruction at 2 years.^{19,21} The benefits of reconstruction do not appear to be age-dependent, but further research of the potential barriers in women >65 may improve their experience and outcomes.

Body mass index (BMI)

Cheng et al²³ found no correlation between BMI and postoperative BREAST-Q scores, despite its association with increased risk of complications.²⁴ Srivanasa et al²⁵ also found higher risk of alloplastic and autologous reconstructive failure in patients with higher BMI. Although obese patients were found to have lower baseline scores for satisfaction with breasts, no significant differences were found at 1-3 years post reconstruction between normal BMI and obese patients.^{26,27} Autologous reconstruction patients with high BMI also reported lower satisfaction with their abdomen at long-term follow-up.²⁷ These considerations may be helpful in counseling patients with higher BMI.

Type of mastectomy

In general, nipple-sparing mastectomy was associated with higher BREAST-Q scores, especially sexual well-being, with follow-up up to 22 months.^{28,29} This relationship held in both treatment and risk-reducing mastectomy groups.³⁰ When compared with unilateral mastectomy, patients with bilateral risk-reducing mastectomy/contralateral risk-reducing mastectomy (CPM) had better BREAST-Q outcomes.³¹ More long-term data examining these differences can be useful when offering riskreducing treatment is under scrutiny due to health care resource limitations.

Should a patient consider immediate or delayed reconstruction?

Several studies have examined the impact of timing of reconstruction on BREAST-Q scores and have not demonstrated significant differences.^{32,33} Immediate autologous reconstruction resulted in improved satisfaction with breasts in the short term (<18 months³⁴), but in prospective studies with >3 year follow-up, postoperative BREAST-Q scores were not found to be significantly different between immediate and delayed reconstruction.^{34,35} Furthermore, in patients with post-mastectomy radiation, when delayed autologous reconstruction was compared to delayed-immediate, no significant difference was found in satisfaction and well-being despite higher rates of mastectomy flap necrosis and tissue expander exposure.³⁶ Overall, only 10 studies assessed the impact of timing prospectively.^{32,34,35,37-43} Considering lower baseline scores in delayed reconstruction patients, assessing post reconstruction is to avoid living with a mastectomy defect; therefore, baseline BREAST-Q scores are expected to potentially improve or be maintained post reconstruction.⁴⁴

Although associated with a significant risk of complications,⁴⁵ the positive impact of immediate reconstruction on BREAST-Q scores is evident. However, more prospective BREAST-Q studies with at least 2-year follow-up that directly compare the timing and type of reconstruction are needed as this type of data will help patients critically think about an intervention with a high complication profile.

What type of reconstruction should a patient consider?

The choice largely depends on the patient's goals and expectations, medical and surgical history, and need for or history of radiation. Regarding autologous reconstruction, comparisons of postoperative BREAST-Q scores of patients with abdominal-based flaps at 2-10 years follow-up⁴⁶⁻⁴⁸ demonstrate that muscle-preserving techniques result in higher satisfaction and abdominal well-being scores. When compared to other flaps, abdominal-based flaps were associated with superior donor site well-being.⁴⁹ Further examination of prognostic factors with long-term follow-up is needed to help guide patient selection and offer support and optimize outcomes.

Alloplastic reconstruction remains the most popular type of reconstruction assessed in most reconstruction studies. Despite its advantages, it is associated with more revision surgeries, questionable longevity, and failures. Studies that compared the traditional two-stage approach of expander to implant versus direct to implant found no significant differences in postoperative QOL data.^{43,50} Similarly, studies that compared prepectoral to subpectoral approach did not identify significant differences in BREAST-Q outcomes with a maximum follow-up of 25 months,⁵¹ even in the case of the nipple-sparing approach.⁵² However, some European studies have found improved QOL outcomes with a prepectoral approach.^{53,54} Implant shape was also not shown to affect BREAST-Q scores.⁵⁵ With respect to ADM, only 2 studies compared implant-based reconstruction with and without ADM and found no significant differences in BREAST-Q scores at 2 years.^{56,57} Prepectoral placement and ADM have significant cost, and with no clear benefit demonstrated to date, more long-term data is needed as well as specific indications for selective use.

Both alloplastic and autologous reconstruction options have advantages and disadvantages, and therefore, direct comparisons may not be meaningful when indications and patients' goals for care vary. When compared to alloplastic, autologous reconstruction has been shown to result in improved BREAST-Q scores in satisfaction with breasts and improved psychosocial and sexual well-being but lower physical well-being scores at up to 5 years.^{36,58,59} Comparative, prospective studies with longer follow-up are required to establish the complication and QOL profile of the different approaches so that patients have a firm understanding of their choices.

Radiation

According to most studies reviewed, radiation is associated with decreased BREAST-O scores with average follow-up of 3.4 years.^{14,33,35,36,50} Autologous reconstruction, immediate and delayed, was associated with high BREAST-O scores.^{38,60} Implant-based reconstruction was associated with higher reconstruction failure and capsular contracture and lower BREAST-Q satisfaction and QOL scores.^{14,25,50,61} Even though radiation to the tissue expander was associated with more complications, BREAST-O scores were similar between 2 stages and direct to implant reconstruction.^{40,43,50} In comparative studies of immediate reconstruction and post-mastectomy radiation, patients with autologous reconstruction scored higher for satisfaction.⁴⁸ Despite lower scores, implant-based reconstruction patients did demonstrate stability over long-term up to 7 years.⁴⁸ Seth et al¹⁴ found no significant differences in BREAST-Q scores between non-radiated and radiated implant-based reconstruction patients after 6 years in a study with a 12 year follow-up, attesting to the potential stability of implants. However, most of these studies were retrospective and cross-sectional, and without the preoperative scores, postoperative scores cannot be put into context. Long-term (>5-year), prospective studies that examine the effect of radiation on timing and type of reconstruction are needed. Data from this review suggest that despite the high risk of complication and failure, long-term satisfaction may not be as significantly affected as previously thought.

What about lumpectomy reconstruction?

Breast conserving therapy

BCT, defined as lumpectomy and radiation, is the treatment of choice in early breast cancer considering the demonstrated equivalent survival outcomes to mastectomy.⁶² Blankenstein et al⁶² also showed that patients found BCT less burdensome than mastectomy, whereas living with bilateral mastectomy was reported equivalent to monocular blindness. We identified 20 studies that used the BCT BREAST-Q module, which was developed in 2016 (*Appendix A*), and only 5 were in 2021. Mean (n) was 736 patients and mean follow-up just under 3 years. The most common domains assessed were satisfaction with breasts and well-being followed by satisfaction with health care team. When BREAST-Q scores were measured in BCT patients alone, satisfaction with breasts and well-being domains declined with time,⁶³ likely reflecting progressive radiation effects, impact of asymmetry, and possible deformity. The rest of the studies compared BCT patients to mastectomy alone and mastectomy with reconstruction. Mastectomy patients consistently reported the lowest BREAST-Q scores.⁶⁴ Interestingly, BCT patients often scored better than implant-based reconstruction patients⁶⁵ but closer to autologous reconstruction patients.⁶⁴ This may reflect the similarities in maintaining a more natural shape and "feel."

Oncoplastic surgery

When BCT is an option, patients prefer to keep native breast tissue, but up to 30% of patients have significant deformity and asymmetry.⁶⁶ Oncoplastic surgery refers to the immediate reconstruction of lumpectomy defects when significant deformity and asymmetry are anticipated. Because it considers the possibility of an improved aesthetic outcome without compromising oncologic safety, OPS has been gaining popularity since the 1990s.⁶⁷ We identified 21 studies, of which only 5 reported preoperative scores. When compared to BCT, OPS patients scored higher in satisfaction with breasts and well-being domains,^{68,69} reflecting the impact of the OPS. BREAST-Q scores for satisfaction and well-being were also found to be high in studies examining different approaches to OPS.⁷⁰ Notably, Acea-Nebril et al⁷⁰ showed that relatively high preoperative scores declined post-OPS, emphasizing the importance of patient education and management of the expectations for a specific procedure. When OPS was compared to mastectomy with immediate reconstruction, BREAST-Q scores were comparable with follow-up up to 84 months.⁷¹

Overall, there appears to be a positive impact of OPS reconstruction. Despite the mostly retrospective nature of this data, these QOL scores should be considered when patients are diagnosed so that they can make informed decisions that address their goals of care, both oncologic and aesthetic. The need for prospective studies that clearly demonstrate the negative impact of BCT deformity on QOL and comparative studies to measure the impact of OPS is highlighted. The follow-up should be at least 2 years given the ongoing radiation effect. Assessing the domains of satisfaction with care can help address gaps in patient education and in the collaboration of surgical radiation oncologists and plastic surgeons. Identifying the ideal candidates for immediate lumpectomy reconstruction will help us decrease the considerable waiting lists for delayed lumpectomy deformity reconstruction.

Considerations in non-breast cancer reconstruction surgery

Breast reduction

Breast reduction to relieve the often debilitating symptoms of macromastia was the eighth most common plastic surgery procedure performed worldwide in 2018.⁷² Coverage varies, and the waiting lists are increasing. We identified only 15 studies; 5 were prospective and only 6 were in 2021. Follow-up time was under 6 years in all but one study⁷³ (21 years). All the studies showed significant improvements in BREAST-Q scores in physical, psychosocial, sexual well-being, and satisfaction with breasts⁷⁴ when compared to a control group or normative data. However, a recent review by Hudson et al⁷² of breast reduction in adolescents concluded that more prospective data for all age groups is needed as limited health care resources may hinder the ability to provide this service.

Breast augmentation

Breast augmentation remains the most popular breast procedure performed as indicated by ASPS statistics.⁷⁵ Cohen et al⁴ identified only 7 studies that utilized the BREAST-Q augmentation module; we found 15 and only 6 of the identified studies were in 2021. This paucity of studies represents an ongoing disparity in the utilization of PROMs in breast augmentation. All the studies in our review demonstrated significant improvements in satisfaction with breasts, outcome, sexual well-being, and psychosocial well-being postoperatively.⁷⁶ Silicone implants are used more commonly with few PRO data supporting this preference.⁷⁷

Like breast reduction, prospective long-term data in augmentation are also required to ensure and expand indications for coverage. Duraes et al¹¹ compared preoperative BREAST-Q scores and showed that satisfaction with breasts and all well-being subdomain scores of aesthetic breast patients were the lowest, comparable only to the delayed reconstruction patient group. Normative data of the BREAST-Q augmentation⁷⁸ and reduction⁷⁹ modules further demonstrate that breast augmentation and reduction patient scores are significantly lower than the norm, indicating the underestimated impact of breast aesthetics on QOL. This appears to be addressed with surgery as indicated by the high postoperative QOL scores (*Appendix A – Breast Augmentation*). It is critical to demonstrate the clear benefits taken for granted with long-term, prospective studies.

Other

The cases of transgender and nonbinary individuals undergoing chest reconstruction are rising, and the BREAST-Q is well suited to measure the impact of breast surgery. In our review, we identified only one study, by Agarwal et al,⁸⁰ a prospective study with 6-month follow-up that showed significant improvement in satisfaction and well-being BREAST-Q scores. Only 2 such studies identified were in 2021. Considering the need for appropriate coverage, we need QOL data that clearly demonstrates the impact of breast surgery in these patients.

Limitations

One of the limitations is the exclusion of non-peer reviewed work and likely valuable clinical data. The extent of bias in our interpretation of the findings is also unknown, as most studies did not report response rates, one of the major shortcomings found in BREAST-Q study methodology.² Selection bias continues to be an issue as most participating patients will have a vested interest in this topic. We only offered a qualitative assessment of the studies identified; however, this work lays the foundation to identify gaps and direct future research efforts.

Conclusion/Future directions

Despite the significant increase in BREAST-Q studies in our review, there remain significant gaps in our understanding of the patient experience. The BREAST-Q, when applied in properly designed prospective studies with adequate follow-up and response rate, can help identify areas of concern and direct patient care and future research efforts.

Perspective on QOL outcomes from more countries for all types of breast surgery is needed. More prospective, long-term data are also needed to facilitate meaningful systematic review studies. Waiting lists for delayed reconstruction across the world are becoming unmanageable, and we need to clearly demonstrate the benefits of immediate reconstruction. Considering the questionable sustainability of health care resources, we need to clearly demonstrate the benefits of all life-changing breast procedures for patients. Finally, normative data from representative samples of the population for all modules of the BREAST-Q are required for meaningful comparisons.

The BREAST-Q is unique in its design to offer data for both satisfaction with outcome and care. The incorporation of the BREAST-Q and prospective collection of center- and region-specific data for every type of breast surgery will generate invaluable information for the provision of comprehensive, patient-centered, and evidence-based care.

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Supplementary materials

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