Shared decision making in breast cancer treatment guidelines: Development of a quality assessment tool and a systematic review

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Abstract

Background: It is not clear whether clinical practice guidelines (CPGs) and consensus statements (CSs) are adequately promoting shared decision making (SDM).

Objective: To evaluate the recommendations about SDM in CPGs and CSs concerning breast cancer (BC) treatment.

Search strategy: Following protocol registration (Prospero no.: CRD42018106643), CPGs and CSs on BC treatment were identified, without language restrictions, through systematic search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR) and online sources (12 guideline databases and 51 professional society websites) from January 2010 to December 2019.

Inclusion criteria: CPGs and CSs on BC treatment were selected whether published in a journal or in an online document.

Data extraction and synthesis: A 31-item SDM quality assessment tool was developed and used to extract data in duplicate.

Main results: There were 167 relevant CPGs (139) and CSs (28); SDM was reported in only 40% of the studies. SDM was reported more often in recent publications after 2015 (42/101 (41.6%) vs 46/66 (69.7%), P = .0003) but less often in medical journal publications (44/101 (43.5%) vs 17/66 (25.7%), P = .009). In CPGs and CSs with SDM, only 8/66 (12%) met one-fifth (6 of 31) of the quality items; only 14/66 (8%) provided clear and precise SDM recommendations.

Discussion and conclusions: SDM descriptions and recommendations in CPGs and CSs concerning BC treatment need improvement. SDM was more frequently reported in CPGs and CSs in recent years, but surprisingly it was less often covered in medical journals, a feature that needs attention.

Keywords
breast cancer, breast cancer treatment, clinical practice guidelines, consensus, shared decision making
1 | INTRODUCTION

Breast cancer (BC) is the most common cancer in women, with 2.1 million new cases each year (25% of all female cancers), and it also causes the greatest number (about 670000 in 2018, 15%) of cancer-related deaths among women. Mortality and morbidity from BC have decreased in recent years thanks to early diagnosis and the combination of new treatments in a growing array of different strategies. The best BC treatment must be personalized, and choosing the ideal approach requires a high degree of specialization, scientific-technical updating, multidisciplinary coordination and patient participation.

This participation in shared decision making (SDM) is considered a keystone in the achievement of sustainable high-quality cancer care, and it becomes especially important when separate treatment options with overall similar potential can yield very different results depending on patients’ preferences. In developed countries, SDM is a legal obligation, and it has been shown to increase the satisfaction of the patient, improve cost-effectiveness and reduce malpractice lawsuits. It is claimed to be a keystone to guarantee good quality cancer care, and it is highly recommended by medical associations.

The implementation of SDM has persistent barriers, and it is still poor. Many authors have proposed strategies for promotion and practical application of SDM. A three-step model introducing choice, describing options and exploring preferences has been suggested. Another proposal involves encouraging patients to make their own care goals that clinicians translate into treatment plans. Decision aids are thought to make the SDM process easier.

Measuring SDM as a quality indicator and reimbursing professionals that actually use SDM have been floated as another idea involving incentivization.

This important subject should be adequately covered in clinical practice guidelines (CPGs) and consensus statements (CSs), especially in those that are published in a medical journal. The aim of this systematic review was to evaluate the characteristics of CPGs and CSs with SDM compared to those without, to develop an SDM quality assessment tool and to collate the specific information and recommendations about SDM concerning BC treatment in women.

2 | METHODS

This systematic review was carried out following protocol registration (Prospero No: CRD42018106643) and using a prospective protocol developed based on recommended methods for literature searches and assessment of guidelines. During the course of the work, no SDM assessment tool was identified in the literature, so we developed such a tool for data extraction in our work. It was reported according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) (see Appendix 1).

2.1 | Data sources and searches

A systematic search combining MeSH terms “shared decision making”, “clinical practice guidelines”, “guidelines”, “consensus”, “breast cancer”, “breast cancer treatment” and including word variants was conducted using MEDLINE covering the period January 2010 to December 2019, without language restrictions. We further searched online databases (EMBASE, Web of Science, Scopus, CDSR, etc.), 12 guideline-specific databases and 51 websites of relevant professional societies (see Appendix ). For completeness, we searched on the World Wide Web and the bibliographies of known relevant publications to identify additional studies of relevance to the review.

2.2 | Study selection and data extraction

We included CPGs and CSs about BC management, produced by governmental agencies or national and international professional organizations and societies. We excluded CPGs and CSs about screening and diagnosis, obsolete guidelines replaced by updates from the same organization, and CPG and CSs for education and information purpose only.

Two reviewers (MMC and IMMN) independently considered the potential eligibility of each of the titles and abstracts from the citations and requested full-text versions. Working independently, reviewers assessed the full text to confirm eligibility. Disagreements were resolved by consensus or arbitration by a third reviewer (MMD). Duplicate articles were identified and removed. Where multiple versions of a CPG or CS were retrieved, the most recent version was reviewed. Data were extracted from selected CPGs and CSs in duplicate, independently. The intraclass correlation coefficient (ICC) was used to assess consistency between reviewers in data extraction, and the reliability level was excellent >0.90. Authoritative guidance on systematic review methods recommends inter-reviewer reliability assessment that is designed to compare measurements obtained by two or more reviewers extracting data from the same papers.

2.3 | Guideline quality assessment and data extraction

We conducted a search to identify a quality assessment tool for SDM. No relevant tools were identified, so we constructed one using consensus to create a checklist from a long list of items identified in the literature searches. The quality of CPGs and CSs for SDM to manage patients with BC was independently evaluated by two different reviewers (MMC and IMMN) using a piloted data extraction form. Disagreements between the two authors (MMC and IMMN) over the risk of bias for particular studies were solved by group discussion involving an arbitrator (MMD) who took the final decision.
### 2.4 Data synthesis

Two authors (MMC and IMMN) synthesized the data extracted to summarize key information within using a piloted data extraction form concerning characteristics of CPGs and CSs with the SDM information and recommendations contained within them. Rate data were compared using chi-square test to examine whether CPGs and CSs with SDM were different to those without SDM.

### 3 RESULTS

#### 3.1 Study selection

Of the 4116 potential citations identified, a total of 167 documents (139 CPGs and 28 CSs) were identified for final evaluation (Figure 1). ICC for reviewer agreement was 0.97.

#### 3.2 Development of a quality assessment tool

Individual quality items were scattered across a number of tools for guidelines assessment. A long list of items was compiled and presented to a group of four BC and SDM specialists in a consensus meeting. This process including several revisions and iterations which led to a 31-item checklist grouped into thirteen domains (see Appendix). Of these, 68% (n = 21) were identified from the AGREE tools and 48% (n = 15) from the RIGHT tools. Only 13% (n = 4) of these items did not appear in any of these two tools. However, the expert consensus advised their inclusion after examining other literature in the bibliography of interest about SDM. The consensus meeting following approval of the 31-item checklist recommended that each item be examined for compliance. The greater the percentage of items complied with, the greater the quality for SDM in the CPG or CS assessed. The consensus meeting did not recommend the construction of a formal score or a cut point for defining quality.

#### 3.3 Study characteristics

The distribution by countries of CPGs and CSs that speak about SDM was irregular (Figure 1). Europe stood out with a total of 25 CPGs and CSs (38%). North America developed 29 (44%) CPGs and CSs (USA: 19 and Canada: 10). South America released six (9%) CPGs and CSs (Colombia, Venezuela, Mexico, Peru and two from Costa Rica). Asia also carried out three (5%) CPGs and CSs (Japan, India and Malaysia). Oceania has developed also three (5%) CPGs and CSs: two from Australia and one from New Zealand. The basic characteristics of the CPGs and CSs including organization, country and year of release are summarized in Table 1. The duration since last update of each CPGs or CSs varied. Some AGO, NCCN and one of the AHS CPGs, and ESMO and the Mexican CS were the most recently updated (highlighted in Table 2). Overall, the last update of the CPGs and CSs with SDM was more recent than that of those without SDM (mean 45 months (range: 3-115) vs 52 months (range: 3-116), P < .001). In this comparison, 9% (n = 15/167) did not specify the month of updated but only the year. SDM was reported more often in recent CPGs and CSs published after 2015 (42/101 (42.0%) vs 46/66 (69.7%), P = .0003) but less often in CPGs and CSs published in medical journal (44/101 (43.5%) vs 17/66 (25.7%), P = .009) (Table 3).

![Flow diagram for study selection of CPGs and CSs](image)
| Name of the CPG                                                                 | Abbreviated name          | Entity            | Country    | Year  |
|--------------------------------------------------------------------------------|----------------------------|-------------------|------------|-------|
| Guidelines on the diagnosis and treatment of breast cancer (2011 edition)      | Chinese BC CPG            | CMH               | China      | 2012  |
| Chinese guidelines for diagnosis and treatment of breast cancer 2018           | Chinese BC diagnosis      | NHCRPC            | China      | 2018  |
| The Japanese Breast Cancer Society Clinical Practice Guideline for radiation  | Japanese RT BC CPG        | JBCS              | Japan      | 2015  |
| The Japanese Breast Cancer Society Clinical Practice Guideline for systemic  | Japanese systemic BC CPG | JBCS              | Japan      | 2015  |
| 2013 clinical practice guidelines (The Japanese Breast Cancer Society):       | Japanese treatment BC CPG | JBCS              | Japan      | 2014  |
| Singapore Cancer Network (SCAN) Guidelines for Adjuvant Trastuzumab Use in    | SCAN early BC CPG         | SCAN              | Singapore  | 2015  |
| Singapore Cancer Network (SCAN) Guidelines for Bisphosphonate Use in the     | SCAN adjuvant BC CPG      | SCAN              | Singapore  | 2015  |
| Breast cancer in women: diagnosis, treatment and follow-up                    | KCE BC CPG                | KCE               | Belgium    | 2015  |
| Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis,         | ESMO BC 2019 CPG          | ESMO              | Europe     | 2019  |
| International guidelines for management of metastatic breast cancer (MBC)     | ESO MBC CPG               | ESO               | Europe     | 2013  |
| The European Society of Breast Cancer Specialists recommendations for the    | EUSOMA 2012 CPG           | EUSOMA            | Europe     | 2012  |
| AGO Recommendations for the Diagnosis and Treatment of Patients with Early   | AGO early BC CPG          | AGO               | Germany    | 2019  |
| Lesions of Uncertain Malignant Potential (B3) (ADH, LIN, FEA, Papilloma,     | AGO uncertain lesions CPG| AGO               | Germany    | 2019  |
| Ductal Carcinoma in Situ (DCIS)                                              | AGO DCIS CPG              | AGO               | Germany    | 2019  |
| Breast Cancer Surgery Oncological Aspects                                    | AGO oncological CPG       | AGO               | Germany    | 2019  |
| Oncoplastic and Reconstructive Surgery                                       | AGO oncoplastic CPG      | AGO               | Germany    | 2019  |
| Adjuvant Endocrine Therapy in Pre- and Postmenopausal Patients               | AGO adjuvant endocrine CPG| AGO               | Germany    | 2019  |
| Adjuvant Cytotoxic and Targeted Therapy                                       | AGO cytotoxic CPG         | AGO               | Germany    | 2019  |
| Neoadjuvant (Primary) Systemic Therapy                                        | AGO neoadjuvant CPG       | AGO               | Germany    | 2019  |
| Adjuvant Radiotherapy                                                        | AGO RT CPG                | AGO               | Germany    | 2019  |
| Therapy Side Effects                                                         | AGO side effects CPG      | AGO               | Germany    | 2019  |
| Supportive Care                                                              | AGO supportive care CPG   | AGO               | Germany    | 2019  |
| Breast Cancer: Specific Situations                                            | AGO-specific situations CPG| AGO              | Germany    | 2019  |
| Breast Cancer Follow-Up                                                      | AGO follow-up CPG         | AGO               | Germany    | 2019  |
| Loco-Regional Recurrence                                                     | AGO recurrence CPG        | AGO               | Germany    | 2019  |
| Endocrine and "Targeted" Therapy in Metastatic Breast Cancer                 | AGO endocrine MBC CPG     | AGO               | Germany    | 2019  |
| Chemotherapy With or Without Targeted Drugs* in Metastatic Breast Cancer     | AGO CT MBC CPG            | AGO               | Germany    | 2019  |
| Osteooneology and Bone Health                                                | AGO osteooneology CPG     | AGO               | Germany    | 2019  |
| Specific Sites of Metastases                                                 | AGO-specific MBC CPG      | AGO               | Germany    | 2019  |
| CNS Metastases in Breast Cancer                                              | AGO CNS MBC CPG           | AGO               | Germany    | 2019  |

(Continues)
TABLE 1 (Continued)

|   | Abbreviated name | Entity | Country | Year   |
|---|------------------|--------|---------|--------|
| 31 | Complementary Therapy Survivorship | AGO survivorship | AGO | Germany | 2019 |
| 32 | Diagnosis and Treatment of Patients with Primary and Metastatic Breast Cancer | AGO primary MBC | AGO | Germany | 2018 |
| 33 | AGO Recommendations for the Diagnosis and Treatment of Patients with Advanced and Metastatic Breast Cancer: Update 2018 | AGO advanced MBC | AGO | Germany | 2018 |
| 34 | DEGRO practical guidelines for radiotherapy of breast cancer VI: therapy of locoregional breast cancer recurrences | DEGRO BC recurrences | DEGRO | Germany | 2014 |
| 35 | DEGRO practical guidelines: radiotherapy of breast cancer I. Radiotherapy following breast conserving therapy for invasive breast cancer. | DEGRO RT conserving BC | DEGRO | Germany | 2013 |
| 36 | DEGRO practical guidelines for radiotherapy of breast cancer IV. Radiotherapy following mastectomy for invasive breast cancer | DEGRO RT mastectomy BC | DEGRO | Germany | 2014 |
| 37 | DEGRO practical guidelines: radiotherapy of breast cancer III—radiotherapy of the lymphatic pathways | DEGRO RT lymphatic | DEGRO | Germany | 2014 |
| 38 | Diagnosis, staging and treatment of patients with breast cancer. National Clinical Guideline No. 7 | NCCP | NCCP | Ireland | 2015 |
| 39 | Breast cancer | Richtlijndatabase BC | Richtlijnen | Netherlands | 2018 |
| 40 | Dutch breast reconstruction guideline | Dutch BCR | DPRS | Netherlands | 2017 |
| 41 | Breast Cancer | IKNL BC | IKNL | Netherlands | 2012 |
| 42 | Cáncer de mama/ Breast Cancer | Fisterra BC | Fisterra | Spain | 2017 |
| 43 | SEOM clinical guidelines in early-stage breast cancer | SEOM early stage | SEOM | Spain | 2018 |
| 44 | SEOM clinical guidelines in advanced and recurrent breast cancer | SEOM advanced BC | SEOM | Spain | 2018 |
| 45 | SEOM clinical guidelines in metastatic breast cancer | SEOM MBC | SEOM | Spain | 2015 |
| 46 | SEOM clinical guidelines in Hereditary Breast and ovarian cancer | SEOM hereditary BC | SEOM | Spain | 2015 |
| 47 | Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy | NICE abemaciclib | NICE | UK | 2019 |
| 48 | Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer | NICE ribociclib | NICE | UK | 2019 |
| 49 | Early and locally advanced breast cancer: diagnosis and management | NICE early and advanced BC | NICE | UK | 2018 |
| 50 | Breast cancer | NICE BC | NICE | UK | 2011 |
| 51 | Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer | NICE familial BC | NICE | UK | 2013 |
| 52 | Breast reconstruction using lipomodelling after breast cancer treatment | NICE lipomodelling | NICE | UK | 2012 |
| 53 | Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DDx,X, IHC4 and Mammostrat | NICE gene expression | NICE | UK | 2013 |
| 54 | Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer | NICE pertuzumab BC | NICE | UK | 2016 |
| 55 | Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer | NICE sentinel lymph | NICE | UK | 2013 |
| 56 | Breast reconstruction following prophylactic or therapeutic mastectomy for breast cancer | AHS reconstruction BC | AHS | Canada | 2017 |

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| Abbreviated name | Entity | Country | Year |
|------------------|--------|---------|------|
| 57 | Adjuvant systemic therapy for early stage (lymph node negative and lymph node positive) breast cancer | AHS early BC | AHS Canada | 2018 |
| 58 | Optimal use of taxanes in metastatic breast cancer (MBC) | AHS MBC | AHS Canada | 2013 |
| 59 | Adjuvant radiation therapy for invasive breast cancer | AHS RT invasive | AHS Canada | 2015 |
| 60 | Adjuvant radiation therapy for ductal carcinoma in situ | AHS RT DCi | AHS Canada | 2015 |
| 61 | Neo-adjuvant (pre-operative) therapy for breast cancer - general considerations | AHS neo-adjuvant | AHS Canada | 2014 |
| 62 | The Role of Trastuzumab in Adjuvant and Neoadjuvant Therapy in Women with HER2/neu-overexpressing Breast Cancer | CCO trastuzumab Her2 + BC | CCO Canada | 2011 |
| 63 | Surgical management of early-stage invasive breast cancer | CCO surgical management BC | CCO Canada | 2015 |
| 64 | Breast irradiation in women with early stage invasive breast cancer following breast conserving surgery | CCO RT | CCO Canada | 2016 |
| 65 | The role of the taxanes in the management of metastatic breast cancer | CCO taxane MBC | CCO Canada | 2011 |
| 66 | Vinorelbine in stage IV breast cancer | CCO vinorelbine | CCO Canada | 2012 |
| 67 | The role of aromatase inhibitors in the treatment of premenopausal women with metastatic breast cancer | CCO aromatase inhibitor MBC | CCO Canada | 2012 |
| 68 | Epirubicin, as a single agent or in combination, for metastatic breast cancer | CCO epirubicin MBC | CCO Canada | 2011 |
| 69 | Adjuvant taxane therapy for women with early-stage, invasive breast cancer | CCO taxane adjuvant therapy BC | CCO Canada | 2011 |
| 70 | Adjuvant systemic therapy for node-negative breast cancer | CCO sQT for node-negative BC | CCO Canada | 2011 |
| 71 | Adjuvant ovarian ablation in the treatment of premenopausal women with early stage invasive breast cancer | CCO ovarian ablation early stage | CCO Canada | 2010 |
| 72 | The role of gemcitabine in the management of metastatic breast cancer | CCO gemcitabine | CCO Canada | 2011 |
| 73 | The role of trastuzumab (herceptin) in the treatment of women with Her2/neu-overexpressing metastatic breast cancer | CCO trastuzumab MBC | CCO Canada | 2010 |
| 74 | Capecitabine in stage IV breast cancer | CCO capecitabine | CCO Canada | 2011 |
| 75 | The role of her2/neu in systemic and radiation therapy for women with breast cancer | CCO her2/neu and RT treatment | CCO Canada | 2012 |
| 76 | Locoregional therapy of locally advanced breast cancer (LABC) | CCO LABC | CCO Canada | 2014 |
| 77 | The role of taxanes in neoadjuvant chemotherapy for women with non-metastatic breast cancer | CCO taxane neoadjuvant therapy | CCO Canada | 2011 |
| 78 | Optimal systemic therapy for early female breast cancer | CCO early BC | CCO Canada | 2014 |
| 79 | Use of adjuvant bisphosphonates and other bone-modifying agents in breast cancer | CCO bone-modifying agent | CCO Canada | 2016 |
| 80 | The Role of Aromatase Inhibitors in Adjuvant Therapy for Postmenopausal Women with Hormone Receptor-positive Breast Cancer | CCO aromatase inhibitors HR+ | CCO Canada | 2012 |
| 81 | Margin width in breast conservation Surgery | ABS margin width BC | ABS UK | 2015 |
| 82 | Antibiotic prophylaxis in breast surgery | ABS AB prophylaxis | ABS UK | 2015 |
| 83 | Management of The malignant axilla In early breast cancer | ABS axilla BC | ABS UK | 2015 |
| 84 | Breast operation note Documentation | ABS BC | ABS UK | 2015 |
| 85 | Update on optimal duration of adjuvant antihormonal therapy | ABS antihormonal therapy | ABS UK | 2015 |

(Continues)
| Abbreviated name (Continued) | Entity | Country | Year |
|-----------------------------|--------|---------|------|
| Oncoplastic breast reconstruction | ABS/BAPRAS oncplastic | UK | 2012 |
| Acellular dermal matrix (ADM) assisted breast reconstruction procedures | ABS/BAPRAS ADM | UK | 2012 |
| Breast Cancer Clinical Quality Performance Indicators | SCT quality indicators | UK | 2016 |
| Treatment of primary breast cancer | SIGN | UK | 2013 |
| Lipomodelling Guidelines for Breast Surgery | JGSA lipomodelling | UK | 2012 |
| Performance and Practice Guidelines for the Use of Neoadjuvant Systemic Therapy in the Management of Breast Cancer | ASBS NaQT BC | USA | 2017 |
| Performance and Practice Guidelines for Mastectomy | ASBS mastectomy | USA | 2014 |
| Performance and Practice Guidelines for Breast-Conserving Surgery/Partial Mastectomy | ASBS breast conserving | USA | 2014 |
| Performance and Practice Guidelines for Axillary Lymph Node Dissection in Breast Cancer Patients | ASBS ALD | USA | 2014 |
| Performance and Practice Guidelines for Sentinel Lymph Node Biopsy in Breast Cancer Patients | ASBS SLND | USA | 2014 |
| Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps | ASPS DIEP and TRAM | USA | 2017 |
| Use of Endocrine Therapy for Breast Cancer Risk Reduction: ASCO Clinical Practice Guideline Update | ASCO endocrine therapy risk BC | USA | 2019 |
| Postmastectomy Radiotherapy: An American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Focused Guideline Update | ASCO postmastectomy RT | USA | 2017 |
| Breast Cancer Surveillance Guidelines | ASCO surveillance | USA | 2013 |
| Selection of Optimal Adjuvant Chemotherapy and Targeted Therapy for Early Breast Cancer: ASCO Clinical Practice Guideline Focused Update | ASCO treatment for early BC | USA | 2018 |
| Systemic Therapy for Patients With Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: ASCO Clinical Practice Guideline Update | ASCO systemic therapy EGR2 BC | USA | 2018 |
| Recommendations on Disease Management for Patients With Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer and Brain Metastases: ASCO Clinical Practice Guideline Update | ASCO EGRF2 MBC | USA | 2018 |
| Integrative Therapies During and After Breast Cancer Treatment: ASCO Endorsement of the SIO Clinical Practice Guideline | ASCO BC treatment | USA | 2018 |
| Chemotherapy and Targeted Therapy for Women With Human Epidermal Growth Factor Receptor 2–Negative (or unknown) Advanced Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline | ASCO EGFR2 advanced BC | USA | 2014 |
| Role of Bone-Modifying Agents in Metastatic Breast Cancer: An American Society of Clinical Oncology–Cancer Care Ontario Focused Guideline Update | ASCO bone-modifying agent MBC | USA | 2017 |
| Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update | ASCO EGFR2 recommendations | USA | 2013 |
| Abbreviated name | Entity | Country | Year |
|-----------------|--------|---------|------|
| 107 Breast Cancer Follow-Up and Management After Primary Treatment: American Society of Clinical Oncology Clinical Practice Guideline Update | ASCO follow-up/management BC | ASCO USA | 2013 |
| 108 Adjuvant Endocrine Therapy for Women With Hormone Receptor–Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update on Ovarian Suppression | ASCO ovarian suppression BC | ASCO USA | 2016 |
| 109 Role of Patient and Disease Factors in Adjuvant Systemic Therapy Decision Making for Early-Stage, Operable Breast Cancer: American Society of Clinical Oncology Endorsement of Cancer Care Ontario Guideline Recommendations | ASCO factors in early BC | ASCO USA | 2016 |
| 110 Use of Adjuvant Bisphosphonates and Other Bone-Modifying Agents in Breast Cancer: A Cancer Care Ontario and American Society of Clinical Oncology Clinical Practice Guideline | ASCO use bone-modifying agents BC | ASCO USA | 2017 |
| 111 Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Focused Update | ASCO biomarkers in early BC | ASCO USA | 2017 |
| 112 Use of Biomarkers to Guide Decisions on Systemic Therapy for Women With Metastatic Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline | ASCO biomarkers in MBC | ASCO USA | 2019 |
| 113 American Society of Clinical Oncology Endorsement of the Cancer Care Ontario Practice Guideline on Adjuvant Ovarian Ablation in the Treatment of Premenopausal Women With Early-Stage Invasive Breast Cancer | ASCO ovarian ablation BC | ASCO USA | 2011 |
| 114 American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Immunohistochemical Testing of Estrogen and Progesterone Receptors in Breast Cancer | ASCO hormonal BC | ASCO USA | 2010 |
| 115 Use of Pharmacologic Interventions for Breast Cancer Risk Reduction: American Society of Clinical Oncology Clinical Practice Guideline | ASCO risk reduction BC | ASCO USA | 2013 |
| 116 Endocrine Therapy for Hormone Receptor–Positive Metastatic Breast Cancer: American Society of Clinical Oncology Guideline | ASCO endocrine BC | ASCO USA | 2016 |
| 117 Invasive Breast Cancer. Basic resources. Version 1.2019 | NCCN invasive BC basic | NCCN USA | 2019 |
| 118 Invasive Breast Cancer. Core resources. Version 1.2019 | NCCN invasive BC core | NCCN USA | 2019 |
| 119 Invasive Breast Cancer. Enhanced resources. Version 1.2019 | NCCN invasive BC enhanced | NCCN USA | 2019 |
| 120 Breast Cancer. NCCN Evidence Blocks. Version 1.2019 | NCCN evidence block BC | NCCN USA | 2019 |
| 121 Breast Cancer. Version 3.2019 | NCCN BC | NCCN USA | 2019 |
| 122 Management of Breast Cancer (2nd Edition) | MHM BC | MHM Malaysia | 2010 |
| 123 Influencing best practice in breast cancer | Australia BC | AG Australia | 2016 |
| 124 Recommendations for staging and managing the axilla | CA axilla | CA Australia | 2011 |
| 125 Recommendations for use of hypofractionated radiotherapy for early operable breast cancer | CA RT | CA Australia | 2011 |
| 126 Recommendations for use of Bisphosphonates | CA bisphosphonates | CA Australia | 2011 |
| 127 Recommendations for the management of early breast cancer in women with an identified BRCA1 or BRCA2 gene mutation or at high risk of a gene mutation | CA management BC | CA Australia | 2014 |
| 128 Guía de Práctica Clínica AUGE Cáncer de Mama | GPC Chile | MSC Chile | 2015 |

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| Name of the CS                                                                 | Abbreviated name                                                                 | Entity       | Country   | Year       |
|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------|-----------|------------|
| 129 Guía de práctica clínica (GPC) para la detección temprana, tratamiento integral, seguimiento y rehabilitación del cáncer de mama¹⁶⁰ | GPC Colombia¹⁶⁰                                                                   | INC          | Colombia  | 2017       |
| 130 Guía de Práctica Clínica del Tratamiento para el Cáncer de Mama¹⁶¹         | GPC Costa Rica¹⁶¹                                                                  | IHCAI        | Costa Rica| 2011       |
| 131 Guía de Práctica Clínica para el Tratamiento del Cáncer de Mama¹⁶²         | GPC Perú¹⁶²                                                                       | DDSS         | Perú      | 2017       |
| 132 Guía para el Cánecer de Mama en Venezuela¹⁶³                                | GPC Venezuela¹⁶³                                                                  | SAV          | Venezuela | 2015       |
| 133 Management of Early Breast Cancer¹⁶⁴                                       | New Zealand BC¹⁶⁴                                                                  | MHNZ         | New Zealand| 2014       |
| 134 The Screening, Diagnosis, Treatment, and Follow-Up of Breast Cancer¹⁶⁵    | Würzburg BC¹⁶⁵                                                                    | UHW          | Germany   | 2018       |
| 135 Breast cancer brain metastases: a review of the literature and a current multidisciplinary management guideline¹⁶⁶ | FESEO brain MBC¹⁶⁶                                                                | FESEO        | Spain     | 2013       |
| 136 Cirugía de la Mama¹⁶⁷                                                      | AEC BC¹⁶⁷                                                                         | AEC          | Spain     | 2017       |
| 137 NCA Breast Cancer Clinical Guidelines¹⁶⁸                                     | NCA BC¹⁶⁸                                                                         | NCA          | UK        | 2019       |
| 138 Breast Cancer: Management and Follow-Up¹⁶⁹                                  | BCMA management and follow-up¹⁶⁹                                                   | BCMA         | Canada    | 2013       |
| 139 Clinical Guidelines for the Management of Breast Cancer¹⁷⁰                  | WMCA BC¹⁷⁰                                                                        | WMCA         | UK        | 2016       |
| 140 Consenso costarricense sobre prevención, diagnóstico y tratamiento del cáncer mamario¹⁷¹ | CS Costa Rica¹⁷¹                                                                  | CMCCCR       | Costa Rica| 2016       |
| 141 Consenso Mexicano sobre diagnóstico y tratamiento del cáncer mamario¹⁷²    | GPC México¹⁷²                                                                      | SSM          | México    | 2019       |
| 142 National consensus in China on diagnosis and treatment of patients with advanced breast cancer¹⁷³ | Chinese BC CS¹⁷³                                                                  | CECM         | China     | 2015       |
| 143 Practical consensus recommendations for hormone receptor-positive Her2-negative advanced or metastatic breast cancer¹⁷⁴ | Indian ICON CS¹⁷⁴                                                                | ICON         | India     | 2013       |
| 144 Indian Solutions for Indian Problems—Association of Breast Surgeons of India (ABSI) Practical Consensus Statement, Recommendations, and Guidelines for the Treatment of Breast Cancer in India¹⁷⁵ | Indian ABSI CS¹⁷⁵                                                                | ABSI         | India     | 2017       |
| 145 Consensus document for management of breast cancer¹⁷⁶                       | Indian ICMR CS¹⁷⁶                                                                  | ICMR         | India     | 2016       |
| 146 4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4)¹⁷⁷ | ABC4¹⁷⁷                                                                          | ESMO         | Europe    | 2018       |
| 147 St. Gallen/Vienna 2019: A Brief Summary of the Consensus Discussion about Escalation and De-Escalation of Primary Breast Cancer Treatment¹⁷⁸ | St. Gallen 2019¹⁷⁸                                                               | St. Gallen   | Europe    | 2019       |
| 148 ESTRO consensus guideline on target volume delineation for elective radiation therapy of early stage breast cancer¹⁷⁹ | ESTRO RT BC¹⁷⁹                                                                    | ESTRO        | Europe    | 2014       |
| 149 Second international consensus guidelines for breast cancer in young women (BCY2)¹⁸⁰ | BCY2¹⁸⁰                                                                          | ESO          | Europe    | 2016       |
| 150 Guidelines for diagnostics and treatment of aromatase inhibitor-induced bone loss in women with breast cancer A consensus of Lithuanian medical oncologists, radiation oncologists, endocrinologists, and family medicine physicians¹⁸¹ | LOEGP¹⁸¹                                                                         | LOEGP        | Lithuania | 2014       |
| 151 Biomarkers in breast cancer: A consensus statement by the Spanish Society of Medical Oncology and the Spanish Society of Pathology¹⁸² | SEOM and SEAP¹⁸²                                                                  | SEOM         | Spain     | 2017       |
| 152 Provincial consensus recommendations for adjuvant systemic therapy for breast cancer¹⁸³ | CCM 2017¹⁸³                                                                      | CCM          | Canada    | 2017       |
### TABLE 1  (Continued)

| Characteristics                                                                 | CPGs or CSs without SDM (n = 101) | CPGs or CSs with SDM (n = 66) | P value |
|---------------------------------------------------------------------------------|----------------------------------|-------------------------------|---------|
| Published after 2015                                                           | 42 (42.0 %)                      | 46 (69.7 %)                   | .0003   |
| CPG                                                                             | 83 (82.1 %)                      | 54 (81.8 %)                   | .95     |
| European guidelines                                                            | 45 (44.5 %)                      | 25 (37.0 %)                   | .21     |
| North American guidelines                                                       | 43 (42.5 %)                      | 28 (42.4 %)                   | .98     |
| South American guidelines                                                       | 2 (1.9 %)                        | 5 (7.5 %)                     | .1      |
| Asia guidelines                                                                 | 9 (8.9 %)                        | 3 (4.5 %)                     | .15     |
| Oceania guidelines                                                              | 3 (2.9 %)                        | 3 (4.5 %)                     | .3      |
| Published in a journal                                                          | 44 (43.5 %)                      | 17 (25.7 %)                   | .009    |

### TABLE 2  Characteristics of the CPGs and CSs regarding SDM
| Entity | First year of publication | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 Japanese RT BC CPG | 2015 | * | | | | | | | | | |
| 9 ESMO BC 2010 | 2010 | * | | | | | | | | | |
| 11 EUSOMA 2012 | 2012 | | | | | | | | | | |
| 12 AGO early BC | 2012 | | | | | | | | | | |
| 14 AGO DCIS | 2002 | * | | | | | | | | | |
| 16 AGO oncoplastic | 2012 | | | | | | | | | | |
| 17 AGO adjuvant endocrine | 2012 | | | | | | | | | | |
| 27 AGO CT MBC | 2012 | | | | | | | | | | |
| 41 IKNL BC | 2008 | | | | | | | | | | |
| 42 Fisterra BC | 2011 | | | | | | | | | | |
| 47 NICE abemaciclib | 2019 | | | | | | | | | | |
| 48 NICE ribociclib | 2019 | | | | | | | | | | |
| 49 NICE early and advanced BC | 2018 | | | | | | | | | | |
| 50 NICE BC | 2011 | | | | | | | | | | |
| 51 NICE familial BC | 2013 | | | | | | | | | | |
| 52 NICE lipomodelling | 2012 | | | | | | | | | | |
| 53 NICE gene expression | 2013 | | | | | | | | | | |
| 54 NICE pertuzumab BC | 2016 | | | | | | | | | | |
| 56 AHS reconstruction BC | 2013 | | | | | | | | | | |
| 57 AHS early BC | 2014 | | | | | | | | | | |
| 63 CCO surgical management BC | 1996 | | | | | | | | | | |
| 64 CCO sQT for node-negative BC | 1998 | | | | | | | | | | |
| 65 CCO ovarian ablation early stage | 2010 | | | | | | | | | | |
| 66 CCO trastuzumab MBC | 1999 | | | | | | | | | | |
| 67 CCO LABC | 2014 | | | | | | | | | | |
| 68 CCO bone-modifying agents BC | 2016 | | | | | | | | | | |
| 86 ABS/BAPRAS oncoplastic | 2012 | | | | | | | | | | |
| Entity | First year of publication | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
|--------|--------------------------|------|------|------|------|------|------|------|------|------|------|
| 88     | SCT quality indicators   | 2016 |      |      |      |      |      |      |      |      |      |
| 98     | ASCO postmastectomy RT   | 2001 |      |      |      |      |      |      |      |      |      |
| 100    | ASCO treatment for early BC | 2016 |      |      |      |      |      |      |      |      |      |
| 104    | ASCO EGFR2 advanced BC   | 2014 |      |      |      |      |      |      |      |      |      |
| 105    | ASCO bone-modifying agent MBC | 2000 |      |      |      |      |      |      |      |      |      |
| 108    | ASCO ovarian suppression BC | 2016 |      |      |      |      |      |      |      |      |      |
| 109    | ASCO factors in early BC | 2019 |      |      |      |      |      |      |      |      |      |
| 110    | ASCO use bone-modifying agent BC | 2017 |      |      |      |      |      |      |      |      |      |
| 116    | ASCO endocrine BC        | 2016 |      |      |      |      |      |      |      |      |      |
| 117    | NCCN invasive BC basic   | 2015 |      |      |      |      |      |      |      |      |      |
| 118    | NCCN invasive BC core    | 2015 |      |      |      |      |      |      |      |      |      |
| 119    | NCCN invasive BC enhanced | 2015 |      |      |      |      |      |      |      |      |      |
| 120    | NCCN evidence block BC   | 2015 |      |      |      |      |      |      |      |      |      |
| 121    | NCCN BC                  | 2015 |      |      |      |      |      |      |      |      |      |
| 122    | MHM BC                   | 2002 |      |      |      |      |      |      |      |      |      |
| 123    | Australia BC            | 2016 |      |      |      |      |      |      |      |      |      |
| 124    | CA axilla                | 2011 |      |      |      |      |      |      |      |      |      |
| 129    |GPC Colombia             | 2013 |      |      |      |      |      |      |      |      |      |
| 130    | IHCAI GPC Costa Rica    | 2011 |      |      |      |      |      |      |      |      |      |
| 131    | GPC Perú                 | 2017 |      |      |      |      |      |      |      |      |      |
| 132    | GPC Venezuela            | 2015 |      |      |      |      |      |      |      |      |      |
| 133    | New Zealand BC          | 2009 |      |      |      |      |      |      |      |      |      |
| 134    | Würzburg BC             | 2018 |      |      |      |      |      |      |      |      |      |
| 136    | AEC BC                   | 2007 |      |      |      |      |      |      |      |      |      |
| 137    | NCA BC                   | 2019 |      |      |      |      |      |      |      |      |      |
| 138    | BCMA management and follow-up | 2013 |      |      |      |      |      |      |      |      |      |
| 139    | WMCA BC                  | 2016 |      |      |      |      |      |      |      |      |      |
3.4 | SDM in CPGs and CSs concerning BC

The analysis of the compliance of the items valued is presented in Figure 2 and Appendix 4. SDM appeared in any section of 66 CPGs and CSs (12/28 (43%) CSs vs 54/139 (39%) CPGs, \( P = .69 \)). SDM appeared in glossary or indexes in only two documents, and only in one, its basis was explained. In general, CSs had higher overall quality than CPGs (CSs' mean 2.833 vs CPGs' mean 1.12 items, \( P < .001 \)) (Appendix).

Overall, 39 (23%) stated the value of SDM as an option in the decision-making process, 14 (8%) provided clear and precise SDM recommendations, 4 (3%) considered benefits versus harms of using SDM, and 4 (2%) identified evidence supporting the use of SDM. Only 9 (5%) of these CPGs and CSs gave advice for the SDM application in practice. The strength of recommendations on SDM was well-detailed in two documents (1%). The information gathered about SDM affected recommendations and was detailed in one (<1%). Limitations of the CPG or CS about SDM recommendations were described in just one of them (<1%).

Only 4 (2%) of these guides emphasized their interest in SDM appearing in the executive summary. Only in three (2%) of the CPGs and CSs, the table of content talked about SDM. Primary affected population with BC was well-defined in 22 (13%) articles, and patients’ subgroups with special consideration were discussed in 7 (4%) documents. Appropriateness and relevance of outcomes were considered in only 2 (1%) CPGs. Only one document detailed the consistency of results across studies. Recommendations about SDM for subgroups were separated in only two articles (1%). Facilitators and barriers to SDM application were described in only two articles too (1%).

Ten items (32%) measured in the data extraction instrument were not included in any CPGs and CSs (n = 10/31). The PICO question related to SDM was not specified, search strategy was not reported, the study design and limitations were not pondered, barriers were not described, the cost of SDM implementation was not specified, adherence to recommendations and the impact were not assessed, description of the cost information and suggestions for further research were not provided and finally, professional, financial or intellectual interest about SDM was not described (Figure 2 and Appendix ). Finally, there were 101 (61%) CPGs or CSs did not talk about SDM.

All three reviewers categorized that the ‘Alberta Health Services’\(^{188}\), ‘Australian Government’\(^{155}\), Ministry of Health from New Zealand\(^{165}\) and Costa Rica ‘IHCAI’\(^{162}\) CPGs and ‘CMCCR’\(^{172}\) CS had the highest overall quality in analysing the decision-making process in BC treatment (Appendix ). In the United States of America, we highlighted two of the ‘American Society of Clinical Oncology (ASCO)’\(^{140}-148\) guidelines and the last version of NCCN\(^{155}\), but with a lower mark if you compare with the ones we named before. In Europe, we found the ‘European Society for Medical Oncology (ESMO)’\(^{41}\), the ‘Asociación Española de Cirujanos (AEC)’\(^{80}\) and the ‘ABS-BAPRAS’\(^{118}\) CPGs with a score of 6 as the best paradigm of a guide that talks about SDM.
| Element                                                                 | With | Without |
|------------------------------------------------------------------------|------|---------|
| SOM appears in some section of the CPG                                  | 66   | 101     |
| SOM appears in the Executive Summary                                   | 4    | 163     |
| SOM appears in the table of contents                                   | 3    | 164     |
| SOM appears in glossary, abbreviations, acronyms or topic indexes      | 2    | 165     |
| SOM basis (concept, benefits, risks and Limitations) are explained     | 1    | 166     |
| Primary affected population is well defined                            | 27   | 145     |
| Patients subgroups that need special consideration are discuss         | 7    | 160     |
| The key (PICO) question related to SOM is specified                    | 167  |         |
| Details of the strategy used to search for evidence about SOM is reported | 167  |         |
| Study design(s) and methodology limitations are pondered               | 167  |         |
| Appropriateness/relevance of outcomes are considered                   | 2    | 165     |
| Consistency of results across studies are detailed                     | 1    | 166     |
| Magnitude of benefit versus magnitude of harm is considered            | 4    | 163     |
| Certainty of the supporting evidence on SOM is indicated               | 5    | 162     |
| Clear, precise and actionable recommendations on SOM is provided        | 13   | 153     |
| Distinctive recommendations about SOM for important subgroups are separated | 2    | 165     |
| Strength of recommendations on SOM is indicated                        | 3    | 164     |
| Facilitators to SOM application are described                           | 3    | 164     |
| Barriers to SOM application are described                               | 167  |         |
| Advice on how recommendations about SOM can be applied in practice is provided | 19   | 158     |
| Additional materials to support the implementation of SOM are provided  | 2    | 165     |
| Types of cost of SOM implementation that were considered are specified  | 167  |         |
| Information/description of the cost information is provided            | 167  |         |
| The information gathered affects recommendations about SOM and it is well detailed | 1    | 166     |
| Criteria to assess adherence to recommendations about SOM              | 167  |         |
| Criteria for assessing impact of implementing these recommendations    | 167  |         |
| Advice on the frequency and interval of measurement of these criteria  | 167  |         |
| Suggestions for further research are provided                          | 167  |         |
| Limitations of the guideline about SOM recommendations are described   | 1    | 166     |
| Declaration of the value of the SOM use is described                   | 10   | 128     |
| Declaration of interest (professionals, financial or intellectual) about SOM use is described | 167  |     |

**Figure 2** The analysis of the compliance of the data extraction items
4 | DISCUSSION

4.1 | Main findings

We developed a standardized quality assessment tool for assessing the coverage of SDM in recommendation documents. Our review and analysis showed that SDM description, clarification and recommendations CPGs and CSs concerning BC treatment were poor, leaving a large scope for improvement in this area. SDM more frequently reported in CPGs and CSs in recent years but surprising SDM was less often covered in medical journals (Figure 3).

4.2 | Strengths and weaknesses

The validity of findings depends on the strength and limitations of methods, which should be understood first before assessing their implications. A key strength of this study was a global perspective with a big number of CPGs and CSs included, without language restrictions or data sources limitations. We developed and deployed a prospective protocol with a specific SDM quality assessment tool incorporating the AGREE II instrument, RIGHT statement and other related papers. Unfortunately, as there were no other similar studies, we could not compare our results with other findings. There have been evaluations of risk of bias in other papers, but our focus was on examining the reporting of guidance about SDM. One perceived limitation of this study could be related to the subjective nature of the data extraction; however, as we used duplicate data extraction with arbitration, we minimized this methodological issue. Quality assessment tool performance may be a further issue, and we addressed this by following a standard methodology for tool development. Not all quality items can have the same relevance and weight, and future research should focus on scoring them creating a threshold for rating quality. Because the items mainly came from two wide-used indexes, demonstrably our tool should be considered to have face validity. Therefore, we are confident that our finding of poverty of SDM information in practice recommendations is trustworthy and merits further consideration.

Inter-examiner reliability should be calculated in systematic reviews as the data extracted should be the same by different reviewers. Intra-examiner reliability is a pre-condition for inter-observer reliability, and so was not calculated or reported. In our paper, the inter-examiner reliability score was found to be excellent (ICC = 0.97).

4.3 | Implications

To our knowledge, information and recommendations about SDM in BC CPGs and CSs have not been systematically analysed previously. Neither did we find a tool to evaluate SDM reporting quality. This is surprising because SDM is a legal obligation and a key component for high-quality patient-centred cancer care. Breast cancer is the paradigm of the situation where a two-way exchange not only of information but also of treatment preferences is needed to find the best option for a particular patient, as different strategies may show a priori similar advantages and disadvantages but possible outcomes are deeply related to the patient’s values and personal situation.

Formal recommendations should promote SDM application in clinical routine practice, but this has proved difficult and slow. It would require changing attitudes, acquiring new skills, developing specific tools and ensuring an environment where communication and sharing perspectives are valued. Effective implementation strategies could be underpinned by SDM detailed in CPGs and CSs as these documents should be expected to provide this specific content. Our work has identified a gap that offers an important contribution in directing further research and debate, including assessment of risk of bias in guidelines. It highlights the need for more objective-specific tools for SDM assessment, evaluation of their psychometric properties and promotion in CPGs and CSs.
CSs for diverse malignancies. Future studies should be required in that direction.

5 | CONCLUSIONS

This systematic review found that BC treatment CPGs and CSs insufficiently addressed SDM. Implementation of this practice is important for high-quality patient-centred cancer care, but lack of knowledge is a known barrier. SDM descriptions and recommendations in CPGs and CSs concerning BC treatment need improvement. SDM was more frequently reported in CPGs and CSs in recent years, but surprisingly it was less often covered in medical journals, a feature that needs attention. In the future, SDM should be suitably explained and encouraged and specific tools should be applied to assess its dealing and promotion in specific cancer treatment CPGs and CSs. Medical journals should play a strong role in promoting SDM in CPGs and CSs they publish in the future.

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CONFLICTS OF INTEREST

The study was conducted in Granada, Spain. There are no conflicts of interest.

AUTHOR CONTRIBUTIONS

Each author certifies that he/she has made a direct and substantial contribution to the conception and design of the study, development of the search strategy, the establishment of the inclusion and exclusion criteria, data extraction, analysis and interpretation. MMC was involved in the design of the study, literature search, data collection and analysis, quality appraisal and writing. IMMN was involved in the literature search and data collection. MMD was involved in the design of this study, analysis of data and writing. LM was involved in writing. KSK was involved in the design of this study and provided critical revision of the paper. ABC was involved in the literature search and data collection. MMD was involved in the design of this study, analysis of data and writing, quality appraisal and writing. IMMN was involved in the design of the study, literature search, data collection and analysis, quality appraisal and writing. MMC was involved in the literature search and data collection. MMD was involved in the design of this study, analysis of data and writing. LM was involved in writing. KSK was involved in the design of this study and provided critical revision of the paper. All authors read and provided the final approval of the version to be published.

DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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**SUPPORTING INFORMATION**

Additional supporting information may be found online in the Supporting Information section.

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