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Breast Cancer EDGE Task Force Outcomes: Clinical Measures of Pain

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Abstract

Background—Pain is one of the most commonly reported impairments after breast cancer treatment affecting anywhere from 16-73% of breast cancer survivors. Despite the high reported incidence of pain from cancer and its treatments, the ability to evaluate cancer pain continues to be difficult due to the complexity of the disease and the subjective experience of pain. The Oncology Section Breast Cancer EDGE Task Force was created to evaluate the evidence behind clinical outcome measures of pain in women diagnosed with breast cancer.

Methods—The authors systematically reviewed the literature for pain outcome measures published in the research involving women diagnosed with breast cancer. The goal was to examine the reported psychometric properties that are reported in the literature in order to determine clinical utility.

Results—Visual Analog Scale, Numeric Rating Scale, Pressure Pain Threshold, McGill Pain Questionnaire, McGill Pain Questionnaire – Short Form, Brief Pain Inventory and Brief Pain Inventory – Short Form were highly recommended by the Task Force. The Task Force was unable to recommend two measures for use in the breast cancer population at the present time.

Conclusions—A variety of outcome measures were used to measure pain in women diagnosed with breast cancer. When assessing pain in women with breast cancer, researchers and clinicians need to determine whether a unidimensional or multidimensional tool is most appropriate as well as whether the tool has strong psychometric properties.

Keywords

Pain; Outcome Measure; Breast Cancer

INTRODUCTION

Breast cancer is the most common cancer affecting women in the United States, with an estimated 232,340 new cases in the United States for 2013.¹ Currently there are approximately 2.9 million American women who are surviving breast cancer, commonly referred to as breast cancer survivors (BCS).² Although improvements have been significant in breast cancer treatment producing more long-term survivors, breast cancer and its treatments continue to be associated with many undesirable symptoms and side effects.³

Pain is one of the most commonly reported impairments after breast cancer treatment affecting anywhere from 16-73% of BCS⁴⁻¹⁰, and has a strong relationship to decreased quality of life and greater self-perceived disability.⁷ A cumulative prevalence of chronic pain has been reported in 43% of women 3 years after receiving a mastectomy for breast cancer.¹¹ The presence of pain soon after breast cancer surgery is a predictive factor for chronic pain.¹² Despite the high reported incidence of pain from cancer and its treatments, the ability to evaluate cancer pain continues to be difficult due to the complexity of the disease and the subjective experience of pain.^{13,14} The etiology of cancer pain may be from many causes such as the cancer itself, treatments (radiation, surgery or chemotherapy), musculoskeletal impairments secondary to treatment, or from unknown causes.¹⁵ Cancer pain can be acute, such as postoperative pain, or chronic lasting three months or more after breast surgery for cancer.¹⁶ The variability in the causes of cancer pain as well as the timing contributes to difficulty in its assessment as well as its control.¹⁷

The American Physical Therapy Association's (APTA) Evaluation Database to Guide Effectiveness (EDGE) Task Force was formed within the Section on Research in 2006. The Task Force's goal was to provide physical therapy professionals with a comprehensive list of outcome measures that can be administered to a specific patient population. The psychometric properties and clinical utility within a particular patient population were detailed with the ultimate goal of creating a central location for physical therapy professionals to have access to this valuable information for implementing evidence-based practice.¹⁸ The Task Force was expanded to include members from several other Sections of the APTA. After the success of the Neurology Section's StrokEDGE Task Force, where 57 outcome measures were assessed in patients with stroke, the Oncology Section created a Task Force with a focus on Breast Cancer Outcomes. The first assessment of breast cancer outcome tools from the Oncology section Task Force targeted scapula, shoulder and glenohumeral impairments and shoulder function and resulted in successful dissemination of the results at the APTA's Combined Sections Meeting in Chicago 2012, as well as four publications in the 2013 *Rehabilitation Oncology* Journal Volume 31, Number 1.¹⁸⁻²¹ Over the past 2 years, the purpose of the Breast Cancer EDGE Task Force has been to continue to assess breast cancer outcome measures with a focus on pain, lymphedema and fatigue. The purpose of this review is to identify evidence-based pain assessment tools in breast cancer survivors using the methodology of the EDGE Taskforce.

METHODS

A primary systematic search using PubMed was performed from April 6, 2012 up to June 1, 2013 and resulted in the retrieval of 872 publications. The search strategy began with the filters (“Breast Neoplasms”[MeSH Terms] AND ((((((“Radiotherapy”[MeSH Terms] OR “Mastectomy”[MeSH Terms]) OR (“Carcinoma/surgery”[MeSH Terms] OR “Carcinoma/therapy”[MeSH Terms])) OR “Lymph Node Excision”[MeSH Terms]) OR “Combined Modality Therapy”[MeSH Terms]) OR “Sentinel Lymph Node Biopsy”[MeSH Terms] OR (“Breast Neoplasms/drug therapy”[MeSH Terms] OR “Breast Neoplasms/radiotherapy”[MeSH Terms] OR “Breast Neoplasms/surgery”[MeSH Terms] OR “Breast Neoplasms/therapy”[MeSH Terms])) OR “Mammoplasty”[MeSH Terms])) AND (((“Pain”[MeSH Terms] OR “Pain Measurement”[MeSH Terms]) OR “Disability Evaluation”[MeSH Terms]) OR “Somatosensory Disorders”[MeSH Terms] OR pain[title]) AND English[lang]. There was no restriction on year of publication. A second systematic search strategy using CINAHL was performed from April 25, 2012 up to June 1, 2013 and yielded 205 publications using the following search terms: MH “Breast Neoplasms/RT /RH/SU”) (MH “Breast Reconstruction”) (MH “Sentinel Lymph Node Biopsy”) (MH “Lymph Node Excision+”) (MH “Mastectomy+”) (MH “Radiotherapy+”) (MH “Breast Neoplasms+”) (MH “Somatosensory Disorders+”) MH “Disability Evaluation”) (MH “Pain Measurement”) (MH “Pain+”)

A third systematic search strategy using PsycINFO® from April, 2012 up to June 1, 2013 and yielded 28 publications using the following search terms (DE “Breast Neoplasms”) AND (DE “Radiation Therapy” OR DE “Mastectomy” OR DE “Plastic Surgery” OR DE “Surgery”) AND (DE “Pain” OR DE “Aphagia” OR DE “Chronic Pain” OR DE “Neuralgia” OR DE “Neuropathic Pain” OR DE “Somatoform Pain Disorder” OR DE “Pain Measurement” OR DE “Pain Perception” OR DE “Disability Evaluation” OR DE “Somatosensory Disorders”). These 3 searches were combined and duplicate publications removed, leaving a total of 1002 articles that included a pain measure in a breast cancer population for our review. The databases were monitored for updates throughout the months of data collection. Through this process an additional 86 articles were retrieved through PubMed and 32 articles through PsychInfo, without duplicates, for a final total of 1120 articles for review by the researchers. (Figure 1)

Titles and abstracts of the articles found in the search were divided among the researchers and reviewed for use of a measure of pain in the breast cancer population. Studies of assessment methodology, pain prevalence and epidemiology, and interventions for pain were all included. Articles were excluded that only measured acute surgical procedure pain and also references where pain was not a primary end point. In addition, the three authors examined reference lists from all selected publications to verify that no pertinent publications were missed during the above-described electronic searches. When warranted, full articles were obtained for review. The authors reviewed the included papers for the use of specific measures of pain, and then constructed a comprehensive list of measures that have been used in studying pain in the breast cancer population.

Once the list of pain assessment tools was compiled, the researchers held multiple conference calls to determine which tools were appropriate for full review as described below. Duplicate measures were excluded. Assessments that primarily measured other constructs such as function or quality of life, and those that consisted of a dichotomous question about the presence of pain (yes or no) were excluded. Included measures of pain were subdivided into the following categories: 1) pain intensity/severity, 2) pain quality, 3) pain-related disability, and 4) measures that combined multiple aspects of the pain experience such as both measuring pain intensity and quality. Based on the above criteria, the researchers came to consensus on a list of 10 pain outcome measures for review. (Figure 1) These measures were divided between the 3 researchers for an independent primary review of the psychometric properties and clinical utility. Reviewers conducted additional literature searches for papers on the psychometric properties of the assessment tools as well as researched cost and availability of the measures. The primary reviews were completed using the Cancer EDGE Task Force Outcome Measure Rating Form (Appendix A) for each of the selected pain outcome measures. In short, one of the authors rated each measure on the qualities of reliability, validity, availability of normal values, minimal clinical important difference (MCID) or minimal detectable change (MDC), and clinical utility. Once completed, a secondary review was conducted by a second author to ensure accuracy. Each pain outcome measure was then rated using a 0-4 scale by consensus of the three authors as a method to determine if a measure could be recommended for widespread clinical use. (Table 1)

RESULTS

After a comprehensive review of the breast cancer literature, 23 different measures of pain were identified for potential inclusion in this review. After applying the inclusion and exclusion criteria, 10 measures were selected for full review using the Cancer EDGE Task Force Outcome Measure Rating. Of the ten measures reviewed (Table 2), a total of eight measures were given the highest rating of 4 (highly recommend) and are thus recommended for clinical use by the researchers of this Task Force. Of the measures of pain intensity/sensitivity, three of the recommended measures, the Visual Analog scale (VAS), Numeric Rating Scale (NRS) and Pressure Pain Threshold are highly recommended for use. In this same category, we are unable to recommend the Gaston – Johansson Painometer for clinical use at this time due to its limited availability and lack of full psychometric testing. Of the measures of pain quality, two of the recommended measures, the McGill Pain Questionnaire (MPQ) and McGill Pain Questionnaire – Short Form (MPQ – SF), are highly recommended for clinical use. Due to limited data on psychometric properties, we are unable to recommend the Neuropathic Pain Scale – CIN at this time. For measurement of pain-related disability, one of the recommended measures, the Pain Disability Index (PDI), is highly recommended. For combined measures of pain intensity and interference, 2 measures, the Brief Pain Inventory (BPI) and the Brief Pain Inventory – Short Form (BPI – SF) are highly recommended.

DISCUSSION

A number of different clinical measures of pain are available for use in the cancer population. This group has identified that the VAS, NRS, Pressure Pain Threshold, MPQ, MPQ – SF, PDI, BPI and BPI – SF are highly recommended for use in the breast cancer population. All of these measures have been used extensively in the breast cancer population and demonstrate excellent measurement properties within the populations for which they were developed. When determining what type of pain outcome scale to administer, researchers and clinicians need to define how they want to assess pain and whether to use a unidimensional or multidimensional tool. In the following sections we will review the properties of the recommended measures in order to allow readers to determine which of the measures may fit their specific needs.

Unidimensional Pain Intensity Measures

Unidimensional tools measure the intensity of pain, without examining the quality or impact of this pain. They are often administered when a single, clearly defined question is to be answered.²² There is both clinical and experimental evidence that shows pain has at least two dimensions, affective and sensory.^{23,24} Some believe that a unidimensional pain scale might not be adequate since there is no way to know which dimension of pain the individual is rating when using these types of scales.²⁵ Nevertheless, these tools are often administered as they are easy to understand and place minimal burden on the patient and clinician.²² The unidimensional pain outcome measures we recommend as a result of this review include the VAS, NRS and Pressure Pain Threshold.

The VAS is a 10 cm-long horizontal line with the words “no pain” anchoring at one end and “pain as bad as it can be” at the other. The VAS has been validated in the acute,²⁶ chronic,²⁷ and cancer populations²⁸ and has been used in over 90 breast cancer studies. This measure has shown acceptable test-retest reliability of 0.80,²⁹ concurrent validity with other pain scales in a cancer population of 0.70,^{29,30} and has an established MCID of 9-11 mm in the breast cancer population.³¹

The NRS has several iterations, but the most commonly used one is the 11-item version where individuals are asked what number would they rate their pain from 0 – 10 where 0 is no pain and 10 is the most severe pain.³² This measure has been validated in a variety of pain populations including chronic^{33,34} low back³⁵, musculoskeletal³⁶, cancer^{29,37} and specifically breast cancer.³⁸ It has been used in approximately 20 studies involving breast cancer survivors. The NRS has established reliability of 0.87^{33,35-37} and convergent validity of 0.85^{29,39} across many populations with pain including breast cancer-related pain.⁴⁰ A reported 2-point change represents a clinically meaningful difference^{34,35} and it has been reported that when an individual with breast cancer rates their pain 5, health related quality of life is impacted.⁴¹

The third unidimensional tool the Task Force recommends is Pressure Pain Threshold. Pressure pain threshold is commonly used to assess the hyperexcitability of the central nervous system.⁴² Pressure pain threshold is defined as “the minimal amount of pressure where a sensation of pressure first changes to pain”.⁴³ Pressure pain threshold is assessed

using a device called an algometer in which a circular probe is attached to a pressure gauge. Pressure is applied at a constant rate to the tissue being tested and is stopped when individuals identify when the sensation first changes from pressure to pain.³¹ This measure has been validated in a variety of pain populations including temporomandibular disorders,^{44,45} patellar tendinopathy,⁴⁶ low back pain,⁴⁷ knee osteoarthritis,⁴⁸ myofascial pain⁴⁹ and has been used in at least five breast cancer studies.^{31,50-53} Pressure pain threshold has established reliability (0.60 – 0.94 with electric algometers being more reliable than force-gauge models)^{31,46,53-57} and good construct and concurrent validity.^{58,59} Prushansky et al 2004⁶⁰ reported a 20% change in pressure is needed to indicate significant change, and results can be compared to published normal values.^{31,52,53,55} According to the oncology section EDGE criteria, a measure can be given a ‘highly recommend’ if it has good psychometric properties and has been used in research with BCS.¹⁹ The acceptable psychometric properties found in multiple populations, and the reference values give the pressure pain threshold a “highly recommended” rating, though the authors acknowledge that the lack of a MDC or MCID in BCS could make it more challenging for clinicians to make decisions based on the results of the measure.

The Gaston-Johansson Painometer was originally developed for the assessment of acute and chronic pain in rheumatoid arthritis, women in labor, and post-operative pain.⁶¹ It includes a visual analog scale for measurement of pain intensity and a list of pain descriptors, although it must be noted that in some investigations the provided descriptive terms were found to be inadequate.⁶² Given the questioning of descriptors used and a lack of sensitivity data and reference values, this measure is not recommended for use at this time.

Multidimensional Pain Measures

While the unidimensional tools primarily measure the intensity of pain, multidimensional tools take into consideration other factors that influence pain perception.²² These factors include the affective contributions, quality and the temporal sequence of pain, and an individual's belief system.²² While multidimensional tools take a more comprehensive approach, the interpretation and use of these tools can be difficult because of their complexity.²² Additionally, multidimensional tools generally take a longer time to complete and can be difficult to understand by the individual. The multidimensional pain outcome measures we recommend as a result of this review include the MPQ, MPQ – SF, PDI, BPI and BPI – SF. Some of the multidimensional pain measures intend to assess the differing qualities of pain, such as the MPQ and the NPS-CIN, while others, such as the PDI, intend to assess the impact of pain on the individual.

Pain Quality Measures

The MPQ is a unique measure because it assesses pain using a multidimensional approach based on the gate control theoretical framework.¹⁵ The MPQ contains three major classes of word descriptors: sensory, affective and evaluative.⁶³ There are three parts to the MPQ including the pain rating index, the number of words chosen and the present pain intensity.⁶³ This measure was developed in an adult population with a wide variety of conditions including cancer.⁶³ The MPQ has been validated in several diagnoses including breast cancer.¹⁵ The MPQ has been used in approximately 10 research studies involving the breast

cancer population. The MPQ has demonstrated a good test-retest reliability of 0.70,⁶³ construct validity,^{14,63-65} concurrent validity ($r=0.31-0.40$)^{64,66-69} and predictive validity.⁷⁰⁻⁷⁴ Reported MDC or MCID for this measure were unavailable, which could make it challenging to make clinical decisions based on the results.

The MPQ – SF was developed from the MPQ to make the multidimensional approach to pain assessment easier and more efficient to administer.^{63,75} The MPQ-SF is comprised of 3 parts: 1) 15 word descriptors that describe two dimensions of pain: sensory and affective, 2) Present Pain Intensity scale and 3) VAS.⁷⁵ The MPQ-SF has been validated and used in pain assessment in a variety of pain conditions including metastatic cancer pain.⁷⁵ The MPQ-SF has been used in over 10 studies examining women with breast cancer. Reliability for the MPQ-SF in individuals with cancer has been shown to be 0.94 (Cronbach's alpha).⁷⁶ Concurrent validity with the long form MPQ was found to be $r = .77$ to $.88$ in patients with cancer pain.⁷⁵ MDC or MCID for this measure was unavailable, which could make it challenging to make clinical decisions based on these results.

The NPS-CIN was developed by combining items from the original Neuropathic Pain Scale and the Pain Quality Assessment Scale in order to measure neuropathic pain from cancer treatment.^{77,78} At the current time, the psychometric properties are incomplete. Initial validity studies have been completed but information on reliability and sensitivity to change is lacking.^{77,78} Because this measure assesses neuropathic pain specific to cancer treatment and has good clinical utility, it may be a useful measure for the BCS population if all of the psychometric properties are found to be favorable.

Pain Disability Measures

The PDI is a multidimensional tool designed to measure the degree in which chronic pain affects an individual's ability to perform a variety of activities.⁷⁹ The PDI contains seven categories: 1) family/home responsibility, 2) recreation, 3) social activity, 4) occupation, 5) sexual behavior, 6) self-care, and 7) life support activity.⁸⁰ Individuals are asked to rate their level of disability on a rating scale (0 = no disability to 10 = total disability).⁸⁰ An overall score is calculated by summing the ratings of the seven categories (0 – 70).⁸⁰ The PDI was developed in individuals with chronic pain from multiple causes as well as low back pain^{80,81} and has been validated in individuals post-surgery,⁸⁰ as well as outpatients and inpatients.⁸¹ The PDI has been used in 3 cross-sectional studies in women diagnosed with breast cancer.^{10,82,83} Reliability of the PDI when administered to the general chronic pain population was 0.87 (Cronbach's alpha).⁸¹ The PDI has been shown to have acceptable concurrent and construct validity in individuals with chronic pain.⁸¹ The PDI has a reported MCID of 6 points for individuals with low back pain.⁸⁴ While the PDI was developed for patients with chronic pain from multiple causes, including cancer-related pain, published psychometrics for the PDI when administered to only a cancer population could not be found. Since the measure has good psychometric properties in mixed chronic pain populations, it is therefore still a recommended measure.

Combined Pain Intensity and Interference Measure

The BPI is a multimodal scale comprised of questions on pain intensity and pain-related interference with function.⁸⁵⁻⁸⁷ There is a total of 32 items on the BPI. Individuals rate their worst, least, average and current pain intensity (including the last 24 hours) as well as the degree to which pain interferes with 7 domains of function: 1) general activity, 2) mood, 3) walking ability, 4) normal work, 5) relations with other persons, 6) sleep, and 7) enjoyment of life using a scale from 0 (no pain) to 10 (pain as bad as you can imagine).⁸⁸ The BPI was developed specifically for use in individuals with cancer⁸⁵ and has been validated in individuals with bone metastases, breast cancer and postoperative cancer patients.⁸⁹ The BPI has been used in over 25 studies involving women with breast cancer. Test-retest reliability in a mixed cancer population ranged from 0.59-0.93.⁹⁰ Reliability of the BPI when administered to a mixed cancer population with metastatic pain ranged from 0.81 – 0.89 (Cronbach's alpha).⁹¹ Construct validity found three factors, pain intensity, activity interference and affective interference that were invariant across age, disease and ethnicity.^{91,92} Although there is no reported MCID or MDC in the literature, increased pain management strategies are recommended when the average of the severity and interaction scores reaches five.⁹³

The BPI-SF is a tool developed specifically for use in individuals with cancer that was modified from the BPI. Due to the amount of time it takes for an individual to complete the BPI (10-15 minutes) as well as the time needed to score the tool,⁸⁵ the BPI – SF was developed. The BPI-SF asks individuals to use a 1-week recall of their pain experience as opposed to a 24-hour recall and has 9 total items as compared to 32 on the BPI.^{94,95} The BPI-SF evaluates the severity of pain as well as the impact pain has on daily function.⁸⁵ The BPI-SF has been used in approximately six studies involving women with breast cancer. Cronbach's alpha was found to be 0.89 in 36 women diagnosed with stage I-IIIa breast cancer.⁹⁶ Construct validity has been reported high for the pain interference (0.71-0.94) and pain severity (0.70-0.91) constructs of the BPI-SF.⁹⁷ The Minimal Important Difference has been reported as 1.2 points for pain severity, 1.6 points for activity-related pain interference, and 1.5 points for mood-related pain interference.⁹⁴

Limitations and Conclusions

There are several factors that should be considered when interpreting the Task Force recommendations. An outcome measure may have been excluded in this review due to a lack of published data; the authors are aware that new studies may have been published after June 1, 2013. For measures that could not be recommended at this time, additional information may become available that might elevate the task force recommendation in the future. The literature search was limited to English-language journals therefore journals in other languages were not reviewed and could limit the number of measures reviewed. Researchers and clinicians are encouraged to review the Task Force recommendations as well as each specific outcome measure for more extensive information. While this article can serve as a guide, ultimately, it is up to the clinician and researcher to identify the best available evidence in addition to patient values and expectations in order to appropriately administer the correct pain outcome measure in the breast cancer population.⁹⁸

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Appendix

Appendix 1. Cancer EDGE Taskforce Outcome Measure Rating Form

Instrument Name:	
Reviewer:	
ICF Domain (check all that apply): <input type="checkbox"/> body function/structure <input type="checkbox"/> activity <input type="checkbox"/> participation	
Type of measure: <input type="checkbox"/> performance-based <input type="checkbox"/> self-report	
Languages available:	
Population developed in:	
Validated populations:	
Instrument properties	
Reliability (test-retest, intra-rater, inter-rater)	
Validity (concurrent, criterion-related, predictive)	
Ceiling/ floor effects	
Sensitivity to change (responsiveness, MCID, MDC)	
Reference Values for Interpretation	
Instrument use	
Equipment required	
Time to complete	
How is the instrument scored?	

(e.g. total score, subscales, etc.)	
Level of client participation required (proxy participation?)	
Effect of Training (if applicable)	
Is this tool appropriate for individual patient decision-making? Yes ___ No ___	
(available MDC, MCID, Likelihood ratios?)	
Comments:	
Availability:	
• Score Sheets:	
___ Public Domain ___ Available but copyrighted ___ Unavailable	
• Instructions:	
___ Public Domain ___ Available but copyrighted ___ Unavailable	
• Computer-based or Web-based scoring available: ___ yes ___ no	
Purchase price:	
Purchase Contact Info:	
Assessment of Overall Usefulness (Primary Reviewer):	
Secondary Reviewer Comments:	

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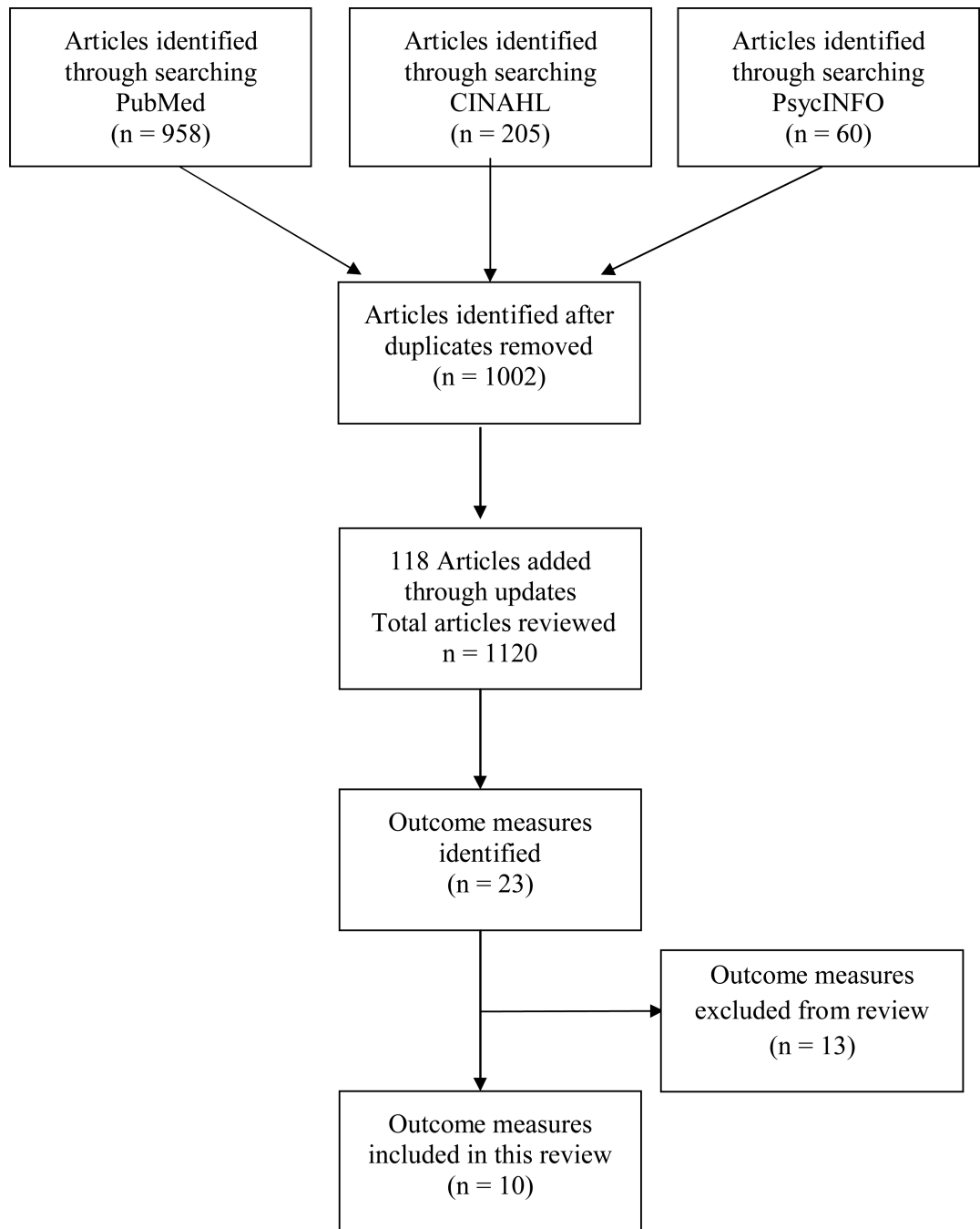


Figure 1.
PRISMA flow diagram

Table 1

Breast Cancer EDGE Rating Scale

4	Highly Recommend	Highly recommended; the outcome has excellent psychometric properties and clinical utility; the measure has been used in research on individuals with or post breast cancer.
3	Recommend	Recommended; the outcome measure has good psychometric properties and good clinical utility; no published evidence that the measure has been applied to research on individuals with or post breast cancer.
2A	Unable to Recommend at this time	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; the measure has been used in research on individuals with or post breast cancer.
2B	Unable to Recommend at this time	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; no published evidence that the measure has been applied to research on individuals with or post breast cancer.
1	Do not Recommend	Poor psychometrics &/or poor clinical utility (time, equipment, cost, etc.)

Table 2

Outcome Measures Sorted by Task Force Rating

Measure	Rating
Pain Intensity/Sensitivity	
Visual Analog Scale	4 – Highly Recommend
Numeric Pain Rating Scale	4 – Highly Recommend
Pressure Pain Threshold	4 – Highly Recommend
Gaston – Johansson Painometer	2A – Unable to Recommend at this time
Pain Quality	
McGill Pain Questionnaire	4 – Highly Recommend
McGill Pain Questionnaire – Short Form	4 – Highly Recommend
Neuropathic Pain Scale – CIN	2A – Unable to Recommend at this time
Pain-related Disability	
Pain Disability Index	4 – Highly Recommend
Combined Pain Measures	
Brief Pain Inventory	4 – Highly Recommend
Brief Pain Inventory – Short Form	4 – Highly Recommend