

REVIEW

Contralateral prophylactic mastectomy for unilateral breast cancer in women at average risk: Systematic review of patient reported outcomes

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Abstract

Objective: The rate of contralateral prophylactic mastectomy (CPM) in women with early, unilateral cancer is relatively high and is increasing around the world a previous study. Women choose this option for many reasons other than reducing their risk of future cancer, including symmetry, reasons related to breast reconstruction and attempting to manage fear of recurrence. This systematic review evaluated patient-reported quality of life outcomes following CPM.

Methods: A literature search of MEDLINE, PubMed and PsycINFO was performed to February 2019. Abstracts and full-text articles were assessed for eligibility according to pre-determined criteria. Data were extracted into evidence tables for analysis.

Results: A total of 19 articles met eligibility criteria and were included in analysis. These included patient-reported data from 6088 women undergoing CPM. They reported high levels of satisfaction with the decision for surgery, low levels of decisional regret and high satisfaction with cosmesis and reconstruction. Breast-specific and general quality of life was high overall but was even better in women choosing breast reconstruction after surgery. Fear of cancer recurrence was high after CPM. Depression, distress and a negative impact on body image were evident; however, levels were high in both CPM and non-CPM groups.

Conclusions: This study provides information that can be used by surgeons and psychologists when counselling women about the potential benefits and harms of CPM. This process must include discussion about the trade-offs such as body image issues and ongoing fear of recurrence in addition to the positive aspect of cancer risk reduction. Women are unlikely to regret their decision for CPM.

KEYWORDS

breast neoplasms, cancer, patient outcome assessment, prophylactic mastectomy

1 | BACKGROUND

For women at average risk of breast cancer with early stage, unilateral cancer, the risk of a future contralateral breast cancer is low, around 0.13% per year. No survival benefit has been found from contralateral prophylactic mastectomy (CPM) in women who do not have a

high-hereditary risk of breast cancer.^{3,4} Despite this low risk and a lack of survival benefit, the rate of CPM in women with unilateral cancer is relatively high and is increasing around the world.^{1,2} In women with a first diagnosis of unilateral invasive breast cancer undergoing mastectomy, the rate of CPM has increased significantly from 4% to 6% to 13% to 24% between 2002 and 2012.^{1,5}

Women often overestimate their risk of contralateral cancer, and this is one factor that may contribute to the high rate of CPM.^{6,7} However, when reasons for CPM have been studied, women have reported that risk is not always the most important factor in their decision-making. Rather, fear of cancer recurrence, the desire for symmetry and reasons related to breast reconstruction are important factors.⁸ A previous systematic review evaluating decision-making found that women who choose CPM are generally satisfied with the decision, although there is a paucity of research examining other patient-reported outcomes (PROs).⁸

Current clinical guidelines recommend against the use of CPM except in women at high genetic risk of breast cancer.⁹ Clinicians have expressed alarm about the increasing trend towards CPM,^{2,10} and this has driven research into decision making and outcomes.⁸ The current study aims to perform a systematic review to evaluate PROs following CPM on general and breast-specific quality of life (QoL) and other outcomes including satisfaction, body image, sexuality, decisional

regret and fear of cancer recurrence. It also aims to provide information to enhance the pre-operative discussion that women considering CPM have with their clinicians.

2 | METHODS

A literature search of MEDLINE, PubMed and PsychINFO was performed to identify eligible studies that included PROs in women with unilateral breast malignancy undergoing therapeutic mastectomy with CPM. Eligibility criteria are shown in online supplemental material (Appendix S1), and the search strategy is shown in online supplemental material (Appendix S2).

Abstracts and full-text papers were screened for eligibility by one author (A.S.) and checked by another (M.B.). Data were extracted from eligible full-text papers and transferred to evidence tables by one author (A.S.) and checked for accuracy by another (M.B. or K.F.). Cases

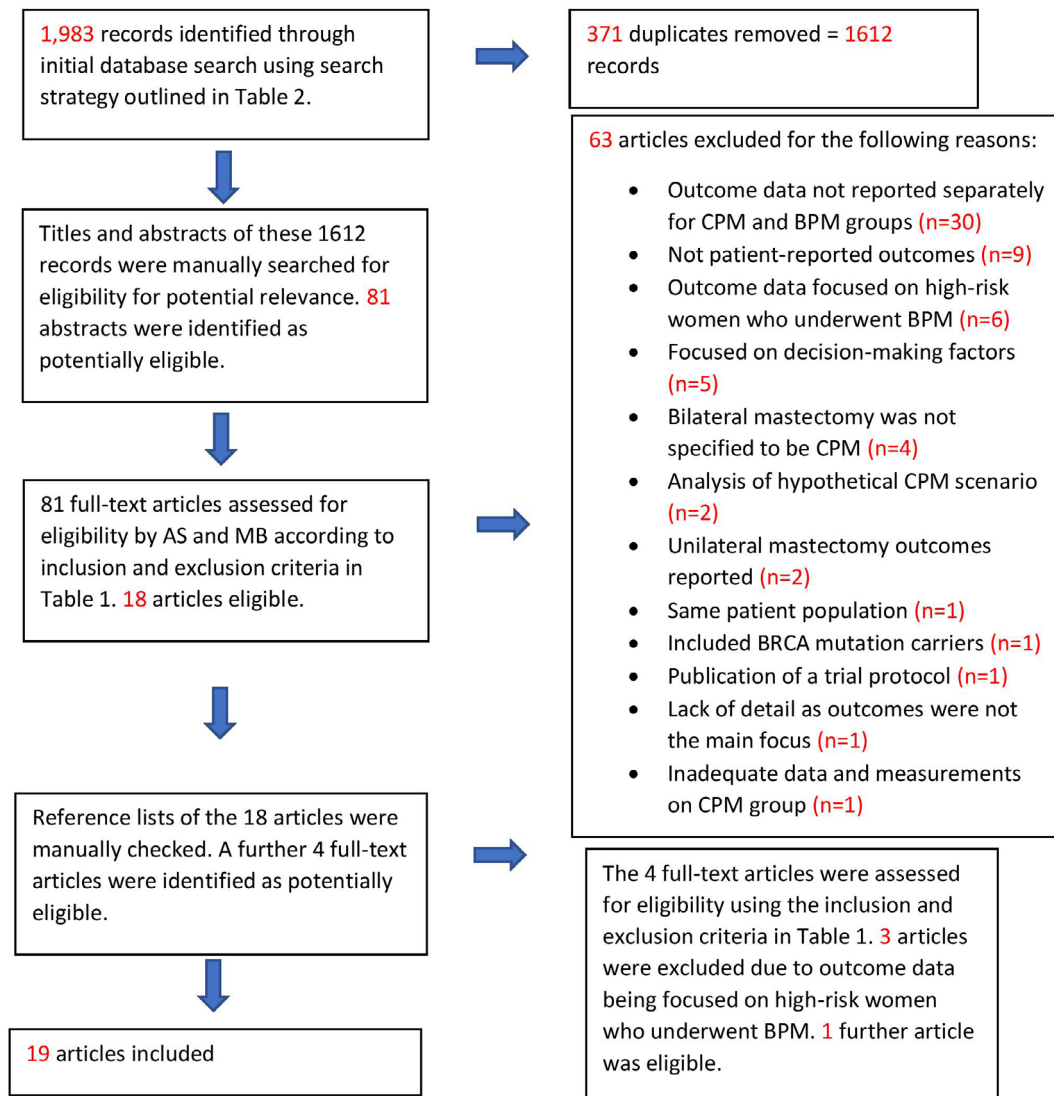


FIGURE 1 PRISMA flowchart

TABLE 1 Characteristics of eligible studies (ordered by year of publication)

Author	Publication year	Country	Study years	Study design	Methodology	Participants (N CPM)	Age (years, mean or median)	Population	Outcomes reported	Outcome measures	Quality score (mean)
Montgomery ²⁸	1999	USA	1954-1998	R	Mail questionnaire and interview	296	53.8 (mean) at CPM	CPM (bilat mastectomy) with or without reconstruction in patients with unilateral BC. No comparison group.	Satisfaction with CPM decision (tool not described), satisfaction with reconstruction (tool not described).	Study-specific questionnaire and follow-up interview with some participants.	18.5
Frost ²⁰	2005	USA	1960-1993	R	Mail questionnaire	583	48 at CPM	CPM for unilateral BC, surveyed at 10 years after BC. Family history of BC. Overlap with population in Frost (2011).	Satisfaction with CPM, self-esteem, feelings of femininity, sexual relationships, level of stress, emotional stability, complications.	Study-specific questionnaire; closed and open questions	17
Nekhlyudov ²⁹	2005	USA	1979-1999	R	Mail questionnaire	431	71% <55 years at CPM	CPM (bilat mastectomy) with or without reconstruction in patients with unilateral BC. No comparison group.	Past and current satisfaction with CPM (single items), current fear of recurrence (single item), current depression (CES-D), current perception of general health (single item from SF-36). Focused on role in decision making; also reported long term outcomes.	Study-specific questionnaire plus validated measures single item from SF-36 and full CES-D.	20
Geiger ²²	2006	USA	1979-1990	R	Mail questionnaire	519	30% <55 years at survey	CPM (bilat mastectomy) vs no CPM (unilat mastectomy or BCS) for unilateral BC.	Contentment with quality of life, satisfaction with CPM, experience of BC thoughts, body image, sexual satisfaction, depression and health perception.	Study-specific questionnaire and adapted items from validated scales; closed questions.	19.5
Tercyak ³²	2007	USA	1997-2003	P	Telephone interview	167	45 at diagnosis	CPM (bilat mastectomy) with or without reconstruction in patients with unilateral BC. No comparison group. All had BRCA testing 15% positive.	Quality of life (FACT-B); psychological distress (Impact of Events Scale; Multidimensional Impact of Cancer Risk Assessment).	Validated scales: FACT-B, IES, MICRA.	21
Spear ³¹	2007	USA	2000-2005	R	Mail questionnaire	47	NR	CPM (bilat mastectomy) with immediate reconstruction in patients with unilateral BC. Comparison bilateral risk-reducing.	Satisfaction with reconstruction (rating scale).	Study-specific questionnaire.	14
Altschuler ¹⁴	2008	USA	1979-1999	R	Mail questionnaire	567	18-80 at survey	CPM vs bilateral prophylactic mastectomy.	Quality of life, satisfaction with CPM decision, BC risk-related worry, body image, sexual satisfaction and overall health perception.	Study-specific mail questionnaire; closed and open questions. Responses classified as "positive," "negative" or "disparate."	20.5

(Continues)

TABLE 1 (Continued)

Author	Publication year	Country	Study years	Study design	Methodology	Participants (N CPM)	Age (years, mean or median)	Population	Outcomes reported	Outcome measures	Quality score (mean)
Frost ^{21,21}	2011	USA	1960-1993	R	Mail questionnaire	269	47.4 at CPM	CPM for unilateral BC, surveyed at 10 years and 20 years after cancer. Family history of BC. Overlap with population in Frost (2005).	Decision conflict scale, LOT-R optimism scale, Trait anxiety, Health concern and Health distress scales, quality of life (single item), body image scale (validated)	Standardised scales with additional study-specific items	19
Han ²³	2011	USA	2005-2007	R	Mail questionnaire	101	Range 20-89	CPM vs no CPM (unilat mastectomy) for unilateral BC. Includes some bilateral BC patients.	Satisfaction with choice of CPM and choice of reconstruction	Study-specific questionnaire.	15.5
Koslow ²⁵	2013	USA	2000-2007 (+2008-2012)	R	Questionnaire	121	46.6 at CPM	CPM (bilat recon) vs no CPM (unilat recon) in patients with unilateral BC undergoing implant reconstruction.	Breast-related QoL (BREAST-Q, 5 domains)	BREAST-Q	21
Rosenberg ³⁰	2013	USA + Canada	NR	R	Mail questionnaire	123	37 at diagnosis	CPM (bilat mastectomy) with or without reconstruction in patients with unilateral BC. No comparison group.	BC worry (CPM survey), Decisional conflict (SURE scale = items from Decisional Conflict Scale), Focused on knowledge and role in decision making; also reported long term satisfaction.	Study-specific questionnaire "CPM survey" 23 items, SURE scale.	20.5
Soran ⁷	2015	USA	2000-2010	R	Mail questionnaire	206		CPM (bilat mastectomy) with or without reconstruction in patients with unilateral BC. No comparison group.	Satisfaction with surgical procedure and overall decision (Single-item questions).	Study-specific questionnaire.	18.5
Buchanan ¹⁸	2016	USA	2011-2012	R	Phone interview and mail questionnaire	17	45.2 at CPM	CPM (bilat recon) vs no CPM (unilat recon) in patients with unilateral BC; comparing fear of recurrence in different groups.	Breast-related QoL (BREAST-Q, 5 domains), Fear of cancer recurrence (Concerns About Recurrence Scale), Interview.	BREAST-Q, Concerns About Recurrence Scale, Semi-structured interview exploring decision making.	19
Hwang ²⁴	2016	USA	NR	R	E-mail questionnaire	1598	53.7 at survey	CPM (bilat mastectomy) vs no CPM (unilat mastectomy) in patients with unilateral BC; comparing reconstruction vs no reconstruction.	Breast-related QoL (BREAST-Q, 4 domains).	BREAST-Q.	19.5
Anderson ¹⁵	2017	USA	2004-2012	R	Mail questionnaire	262	55 at diagnosis	CPM (bilat mastectomy) vs no CPM (unilat mastectomy) with or without recon in patients with unilateral BC; comparing satisfaction and body image in different groups. Included BCS patients.	Satisfaction with CPM decision (single item), Satisfaction with reconstruction (single item), body image (Body Image Scale, adapted, 5 items).	Study-specific questionnaires and adapted validated body image scale.	20

TABLE 1 (Continued)

Author	Publication year	Country	Study years	Study design	Methodology	Participants (N CPM)	Age (years, mean or median)	Population	Outcomes reported	Outcome measures	Quality score (mean)
Cornell ¹⁹	2017	USA	2010-2015	R	Mail questionnaire	67	56 at diagnosis	CPM (bilat mastectomy) vs no CPM (unilat mastectomy) for unilateral BC. Also included BCS cohort.	Sexual function, reported pre-op, and post-op at regular intervals.	Female sexual functioning index (FSFI)- validated questionnaire (19 items).	19.5
Momoh ²⁷	2017	USA + Canada	2012-2014	P	In-person questionnaire	604	43% 40-49 years	CPM (bilat recon) vs no CPM (unilat recon) in patients with unilateral BC; comparing implant vs autologous reconstruction.	Breast-related QoL (BREAST-Q, 4 domains), Health-related quality of life (GAD), Anxiety (PROMIS).	BREAST-Q, GAD-7, PROMIS.	22
Kuykendall ²⁶	2017	USA	2011-2015	R	Mail questionnaire	65	Not reported	CPM (bilat recon) vs no CPM (unilat recon) in patients with unilateral BC; comparing implant vs autologous reconstruction.	Breast-related QoL (BREAST-Q, 10 domains).	BREAST-Q.	21
Bloom ¹⁶	2019	USA	NR	R	In-person interview	45	45 at interview	CPM for unilateral, early-stage BC and low genetic risk. Interview exploring decision and effects.	Decision making, short term and long term impacts of CPM.	Semi-structured interview; open questions.	16.5

Abbreviations: BC, breast cancer; CPM, Contralateral prophylactic mastectomy; NR, not reported; P, Prospective; QoL, quality of life; R, Retrospective.

of uncertain eligibility or discrepant data were solved by consensus. Data on study design, participants, methodology and outcomes were extracted. Data were examined for common themes and were presented in summary tables.

Each study was allocated a quality score by two authors using an adaptation of the QualSyst score which was described by Kmet et al¹¹ and adapted for use in a previous systematic reviews of PROs in breast cancer by Flitcroft et al.^{12,13} Studies were scored on 12 items on a 0 to 2 scale for a total possible score of 24. The mean of scores from the ratings was calculated.

3 | RESULTS

The outcomes from the search strategy are shown in the PRISMA flowchart in Figure 1. The search identified 1612 abstracts (earliest date searched to February 2019). A total of 81 abstracts met eligibility criteria; 81 full-text articles were reviewed, 63 were subsequently found to be ineligible, and one article was added following review of reference lists of eligible studies. A total of 19 studies were eligible for inclusion in the analysis.^{7,14-32}

3.1 | Study characteristics

The 19 eligible studies included PROs from 6088 women. The study characteristics are shown in Table 1. The studies were published between 1999 and 2005. A total of 17 studies were performed in the United States and two across both the US and Canada. There were two prospective and 17 retrospective studies. Participants provided information by questionnaire (15 studies), interview (two studies) or a combination of both (two studies).

3.2 | Study quality

All studies were rated for quality by two authors against a standardised checklist¹¹⁻¹³ There was good concordance between raters, with a mean difference in scores of 1.6 (range 0-3) on the 24-point scale. There were differences in quality scores between included studies with the lowest score 14 and the highest score 22 out of 24. Studies were most likely to be rated lower if they did not adequately describe the study sample or sampling strategy did not describe outcome measures adequately or did not connect the study to the wider body of knowledge. The mean study score was 19.1 (median 19.5). Of the 19 studies, eight had a quality score over 20, indicating a high quality.

3.3 | PROs evaluated in studies

The studies reported a range of PROs, as shown in Tables 1 to 3 and online supplemental material (Appendix S3). These were grouped into

10 main domains: breast-related QoL reported in five studies,^{18,24-27} satisfaction with decision for CPM (12 studies),^{7,14-16,20-23,28-31} satisfaction with reconstruction and cosmesis (four studies),^{15,16,30,31} overall QoL (three studies),^{21,22,32} fear of cancer recurrence (five studies),^{16,21,22,29,30} body image (four studies),^{15,21,22,30} sexuality (four studies),^{16,19,22,30} distress (three studies),^{21,22,32} combined body image/sexuality (two studies)^{14,20} and other outcomes (five studies).^{21,22,29,30}

3.4 | Breast-related QoL

Five studies reported breast-specific QoL using Breast-Q^{18,24-27} (Table 2). The largest study (Hwang et al²⁴) had almost 1600 women in the CPM group. It compared Breast-Q results between women who chose CPM and those who did not and reported results in reconstruction and no-reconstruction groups. In women who did not choose reconstruction, there was no difference in scores for any domain between CPM and no-CPM groups. Reconstruction was associated with better QoL than no reconstruction regardless of choice for CPM. Scores in the "satisfaction with breast" domain were higher in the CPM group compared to the unilateral mastectomy group; however, the scores for psychosocial and physical well-being domains were lower in the CPM group.²⁴ Two further studies using Breast-Q showed better satisfaction in the CPM groups compared to unilateral mastectomy groups,^{25,27} and the remaining two studies showed better QoL scores in the group that did not undergo CPM.^{18,26}

3.5 | Overall QoL

Three studies reported overall QoL^{21,22,32} (Table 3). One reported good QoL (8.7 out of 10) at 20 year follow-up on a single-item question in a CPM cohort without a comparison group.²¹ Another found good QoL and no difference between CPM and no-CPM groups evaluated by a single-item.²² The third used FACT-B and found good QoL with no difference in CPM and no-CPM groups 12 months after surgery.³²

3.6 | Satisfaction with the decision for CPM

A total of 12 studies evaluated at least one aspect of satisfaction or regret with the decision for CPM^{7,14-16,20-23,28-31} (Table 3). The majority of these studies assessed satisfaction and regret with a single-item closed question. Among 10 studies exploring satisfaction about the choice for CPM,^{14-16,20-23,28-30} 82% to 98% of participants undergoing CPM expressed satisfaction with the decision. Satisfaction with the decision for CPM was lower in women who had surgical complications,²⁰ had a poor cosmetic result, a diminished sense of sexuality or lack of information about surveillance vs CPM.²⁸ Satisfaction was higher in women choosing simple mastectomy with no reconstruction in one study.²⁰ Two studies compared satisfaction with

the decision in women undergoing CPM and women choosing against CPM^{15,23} and one showed no difference between the groups²³ and the other showed higher satisfaction in the CPM group (97%) compared to the no-CPM group (89%, no *P* value reported). One study that used both closed- and open-ended questions found that satisfaction was 85% in a CPM cohort on the closed question but the open-ended question showed responses that were positive in 30%, negative in 33% and disparate in 35% of the sample.¹⁴ Six studies asked a CPM cohort if they would make the same decision again or recommend the procedure to other women; 83% to 97% responded that they would do the same again or recommend it.^{7,16,20,21,30,31} The one study that compared a CPM to a no-CPM group reported that 98% of the CPM group and 77% of the no-CPM group would make the same decision again.²³

Two studies used validated questionnaires to assess decisional regret. One study of 269 women undergoing CPM with 10 and 20 year follow-up used the Decision Conflict Scale and found a mean score of 1.4 (scale 1-4), representing very low decisional conflict and stable findings across both time periods.²¹ The other used the SURE scale and found 87% of women undergoing CPM scored 4/4 indicating no decisional conflict.³⁰

3.7 | Satisfaction with reconstruction and cosmesis

Four studies reported satisfaction with reconstruction and cosmesis^{15,16,30,31} (Table 3). In two studies, satisfaction was high.^{15,31} One reported 94% overall satisfaction³¹ and in another, there was no difference between bilateral (CPM) and unilateral mastectomy groups in satisfaction with reconstruction (80% vs 79%, no *P* value reported).¹⁵ However, another interview study of 45 women reported that 89% of the women choosing reconstruction after CPM said the reconstruction did not live up to expectations and felt that their expectations had been unrealistic for sexuality, reconstruction feeling like part of their body and risk of surgical complications. Despite this, 91% said that they would make the same decision again.¹⁶ A further study in women <40 years reported that 45% felt the cosmetic result was as expected, 34% worse than expected and 25% better than expected; 90% would make the same decision again and SURE scores showed low decisional conflict.³⁰

3.8 | Fear of cancer recurrence

Five studies reported fear of cancer recurrence^{16,21,22,29,30} (online supplemental material Appendix S3). All of these studies reported ongoing moderate to high levels of cancer or health worry following CPM. One study used a validated questionnaire (Health Concern Score) and found moderate levels of concern in a cohort of 269 women at 20 years.²¹ The remaining studies used questionnaires developed for the individual studies that included an item about fear of recurrence. Current concern about cancer was reported by 49%, 53%, 82% and 90% of CPM patients in these studies.^{16,22,29,30} Only one of these studies had a comparison group

that did not have CPM, and this reported concern about cancer to be higher in the non-CPM group (74% reporting worry) compared to the CPM group (50%, *P* < .05).²²

3.9 | Body image and sexuality

Four studies reported body image^{15,21,22,30} (online supplemental material Appendix S3). Four reported sexuality^{16,19,22,30} and two studies reported these two outcomes together.^{14,20} Three studies used the validated Body Image Scale, either in full or in part, and two compared a CPM group to a no-CPM group. These all showed that women reported concerns about their body image; however, there was no significant difference between CPM and no-CPM groups^{15,22} with the exception of women who underwent CPM without reconstruction who had slightly lower body image scores.¹⁵ When asked if body image was as expected, 49% said yes, 31% said that it was worse than expected and 23% said that it was better than expected.³⁰ Similarly, in studies examining sexuality, there was no difference in score between the CPM and no-CPM groups.^{19,22} In an interview study, women reported feeling emotionally closer to partners after the surgery compared to before the surgery, however sexually more distant, with chest numbness related to CPM to be a major factor (no comparison group).¹⁶

One of the studies that examined global psychological issues found that women reported CPM to have a greater adverse effect on body image than other domains such as femininity, sexuality, relationships and self-esteem.²⁰ The other found that women had generally positive comments about the impact of CPM on body image, sexuality and emotional domains; this was compared to generally negative comments from high-risk women without cancer undergoing bilateral prophylactic mastectomy.¹⁴

3.10 | Distress

Distress was reported in three studies^{21,22,32} (online supplemental material Appendix S3). Two of these used the Impact of Events Scale and found that cancer related distress was moderately high, but there was no difference between CPM and no-CPM groups. A further study used a more general Health Distress Score and found low distress in a CPM group (no comparison group) at 20 years.²¹

3.11 | Other outcomes (five studies)

Several other outcomes were reported (online supplemental material Appendix S3). These included depression (two studies, prevalence of depression 27% in both, with no difference between CPM and no-CPM groups.^{22,29} There was also no difference between groups for general health perception.²² There were low levels of anxiety and high levels of optimism in a CPM group (no comparison group),²¹ and pain and numbness were "about the expected level" in 40% and 51%.³⁰

TABLE 2 Results of studies assessing breast-related quality of life using Breast-Q, ordered by number of participants***

Author	N (CPM group)	Timing of measurement	Groups assessed	Results for women undergoing CPM							Results/conclusions
				Breast-Q satisfaction with breast	Breast-Q satisfaction with outcome	Breast-Q physical well-being abdomen	Breast-Q psychosocial well-being	Breast-Q physical well-being chest/upper body	Breast-Q sexual well-being		
Hwang ²⁴	1598	1.6 years (median) post-surgery	CPM with reconstruction	62	nr	nr	71.7	74.5	50	CPM (bilateral recon) higher satisfaction with breast compared with no CPM (unilat recon) at the expense of lower psychosocial and physical well-being	
			CPM without reconstruction	54	nr	nr	69.1	75	39.9	No differences in any domain scores in women not having reconstruction	
			CPM with and without reconstruction	60.4	nr	nr	71.2	74.6	46.9	Reconstruction better quality of life than no reconstruction regardless of choice for CPM	
Momoh ²⁷	604	1 year post-surgery	CPM with implant reconstruction	50.25	nr	n/a	63.05	66.22	50.65	CPM with bilat recon associated with better satisfaction than no CPM with unilat recon	
			CPM with autologous reconstruction	82.96	nr	79.98	65.57	67.76	52.41	No differences in satisfaction between groups	
Koslow ²⁵	121	52 months (median) post-surgery	CPM with implant reconstruction	64.4	74.8	nr	75.4	77.4	55.1	CPM significantly better satisfaction with breast and satisfaction with outcome.	
Kuykendall ²⁶	65	nr	CPM with implant reconstruction	62.7	69.3	nr	71.6	69.5	51.6	No significant differences between CPM and no-CPM in group with implant recon	
			CPM with autologous (DIEP) reconstruction	69	61	nr	71.2	66.5	49.5	No-CPM group better satisfaction with outcome and sexual well-being in women undergoing DIEP	
			CPM with implant or autologous reconstruction	64.3	67.4	nr	71.5	68.7	51	Overall, no-CPM (unilat recon) significantly better satisfaction with outcome, psychosocial well-being and sexual well-being	

TABLE 2 (Continued)

Author	N (CPM group)	Timing of measurement	Groups assessed	Results for women undergoing CPM						Results/conclusions
				Breast-Q satisfaction with breast	Breast-Q satisfaction with outcome	Breast-Q physical well-being abdomen	Breast-Q psychosocial well-being	Breast-Q physical well-being chest/upper body	Breast-Q sexual well-being	
Buchanan ¹⁸	17	22 months (mean) post-surgery	Overall- CPM	82.2	89.9	nr	88 ^a	74.4	71 ^a	CPM associated with better satisfaction with breast and outcome (non-significant); No CPM (unilateral reconstruction) associated with better physical well-being (chest, significant)

^aResult estimated from figure.

Abbreviations: CPM, Contralateral prophylactic mastectomy; N, number; NR, not reported.

4 | DISCUSSION

This review includes PROs from 19 studies of 6088 women with unilateral cancer undergoing CPM (bilateral mastectomy). Significant heterogeneity was noted among studies. Different methodology, outcomes and measurement tools were used in different studies, and outcomes were measured at varying time intervals. Study quality also varied and fewer than half the studies had a quality score >20 (out of 24).

The majority of studies focused on how women felt about the decision to undergo CPM. Overall, these showed that women were very comfortable with the decision they had made. Satisfaction with the decision was 82% to 98% across 10 studies, levels of decisional regret were low, and despite many women being disappointed with their cosmetic outcome (up to 89% in one study), most women reported they would make the same decision again and/or recommend CPM to other women.¹⁶ This evidence can provide clinicians with reassurance that women who are taking control of their cancer and requesting CPM despite low risk of contralateral cancer are unlikely to regret their decision.

The impact of surgery on body image was significant in women undergoing CPM. However, in studies that compared a CPM group with a non-CPM group, there was no difference between groups.^{15,22} This implies that it is the cancer surgery overall, not specifically the removal of the contralateral breast, that is the cause. This is consistent with previous studies showing that body image is dramatically and adversely affected by breast cancer surgery, even when surgery is unilateral and the breast is conserved.³³

A previous systematic review examining reasons for women choosing CPM found that fear of cancer recurrence was the most important factor in the decision.⁸ Other research has shown that fear of recurrence was higher in women having breast conservation rather than mastectomy on their ipsilateral side.³³ In the present review, fear of cancer recurrence was still prevalent among groups of women who had undergone CPM. This shows that CPM probably does not reduce fear of recurrence even though women may expect it to at the time they make the decision. This has important implications for pre-operative counselling and informed consent. It also demonstrates that psychological strategies, not surgery, should be used to manage this condition.

The previous review identified the desire for good cosmesis, symmetry and/or reconstructive reasons as the second most important factor in the decision to undergo CPM.⁸ The present study did not find that satisfaction with the cosmetic outcome was any different for women undergoing CPM compared to unilateral surgery.^{15,31} However, there were only two studies that examined this issue. It is also possible that there is significant selection bias as women who are most likely to experience asymmetry (such as those with larger breasts) may be more likely to undergo CPM.

A patient requesting CPM from her surgeon may present an ethical dilemma. Patient-centred care is the aim, and the operation of CPM is associated with high levels of patient satisfaction. It is, however, a major operation with significant potential complications

TABLE 3 Results of studies assessing satisfaction with decision and satisfaction with reconstruction, ordered by number of participants

Author	N (CPM group)	Timing of measurement	Outcome and measurement tool	Groups assessed	Results/conclusions
Overall Quality of Life					
Frost (2011) ²¹	269	10 and 20 years	Multiple outcomes assessed at two follow-up times; Collection of validated questionnaires	CPM (bilat mastectomy)	Overall quality of life high; 10-point scale single item (Range 0-10, higher score better qol). 20 year follow-up: 8.7 mean.
Geiger ²²	519	nr	Multiple outcomes assessed at follow-up. Study specific questionnaire.	CPM (bilat mastectomy) vs No CPM (unilat mastectomy or BCS)	Contentment with QoL good (single item from FACT-B). CPM group 76.3 satisfied "quite a bit" or "very much." No difference between groups.
Tercyak ³²	167	1 and 12 months after CPM	CPM (bilat mastectomy) with or without reconstruction in patients with unilateral BC. Comparison group non-CPM: unilat mastectomy or BCS (combined)	CPM (bilat mastectomy). 81% had reconstruction. Scores at 12 months.	FACT-B score (mean). CPM 115.9; non-CPM 116.9 (non-significant difference at 12 months)
Satisfaction with decision					
Frost (2005) ²⁰	583	10 years	Multiple outcomes relating to decision and satisfaction assessed at 10 years follow-up; study-specific questionnaire	CPM (bilat mastectomy)	Overall satisfaction with decision high. 83% satisfied or very satisfied. Lower satisfaction levels in women with surgical complications and subcutaneous mastectomy compared to simple mastectomy. Higher satisfaction for no reconstruction vs reconstruction. Would choose CPM again: 83%
Altschuler ¹⁴	567	3-22 years	Satisfaction with CPM decision (Single item closed question)	CPM (bilat mastectomy)	Satisfaction with decision (closed question n = 223): satisfied 85.2% not satisfied 14.8%. Better satisfaction expressed in closed and open questions for CPM compared to bilateral prophylactic mastectomy. Satisfaction with decision (open question n = 280): positive 30.1%, negative 33.9%, disparate 35.8% Despite high level of satisfaction, around 1/3 of women expressed disparate comments.
Geiger ²²	519	nr	Multiple outcomes assessed at follow-up. Study specific questionnaire.	CPM (bilat mastectomy) vs No CPM (unilat mastectomy or BCS)	Satisfaction with CPM decision high (single item, developed for study). CPM group 86.5% "satisfied" or "very satisfied."
Nekhlyudov ²⁹	431	60% had CPM within the past 10 years	Focused on decision making roles (alone or shared with doctor); also reported psychosocial outcomes. Focused on decision making roles (alone or shared with doctor); also reported psychosocial outcomes.	CPM (bilat mastectomy) CPM (bilat mastectomy)	Satisfaction with choice for CPM (6 months). 352/431 (81.7%) satisfied. Active decision making roles more likely to be satisfied at 6 months. Satisfaction with choice for CPM (current). 367/431 (85.2%) satisfied. Decision making roles not related to current satisfaction.
Montgomery ²⁸	296	Median 4.9 years; 53% > 10 years	Assessed satisfaction with decision (regret) with study-specific questionnaire. Follow-up phone interview with women who expressed regret to assess reasons.	CPM (bilat mastectomy)	Satisfaction with choice for CPM. Low level of regret. 278/296 (94%) satisfied. Reasons for regret: poor cosmetic result (CPM or recon), diminished sense of sexuality, lack of education regarding alternative surveillance methods or CPM efficacy.

TABLE 3 (Continued)

Author	N (CPM group)	Timing of measurement	Outcome and measurement tool	Groups assessed	Results/conclusions
			Assessed satisfaction with decision (regret) with study-specific questionnaire. Follow-up phone interview with women who expressed regret to assess reasons.	CPM (bilat mastectomy)	Satisfaction with choice for reconstruction. 37.5% had reconstruction; 12/111 (10.8%) with CPM and reconstruction had regrets. 6/185 (3.2%) with CPM and no reconstruction had regrets. CPM and no recon (3.2%) had lower regret than CPM with recon (10.8%).
Frost (2011) ²¹	269	10 and 20 years	Multiple outcomes assessed at two follow-up times; Collection of validated questionnaires	CPM (bilat mastectomy)	Decision- conflict scale (Range 1-5, high score = greater conflict) 20 year follow-up: 1.4 mean; 95% satisfied with their decision. Very low decisional conflict score. Stable findings between 10 and 20 year surveys. Overall satisfaction with decision high: 20 year follow-up: 90% satisfied or very satisfied. Would choose CPM again: 20 year follow-up: 92% would choose CPM again. Stable between 10 and 20 year surveys.
Anderson ¹⁵	262	3.6 years (mean)	Satisfaction with CPM decision (single item)	CPM (bilat mastectomy) vs No CPM (unilat mastectomy)	Satisfaction with decision for CPM: CPM group 97% satisfied with decision; No-CPM group 89% satisfied with decision. Satisfaction slightly higher in CPM compared to no-CMP groups (<i>P</i> -value <i>nr</i>)
Soran ⁷	207	93% > 1 year	Focused on decision making role and reasons; also reported satisfaction with decision. Focused on decision making role and reasons; also reported satisfaction with decision.	CPM (bilat mastectomy) CPM (bilat mastectomy)	Would recommend to other women (single item). 191/200 (92.7%) would recommend to others. High level of satisfaction. Satisfaction with surgical procedure of CPM (single item). 200/206 (91.7%) satisfied. High level of satisfaction. (Single item). 199/206 (96.6%) would choose CPM again.
Rosenberg ³⁰	123	2.1 years mean	Focused on decision making role and reasons; also reported psychosocial outcomes.	CPM (bilat mastectomy) with or without recon	Decisional conflict about choice for CPM low (SURE scale). 87% of respondents scored 4/4, indicating no decisional conflict Satisfaction with choice for CPM high. 80% of women were extremely confident in their decision to undergo CPM and 90% of respondents would definitely choose CPM if deciding again.
Han ²³	101	<i>nr</i>	Assessed satisfaction with decision for CPM and for reconstruction. Study specific mailed questionnaire.	CPM (bilat mastectomy) vs No CPM (unilat mastectomy)	Satisfaction with choice for reconstruction high. 125/242 52% (CPM and no-CPM combined) had reconstruction; 89% of all patients satisfied with their decision for or against reconstruction; no difference between CPM/no-CPM groups. Satisfaction with choice for CPM high. CPM group 99/101 (98%), No-CPM

(Continues)

TABLE 3 (Continued)

Author	N (CPM group)	Timing of measurement	Outcome and measurement tool	Groups assessed	Results/conclusions
Spear ³¹	47	Mean 31 months	CPM (bilat mastectomy) with immediate reconstruction in patients with unilateral BC. Comparison bilateral risk-reducing.	CPM (bilat mastectomy)	group 90/117 76.9% would make the same decision again. CPM statistically significantly more likely to make same decision again High satisfaction; 31/32 (98%) would choose again.
Bloom ¹⁶	45	1-10 years	Decisional regret (Semi-structured interview; open questions)	CPM (bilat mastectomy)	Satisfaction with decision 41/45 (91%) would make the same decision again.
Satisfaction with reconstruction and cosmesis					
Anderson ¹⁵	262	3.6 years (mean)	Satisfaction with reconstruction (single item)	CPM (bilat mastectomy with recon) vs No CPM (unilat mastectomy with recon)	Satisfaction with breast reconstruction high: CPM group 80% satisfied; No-CPM group 79% satisfied. Young women, all <40 years. >90% reconstruction rate.
Rosenberg ³⁰	123	2.1 years (mean)	Focused on decision making role and reasons; also reported psychosocial outcomes.	CPM (bilat mastectomy) with or without recon	Cosmetic result. Worse than expected 34%; about what expected 45%; better than expected 25%
Spear ³¹	47	31 months (mean)	CPM (bilat mastectomy) with immediate reconstruction in patients with unilateral BC. Comparison bilateral risk-reducing.	CPM (bilat mastectomy)	Satisfaction with reconstruction. Overall 30/32 (94%) satisfied. Highly satisfied 30/32 (53%); Very satisfied 8/32 (25%); Mod satisfied 4/32 (13%); Satisfied 1/32 (3%); Disappointed 2/32 (6%); Very disappointed 0/32 (0%)
Bloom ¹⁶	45	1-10 years	Semi-structured interview; open questions	CPM (bilat mastectomy)	Satisfaction with reconstruction. 38/45 had reconstruction; 89% said recon did not live up to expectations; reported that their expectations were unrealistic for sexuality, feeling like part of their body and potential surgical complications

Abbreviations: BC, breast cancer; CPM, Contralateral prophylactic mastectomy; N, number; NR, not reported; QoL, quality of life.

especially when it is performed with immediate breast reconstruction. The competing principles of “autonomy” and “non-maleficence” are challenging to work through. It may require several consultations and the input of a clinical psychologist to fully inform the patient about the risks of the surgery, the potential outcomes and the lack of impact on fear of recurrence.

4.1 | Study limitations

The main limitation of this review is the heterogeneity of the studies: a large variety of different outcomes, time points and measures were used in the studies and this makes conclusions difficult to draw. Study quality was highly variable, and the majority was retrospective. All of the studies were performed in the United States and Canada, so the generalisability to other countries with

different health systems and cultures (such as Europe and Australia) is uncertain.

4.2 | Clinical implications

This study provides information that can be used by surgeons and psychologists when counselling women about the potential benefits and harms of CPM. The discussion about CPM at the time of cancer diagnosis is a complex one. A key benefit of CPM is cancer risk reduction; however, most women are not at high risk of contralateral cancer and this must be explained. The conversation must include discussion about the trade-offs of CPM such as body image issues and the ongoing fear of recurrence that persists despite bilateral surgery. Women appear to accept these negative aspects of CPM and are unlikely to regret their decision for CPM even when they are experiencing adverse long-term effects.

5 | CONCLUSION

In conclusion, this review has built on previous research and added more depth to the understanding of this area by presenting a detailed evaluation of studies of PROs following CPM. Significant heterogeneity was found, presenting challenges for synthesis of the data. Women undergoing surgery reported high levels of satisfaction with the decision, low levels of decisional regret and high satisfaction with cosmesis and reconstruction. General and breast-specific QoL were high. Depression, distress and a negative impact on body image were evident; however, levels were high in both CPM and non-CPM groups. Fear of cancer recurrence was high after surgery. Women must be informed about the potential benefits and harms of surgery, and the decision process must include counselling about these factors in addition to the discussion about risk of future cancer.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY

The data that support the findings of this study are openly available in Mendeley Data v2 at <https://doi.org/10.17632/9369258c3s.2> [10.17632/9369258c3s.2].³⁴

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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