International Journal of Advances in Medicine
Sutanto KW et al. Int J Adv Med. 2025 Jul;12(4):419-426
http://www.ijmedicine.com
pISSN 2349-3925 | eISSN 2349-3933
DOI: https://dx.doi.org/10.18203/2349-3933.ijam20251941

Systematic Review

Breast cancer incidence after prophylactic mastectomy: a systematic review

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Received: 18 May 2025
Revised: 13 June 2025
Accepted: 16 June 2025

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ABSTRACT

Nowadays, many women in the world are living in fear of encountering breast cancer (BC). In 2020, WHO stated that BC is the most common cancer in the world and the fifth most common leading cause of cancer-related death. The progress made in medical science has made it possible for women to undergo prophylactic mastectomy (PM), which lowers their chances of developing BC. This article will discuss the incidence of BC after PM in women with no prior history of BC in one or both breast tissues. A systematic literature search was done in some databases, namely ProQuest, EBSCO, and PubMed, with a total of 380 articles. After a thorough screening, eight articles that met the criteria were enrolled. In addition, two articles were added from a manual search using Google Scholar. Of those articles, the risk of bias was assessed using the risk of bias tools from CLARITY. All articles suggested that most patients are middle-aged women, mostly around 45 years old. The surgical technique used in most cases is nipple-sparing mastectomy (NSM) due to its cosmetic advantage. Moreover, mutations in the BRCA gene were found to be positive in PM patients. The incidence of BC is substantially reduced after PM, reducing it to approximately 90%. The rest of it still has a chance to develop BC. PM may reduce the incidence of BC. However, further research, specifically on PM, is required to find out the long-term effect and efficacy.

Keywords: Prophylactic mastectomy, Breast cancer, Incidence

INTRODUCTION

Breast cancer (BC) is the most frequently diagnosed cancer among women in the United States. While it ranks second in terms of overall cancer-related deaths among women after lung cancer and remains the primary cause of cancer-related deaths among Black and Hispanic women.[1,2] WHO stated that BC is the most common cancer in the world and the fifth most common leading cause of cancer-related death. In 2020, there were 2.3 million women diagnosed with BC and 685,000 deaths globally. By the end of 2020, there were 7.8 million women alive who had been diagnosed with BC within the previous five years.[3] Around 287,850 new cases of invasive BC and 51,400 cases of ductal carcinoma in situ (DCIS) are detected among women in the United States in 2022. Additionally, in 2023 it is estimated that there will be 300,590 new cases, and 43,700 women will lose their lives due to BC.[1,2,4] According to a 2017 study by the global burden of disease cancer collaboration, there was a 33% increase in BC cases from 2005 to 2015. There was a

21.3% increase in BC mortality from 439,800 to 533,600 in the European Union from 2005 to 2015, despite decrease of 91,000 death cases in 2012.[5]

There are many different factors that can increase the risk of developing BC. There are two types of risk factors: modifiable and nonmodifiable. There are some people who have a high risk of BC, people with a strong family history of BC, especially those who have BRCA 1 and BRCA 2 genetic mutations. People with this gene mutation also have a high risk of ovarian cancer.[6,7] Nowadays we know that BC can be prevented, especially in patients with BRCA1 and BRCA2 mutations. There are several strategies or interventions that are used to prevent BC occurrence and recurrence. There are a variety of interventions that can be used to prevent BC, including lifestyle modification, early detection with imaging, taking estrogen-only hormone therapy after hysterectomy, selective estrogen receptor modulators or aromatase inhibitors and inactivators, ovarian ablation, and risk-reducing PM.[8] When people have a strong familial history of BC or the presence of the BRCA1 or BRCA2 mutation is confirmed, PM procedure is an option that is considered as a preventive measure. After the patient has received PM, it can reduce the risk of BC approximately 90%.[9,10] In women with a BRCA1 or BRCA2 mutation, prophylactic bilateral total mastectomy (TM) reduces the incidence of BC at three years of follow-up.[9]

PM is an emerging method for reducing the risk of BC, and it holds significant importance, especially for individuals with BC gene mutations. In the United States, the use of both preventive bilateral and contralateral mastectomies has significantly increased over the last decades. Healthy women with a high risk of BC may be suitable for bilateral PM, while unilateral mastectomy is performed for non-invasive breast abnormalities or as an adjunct to a therapeutic mastectomy in the opposite breast.[11,12] Technique that used in PM are TM, nipple sparing mastectomy, and skin-sparing mastectomy.[11] Assessing the benefits of bilateral PM is challenging due to the lack of precise estimation.

However, an examination of BC occurrence in studies involving individuals who have previously undergone the procedure allows us to gauge its potential advantages. PM has reduced the incidence of BC, ranging from 80 to 95% and an expected increase in life expectancy of 2.9 to 5.3 years. Additionally, women who undergo PM experience psychological benefits, including a 70 percent satisfaction rate and a 74 percent decrease in emotional concerns related to the development of BC.[13]

Despite the high effectiveness of PM, there remains a possibility that patients may develop BC even after undergoing PM. This study will be further examined to provide a more comprehensive analysis of the occurrence of BC in patients following the performance of the procedure.

METHODS

This systematic review followed the preferred reporting items guidelines for systematic reviews and also meta-analysis (PRISMA) 2020.

The PRISMA 2020 diagram are provided in Figure 1.[14]

Literature search

We conducted a comprehensive literature search to assess the family history and status of BRCA gene mutation in patients undergoing any form of PM using several search engines, such as ProQuest, PubMed, and EBSCOhost. We retrieved all articles from February 2024 to April 2024.

The keywords that we have used are as follows: (Prophylactic breast mastectomy or preventive breast mastectomy) AND (BC rate or BC incidence). Literature search was limited to those published in English language and full-text. In addition, we manually searched additional possible studies for references.

Study selection

The inclusion criteria are: Women of all ages who underwent prophylactic breast mastectomy, patient with healthy breast tissues, including those who had history of BC and did contralateral prophylactic breast mastectomy, patients with BC risk factors, all included studies are primary research articles done in human.

On the other hand, the exclusion criteria are: Women who had a contralateral BC metastasis, patients with a history of any type of cancer, patient with chemotherapy or hormonal therapy, and articles which are reviews, letter to editor, case report.

Data extraction

Two authors extracted all the necessary information independently from the gathered articles, and another 2 authors resolved their differences. The extracted data were as follows: The name of the first author and publication year; age; family history; BRCA status; incidence of BC in the operated breast.

Quality assessment

The quality of the articles included in this study was assessed using CLARITY tools, as shown in Table 1 which was used to assess the risk of bias in cohort studies. This tool consists of eight points that assessed study population, exposure, outcome of interest, study matching, prognostic factor, main outcome, follow-ups, and similarities in co-intervention within the studies. The risk of bias was assessed by two independent reviewers, while another two reviewers resolved their differences.

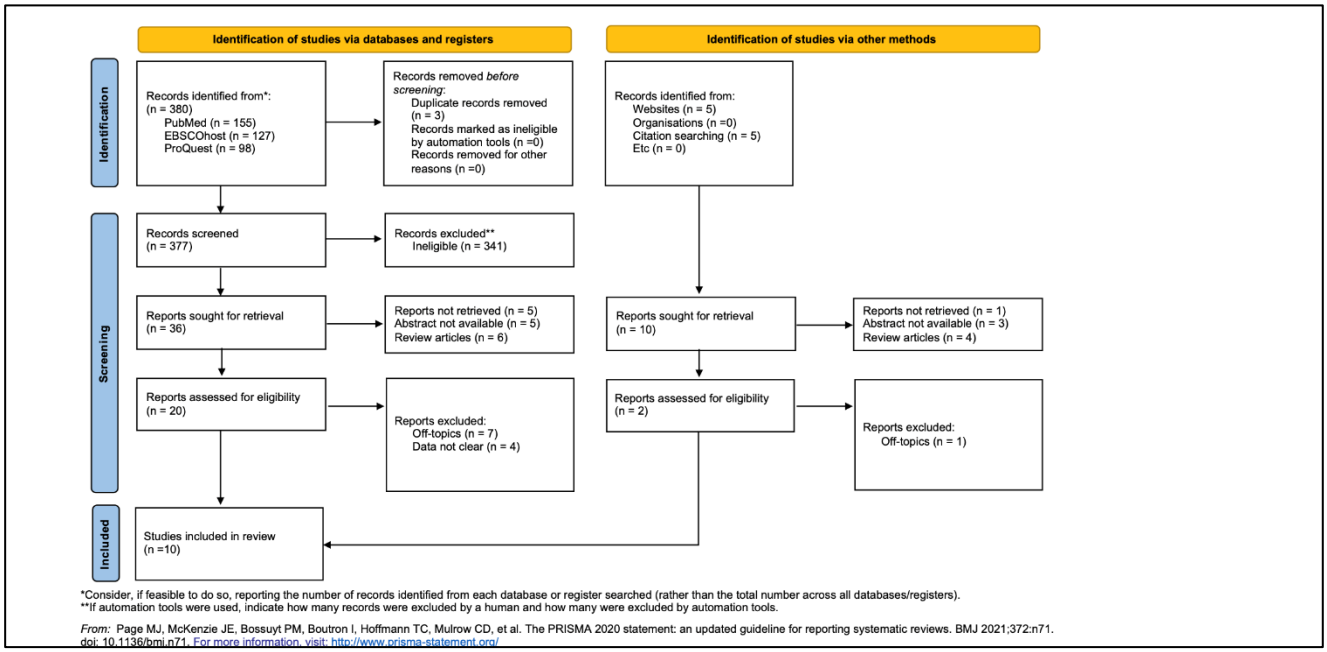

Figure 1: PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources.

Table 1: CLARITY (RoB for Cohort study).

CLARITY (RoB for Cohort study)	Alvarado et al (2012)	Guilfoyle et al (2014)	Wevers et al (2013)	Moo et al. (2016)	Peled et al (2014)	Eck et al (2014)	Rebbeck et al (2004)	Meijers-Heijboer (2001)	Hartmann et al (2001)	Hartmann et al (1999)
Was selection of exposed and non-exposed cohorts drawn from the same population?	4	4	4	4	4	4	4	4	4	4
Can we be confident in the assessment of exposure?	4	4	4	4	4	4	4	4	4	4
Can we be confident that the outcome of interest was not present at start of study?	4	4	4	3	3	4	4	4	3	4
Did study match exposed and unexposed for all variables that are associated with outcome of interest/did statistical analysis interest/did statistical analysis adjust for these prognostic variables?	2	4	3	4	3	3	4	4	3	4
Can we be confident in the assessment of the presence or absence of prognostic factors?	4	4	4	4	4	4	4	4	4	4
Can we be confident in the assessment of outcome?	4	4	4	4	4	4	4	4	4	4
Was the follow up of cohorts adequate?	3	3	4	4	4	3	4	4	4	2
Were co-interventions similar between groups?	3	3	4	3	3	3	3	4	3	4
4	Definitely yes									
3	Probably yes									
2	Probably no									
1	Definitely No									

RESULTS

Out of 380 articles, we systematically excluded articles that did not fit our study protocols, until 9 articles remained. Further search done manually added only 1 article, thus making a total of only 10 articles that can be used. Those 10 articles were critically appraised using the

CLARITY tools, and the results showed that all 10 articles have low risk of bias.

The average age of women who underwent PM was around 45 years old. The youngest participant was aged 19 years old, while the oldest was 88 years old. The hereditary factors data that contributed to BC were obtained from family history and also from the BRCA status, which showed the expression of gene mutation in BRCA 1 and/or BRCA 2. Not all women who undergo PM have a positive family history of BC. This is the same in the case of BRCA status, even though most of patient prepared for PM would usually go through a series of medical examination, the data is still limited to research purpose only. This can be shown by only 6 out of 10 articles included in this study that presented the BRCA testing results. From which, only 3 articles have shown a significant correlation in patients who undergo PM and only 2 articles included the BRCA subtype (BRCA 1 and BRCA 2). Regardless of the BRCA status, there is only one article that differentiated the efficacy of bilateral PM in women at high risk and moderate risk for BC in relation to family history.

PM in all the articles included in this study were done on both or either side of the breast. Several articles also discussed about contralateral PM (CPM) which was done to prevent the spreading of BC from the affected side to the healthy contralateral breast. Surgical techniques that are used in PM are TM, nipple sparing mastectomy (NSM), and skin sparing mastectomy (SSM). The most technique used for PM was subcutaneous mastectomy. Subcutaneous is further divided into two techniques (NSM and SSM)

PM has been shown to reduce the BC incidence from 85% to 90 %. Six studies also included data about the incidence of BC even after PM, even though the risk of BC should have been significantly reduced after the surgery. The incidence of BC after PM was approximately 0% to 7%, while the protective effect duration of PM averaged around 13 years. In correlation with the surgical technique, we also found an article that stated difference of BC incidence between two types of technique (subcutaneous and TM).

Table 2: Table of results.

Authors	Year	Country	Age (in years)	Family history	BRCA (+)	Operation technique	Incidence
Alvarado et al[16]	2012	USA	Age at diagnosis 132 patients (6.5%) aged <40, 1,690 (83 %) aged 4070, 215 (10.5%) aged >70.	-Any breast/ ovarian cancer <40=(64.4%) 40-70=(47%) >70=(39.1%) -First degree family <40=(19.7%) 40-70=(20.5%) >70=(28.8%)	-	-BCS=<40=56 (42.4), 40-70=1015 (60.1), >70=145 (67.4) -Mastectomy=<40=76 (57.6), 40-70=675 (39.9), >70=70 (32.6) -Immediate breast reconstruction (in patient who underwent mastectomy)=<40=64 (82.1), 40-70=449 (66.4), >70=11 (15.7) -CPM=<40=28 (21.2), 40-70=118 (7.0), >70=4 (1.9)	
Guilfoyle et al[23]	2014	USA	-	Patient undergo a CPM with family history 7%	Patients undergo CPM with BRCA+ (4<9%>)		
Wevers et al[26]	2014	UK	-Age at diagnosis mean 44.9 (range 19-79) -Age control 44.8 (25-72)	-	BRCA 1 8 (4.7%) control 5 (9.3%) BRCA 2 9 (5.2%) control 0 (0%)	-Unilateral breast conserving surgery 76 (42.7%) control 39 (44.8%) -Bilateral breast conserving surgery 0 (0%) control 4 (4.6%) -Unilateral mastectomy 76 (42.7%) control 35 (40.2%) -Bilateral mastectomy 26 (14.6%) control 8 (9.2%) -Breast conserving on 1 side with a contralateral mastectomy 0 (0%) control 1 (1.1%) -Delayed CPM 8 (4.5%) control 5 (5.7%) -Prophylactic salpingo-oophorectomy within 1 year follow-up 28 (15.7%) control 9 (10.3%)	

Continued.

Authors	Year	Country	Age (in years)	Family history	BRCA (+)	Operation technique	Incidence
Moo et al[25]	2016	USA	Median age at surgery 48 (25-68)	-	49 (11.9%)	NSM	23 (6.3%)
Peled et al[21]	2014	USA	-Mean age BRCA (+) 44.1 -Mean age BRCA (-) 46.2	-	26/ 52 (50%)		0%
Eck et al[24]	2014	USA	-Median age overall 61 (23-88) -Median age unilat. mast. 65 -Median bilat. mast. 55	-		All type --> CPM	
Rebbeck et al[20]	2004	USA	Mean age 38.1 (20.663.4)	-	78.40%	-Simple mastect. --> 474 (6.5) -Subcutaneous mastect. --> 292 (8.7%) -Modified radical mastect. OR radical mastect. --> 3 (3.0%) -Not specified --> 232 (2.5%)	BC was diagnosed in 2 (1.9%) of 105 women who had bilateral PM, and in 184 (48.7%) of 378 matched controls who did not have the procedure
Meijers-Heijboer et al[9]	2001	UK	-Mean age 37.7±7.7 -Median age 35.8 -Range (23-58)	-	BRCA1 64/76 (84%) BRCA2 12/76 (16%)	Standard, bilateral, simple TM	No cases of BC were observed after PM after a mean (±SE) follow-up of 2.9±1.4 years, whereas eight BCs developed in women under regular surveillance after a mean follow-up of 3.0±1.5 years
Hartmann et al[10]	2001	UK	-Median age at prophylatic mastectomy= 40.5 -Mean age at diagnosis of BC in the family=47.7	Median number of breast/ ovarian cancer family=4	BRCA 2 positive 82 % among high risk women		None of the 26 women has developed BC after a median of 13.4 years of followup (range, 5.8-28.5 years). Three of the 214 women are known to have developed a BC after PM. For two of these women, BRCA1 and BRCA2 screening was negative, and no blood specimen was available for the third.
Hartmann et al[11]	1999	UK	-Median mastectomy in moderate risk 42 -Median mastectom in high risk 42	According to the Gail model, 37.4 BCs were expected in the moderate-risk group; 4 BCs occurred (reduction in risk, 89.5%; p<0.001). We compared the numbers of BCs among the 214 high-risk probands with the numbers among their 403 sisters who had not undergone PM		Bilateral prophylactic subcutaneous mastectomy dan TM (n=639) - Moderate risk = subcutaneous 90 % and 10 % TM - High risk = subcutaneous 89% and 11 TM	BC developed in 7 women after PM median time from PM to developed BC was 6 years all 7 women undergo bilateral subcutaneous mastectomy, there was no significant difference in the incidence of BC between the women who underwent subcutaneous mastectomy and those who underwent TM (7 of 575 women vs. 0 of 64 women, p=0.38);

DISCUSSION

Nowadays, the trend of PM has been slowly increasing. Over the past two decades, the rates of CPM have increased by threefold. This trend can be attributed to various factors, such in individuals carrying the pathogenic variant in the BRCA1/2 gene, have showed to experience the most significant survival benefits. Furthermore, on May 14th, 2013, Angelina Jolie publicly disclosed her decision to undergo bilateral risk-reducing mastectomy (BRRM) due to her positive BRCA status.[15]

There are many variables and factors that contribute to developed BC. There are two type of risk factors, modifiable and nonmodifiable. The examples of non-modifiable risk factors are older age, genetic mutation, reproductive history, women with dense breast tissue, personal history of breast or ovarian cancer, previous treatment using radiation therapy, and exposure to the drugs diethylstilbestrol (DES). On the other hand, the examples of modifiable risk factors are sedentary lifestyle, overweight or obesity post-menopause, hormonal contraceptive, reproductive history, and alcohol. There are some people who have high risk of developing BC, such as people with a strong family history of BC, especially those who have BRCA 1 and BRCA 2 genetic mutations. People with this gene mutation also have a high risk of ovarian cancer.[6,7]

Most of the patients who underwent PM came from younger age group. Alvarado et al stated in her article that women aged younger than 70 years old would preferably have PM to reduce the risk of BC. Even in the case of already having BC on one side of the breast, younger women would still do CPM alongside with neoadjuvant therapy such as chemotherapy and radiotherapy with the hope of lowering the risk of recurrence. On the other side, older women would prefer more passive approach with the purpose of palliative care. In addition to that, the family of women diagnosed with BC usually got the diagnosis of BC at the average age of 47.7.[16]

The discovery of genetic markers BRCA1 and BRCA2 have become increasingly important in determining risk of BC. 50-80% women with BRCA1-positive mutation are estimated to have higher risk of developing BC at the age of 65. After the patient has gone through PM, it could reduce the risk of BC approximately 90%.[9,10] In women with a positive BRCA1 or BRCA2 mutation, prophylactic bilateral TM reduces the incidence of BC at three years of follow-up.[9] However, BRCA status testing is not routinely done in women with high risk of BC in Indonesia. Apart from the high cost that is currently not covered by the national health system, there is still limited guidelines for PM. Other than that, Indonesian women still hesitate the idea of PM, especially when there is not any absolute indication, such as clinical symptoms or supporting radiologic imaging results.

High risk patients have features suggestive of an autosomal dominant predisposition to BC. Established criteria for high-risk are one or more relatives with BC, early age cancer diagnosis, and a family history of ovarian cancer, bilateral BC, or BC in male members.[17] In addition, for patient with BC who have undergo mastectomy, results of triple negative in luminal immunohistochemistry (IHC) testing also categorized as high risk. The occurrence of multiple cases of early-onset BC and/or ovarian cancer within a family suggests a higher probability of a BRCA1 or BRCA2 mutation.[10] Performing tests on at-risk family members can help to identify those who carry the same familial variant and, as a result, require heightened surveillance and targeted treatments in the event of a cancer diagnosis.[18] According to Meijers et al the yearly incidence of BC for patients with a high risk without undergoing PM was 2.5% and the five-year cumulative incidence was 12 percent.[9]

There are several techniques that can be used for PM, such as those mentioned in the previous section. Among those, the most common technique for PMs is subcutaneous mastectomy such as NSM. Other technique used in subcutaneous mastectomy is skin-sparing mastectomy (SSM), which will remove a significant amount of breast tissue while preserving the overlying skin. Both techniques will give better cosmetic results for patients and the positioning of the incision allowed better blood circulation around the nipple-areolar complex (NAC), reducing the risk of ischemic nipple complication. Both techniques will give better cosmetic results for patients. However, as stated by Hartmann et al subcutaneous procedures still carry the risk of recurrence due to the fact that it is not possible to remove all the tissue at risk of malignancy in these procedures. In his study, there are no significant difference between the two techniques, despite the statistics result in the study found that 7 out of 575 people who underwent a subcutaneous mastectomy suffer BC. Another study from Rebeck et al also stated the occurrence of BC would have happened regardless of the type of procedure performed. This is probably because the cancer was already present as microscopic primary BC that has metastasized to the axillary lymph nodes at the time of surgery. Hence, TM is considered the best procedure for PM because this procedure removes large portion of breast tissue, including the NAC, while still preserving the muscle tissue and axillary lymph node beneath the breast.[10,17,19-21]

PM has reduced the incidence of BC around 85 to 90%. Despite of it having significantly high reduction rate, it is still possible for the patient to get BC after PM. Rebbeck et al stated among 105 women who underwent bilateral PM, two individuals (1.9%) were diagnosed with BC. In comparison, among 378 matched controls who did not undergo PM, 184 individuals (48.7%) were diagnosed with BC. These findings were observed over a mean follow-up period of 6.4 years. From this result we can conclude that PM is an effective method for reducing the risk of BC.[18,20] Other than that, PM also provide a

protective effect around 13 years after the procedures.[10,17,20] In a study conducted in 2015, 63 women carrying BRCA1 or 2 gene mutation who underwent NSM reported no newly diagnosed BCs at a median follow-up of 26 months supporting the same conclusion.[22]

CONCLUSION

PM has emerged as a promising solution for patients at high risk of developing BC, particularly those with a positive BRCA mutation. Many researches have consistently shown that PM significantly reduces the incidence of BC and decreases the risk of death from the disease. However, in a clinical setting, it is essential to consider various factors beyond the remarkable benefits PM. A thorough and adequate education must be given to patients, informing them about the risk and complication of the procedure. Furthermore, healthcare professionals can support patients in making informed decisions regarding PM while taking into account their individual circumstances and preferences.

Our suggestion regarding PM, further clinical research and trials can be done to gather information that will serve as a foundation to establish a specific prophylactic treatment guideline. Furthermore, the guidelines hopefully will provide a personalized approach that is adjusted to the clinical condition of the patients.

ACKNOWLEDGEMENTS

Authors would like to thank all colleagues from the surgery department, Diponegoro university and school of medicine and health sciences, Atma Jaya Catholic university of Indonesia for all the support and contributions provided.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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Cite this article as: Sutanto KW, Prayogo DL, Wikanta ER, Stephanie I. Breast cancer incidence after prophylactic mastectomy: a systematic review. Int J Adv Med 2025;12:419-26.