

Preventive health care, 2001 update: Should women be routinely taught breast self-examination to screen for breast cancer?

Nancy Baxter, with the Canadian Task Force on Preventive Health Care

Abstract

Objectives: To evaluate the evidence relating to the effectiveness of breast self-examination (BSE) to screen for breast cancer and to provide recommendations for routine teaching of BSE to women in various age groups as part of a periodic health examination.

Options: Routine teaching of BSE to women.

Evidence: The electronic databases MEDLINE, PreMEDLINE, CINAHL, HealthSTAR, Current Contents and the Cochrane Library were searched for abstracts and full reports of studies published from 1966 to October 2000 that evaluated the effectiveness of BSE in reducing breast cancer mortality. In addition, references of key papers were searched and experts consulted to ensure that all relevant articles had been identified.

Outcomes: Prevention of death from breast cancer was viewed as the most important outcome; other outcomes examined included the stage of cancer detected, the rate of benign biopsy results, the number of patient visits for breast complaints, and psychological benefits and harms.

Values: The recommendations of this report reflect the commitment of the Canadian Task Force on Preventive Health Care to provide a structured, evidence-based appraisal of whether a manoeuvre should be included in the periodic health examination.

Benefits, harms and costs: Breast cancer is the most frequently diagnosed cancer among Canadian women, accounting for 30% of all new cancer cases each year. In 2000 an estimated 19 200 Canadian women would have been diagnosed with breast cancer, and 5500 would have died from the disease. To date, 2 large randomized controlled trials, a quasi-randomized trial, a large cohort study and several case-control studies have failed to show a benefit for regular performance of BSE or BSE education, compared with no BSE. In contrast, there is good evidence of harm from BSE instruction, including significant increases in the number of physician visits for the evaluation of benign breast lesions and significantly higher rates of benign biopsy results.

Recommendations:

- *Women aged 40–49 years:* Because there is fair evidence of no benefit, and good evidence of harm, there is fair evidence to recommend that routine teaching of BSE be excluded from the periodic health examination of women in this age group (grade D recommendation).
- *Women aged 50–69 years:* Because there is fair evidence of no benefit, and good evidence of harm, there is fair evidence to recommend that routine teaching of BSE be excluded from the periodic health examination of women in this age group (grade D recommendation).
- The lack of sufficient evidence to evaluate the effectiveness of the manoeuvre in women younger than 40 years and those 70 years and older precludes making recommendations for teaching BSE to women in these age groups. The follow-

Research

Recherche

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A list of the task force members appears at the end of the article.

This article has been peer reviewed.

CMAJ 2001;164(13):1837-46

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ing issues may be important to consider: *Women younger than 40 years*: There is little evidence for effectiveness specific to this group. Because the incidence of breast cancer is low in this age group, the risk of net harm from BSE and BSE instruction is even more likely. *Women 70 years and older*: Although the incidence of breast cancer is high in this group, there is insufficient evidence to make a recommendation concerning BSE for women 70 years and older.

- *Important note*: Although the evidence indicates no benefit from routine instruction, some women will ask to be taught BSE. The potential benefits and harms should be discussed with the woman, and if BSE is taught, care must be taken to ensure she performs BSE in a proficient manner.

Validation: The findings of this analysis were reviewed through an iterative process by the members of the Canadian Task Force on Preventive Health Care. The task force sent the final review and recommendations to 4 independent experts, and their feedback was incorporated in the final draft of the manuscript.

Sponsors: The Canadian Task Force on Preventive Health Care is funded through a partnership between the Provincial and Territorial Ministries of Health and Health Canada.

In 1994 the Canadian Task Force on the Periodic Health Examination (now the Canadian Task Force on Preventive Health Care) concluded that there was insufficient evidence to recommend for or against breast cancer screening using breast self-examination (BSE) (grade C recommendation).¹ This review examines the evidence published since 1994 and makes recommendations about the value of routine teaching of BSE to women in various age groups.

For breast cancer screening in general, current evidence supports mammography and clinical breast examination for women aged 50–69 years.¹ For women aged 40–49, the evidence is insufficient to recommend for or against routine screening (although upon reaching the age of 40, Canadian women should be assisted in deciding at what age they wish to initiate mammography).² For women over 70, there is limited evidence regarding the benefit of screening.

Many breast tumours are found by women themselves,³ even in highly screened populations.⁴ However, in women regularly performing BSE, many self-detected tumours are found incidentally, not during self-examination.^{3–6} In one study, only 7.6% of women with breast tumours who were practising regular BSE actually detected the tumour by means of self-examination.³ In addition, tumours developing between screens in some age groups (e.g., 50–69) may be inherently more aggressive and thus may not be influenced by slightly earlier detection with BSE.

Burden of suffering

Breast cancer is the most frequently diagnosed cancer among Canadian women, accounting for 30% of all new cancer cases each year. In 2000 an estimated 19 200 Canadian women were diagnosed with the disease, and an estimated 5500 women died from it.⁷ The current age-standardized incidence and mortality rates for Canada are

106 and 27 per 100 000 respectively, with a lifetime risk of death of 1 in 25.8.⁷ Breast cancer is the leading cause of person-years of life lost for women.⁸ The most important risk factor for breast cancer in women is age;⁹ the disease is rare in women under 30.¹⁰ Because most women with breast cancer have no other identifiable risk factors,^{11–13} the effectiveness of teaching BSE should be demonstrated in the general population if it is to affect disease burden.

Methods

With the help of a reference librarian, the electronic databases MEDLINE, PreMEDLINE, CINAHL, HealthSTAR, Current Contents and the Cochrane Library were searched for articles published from 1966 to October 2000 using the following key words: “breast diseases,” “breast self-examination,” “palpation,” “mass screening” and “clinical trials.” The search was limited to English-language abstracts and studies involving humans. Related articles and references of key papers were searched and experts consulted to ensure that no important research was missed. Abstracts of all retrieved papers were read; those relevant to the review were critically appraised.

Prevention of death from breast cancer was viewed as the most important outcome; other outcomes included stage of cancer detected, benign biopsy rate, number of patient visits for breast complaints, and psychological benefits and harms.

The evidence was reviewed systematically using the methodology of the Canadian Task Force on Preventive Health Care.¹⁴ In brief, the principal author rated the quality of the evidence using the methodological hierarchy (Appendix 1). Preliminary drafts of the manuscript were circulated to the task force, comprising expert clinicians and methodologists, before it met in November 1999 and January 2000. A further draft incorporating feedback from 4 independent experts was finalized and endorsed by the task force. Procedures to achieve adequate documentation, consistency, comprehensiveness, objectivity and adherence to the task force’s methodology were maintained at all stages during review development, the consensus process and production of the final manuscript.

Results

Breast self-examination

BSE is a systematic method of self-inspection and palpation of the breast and axilla. There is no conclusive evidence regarding the most effective technique, the best teaching and reinforcement methods or the optimal frequency. Women's ability to detect lumps in silicone breast models has been found to correlate with the number of steps taken in the breast examinations,¹⁵⁻¹⁷ the length of the examination,^{15,18-20} the completeness of the search^{16,21} and the use of the pads of the fingers.^{17,20} Individual aspects of BSE associated with the greatest accuracy and long-term compliance have not been fully elucidated. The currently recommended frequency of once monthly has not been determined with scientific rigour.

In a review of interventions to enhance BSE practice,²² the most effective teaching methods were provision of information, demonstration with individual skills training, and feedback plus prompts such as mailed reminders. Although this review compares studies varying in type of participant and methodology, there is significant evidence that increasing the intervention strategy can improve compliance with BSE.

The overall sensitivity of BSE alone has been estimated to be 26% among screened women, assuming that all interval cancers were detected by BSE.^{23,24} Sensitivity varied with age, from 41% among women aged 35-39 to 21% among those aged 60-74. Specificity was not estimated. In studies of lump detection in silicone breast models, sensitivity ranged from 40% to 89%, and specificity from 66% to 81%.^{25,26} Although sensitivity improved with training, so did the rate of false-positive detection.¹⁹ Sensitivity with the silicone breast model was significantly lower among women over 60.²⁶

Effect of self-examination on breast cancer mortality

Details about studies that have evaluated the effectiveness of BSE in reducing breast cancer mortality are presented in Table 1 (randomized and quasi-randomized controlled trials²⁷⁻³⁴) and Table 2 (cohort and case-control studies³⁵⁻³⁹).

Randomized and quasi-randomized controlled trials

Two randomized controlled trials (RCTs) were conducted in populations with little concomitant screening.

Table 1: Summary of randomized and quasi-randomized controlled trials evaluating the effects of breast self-examination (BSE) on breast cancer outcomes

Trial	Participants	Follow-up/outcomes measured	Results	Strengths/potential biases
Shanghai RCT of BSE training ²⁷	Women aged 31-64; residents of Shanghai and current or former employees of Shanghai Textile Industry Bureau (STIB). Randomly assigned at factory level to BSE training group (<i>n</i> = 133 375) or control group (<i>n</i> = 133 665)	Follow-up: 5 yr Outcomes: breast cancer mortality (from STIB tumour and death registry), and follow-up of breast cancer cases, tumour stages and no. of benign lesions detected	No difference between groups in breast cancer mortality or stage of breast cancer; higher rate of benign biopsy results in BSE group than in control group (1.1% v. 0.5%)	Randomized trial, high participation and compliance rates; no concurrent screening programs. Inadequate length of follow-up (further follow-up underway). Political changes in China may affect ability to complete the study
Russian/WHO RCT of BSE training ²⁸⁻³²	Women aged 40-64; residents of Leningrad (St. Petersburg), randomly assigned at medical clinic level to BSE training group (<i>n</i> = 57 712 at 9 yr) or control group (<i>n</i> = 64 759 at 9 yr)	Follow-up: 9 yr Outcomes: breast cancer mortality among women diagnosed with breast cancer at oncology referral centre and medical clinic, tumour stages and rate of benign biopsy results	No difference between groups in breast cancer mortality or stage of breast cancer; higher rate of benign biopsy results in BSE group than in control group (at 5 yr: RR = 1.5, 95% CI 1.1-1.9)	Randomized trial, high participation rate; no concurrent screening. Decrease in compliance over time; inadequate power (further follow-up underway). Political changes in Russia may affect ability to complete the study
United Kingdom quasi-randomized controlled trial of breast cancer screening ³³⁻³⁴	Women aged 40-49 from 8 geographic areas assigned to following groups by centre: Screening by CBE and mammography (2 centres) (<i>n</i> = 45 607) BSE instruction (2 centres) (<i>n</i> = 63 373) Control group (4 centres) (<i>n</i> = 127 123)	Follow-up: mean 14.4 yr (98.2% of women traced) Outcome: breast cancer mortality (from tumour registry records), rate of benign biopsy results	No difference between groups in breast cancer mortality (RR = 0.99, 95% CI 0.87-1.12); no significant difference detected in secondary analysis by 5-yr age groups. Rate of benign biopsy results significantly higher in BSE group than in control group (0.91% v. 0.61%)	Differences across centres in demographics, rates of breast cancer, medical services, attendance at BSE instruction sessions (31% and 53% at 2 centres respectively) and breast cancer treatment patterns. No assessment of prevalent cancers, or BSE frequency or technique. Last years of follow-up overlapped with large national breast cancer screening study

Note: RCT = randomized controlled trial, WHO = World Health Organization, CBE = clinical breast examination, RR = relative risk, CI = confidence interval.

One trial involved 267 040 women aged 31–64 recruited from 520 factories in Shanghai, China.²⁷ The 133 375 women in the intervention group received extensive BSE training using silicone breast models and personalized instruction, followed by 2 reinforcement sessions and multiple reminders to practise the technique. Women were followed up for the development of breast cancer and death, confirmed by registry data. If the follow-up of breast cancer deaths continues through a 10-year period, the power

to detect a 30% reduction in breast cancer mortality will be 80%. After the first 5 years of follow-up, the cumulative breast cancer mortality rate was not significantly lower among women who received BSE instruction than among the control subjects (30.9 v. 32.7 per 100 000 woman-years). Similar numbers of breast tumours were detected in both groups (331 in the BSE group and 322 in the control group). No consistent, large or significant differences in tumour size or stage were found between the 2

Table 2: Summary of cohort and case-control studies evaluating BSE as a screening technique for breast cancer

Study	Participants	Exposure	Results	Strengths/potential biases
Holmberg et al ³⁵ (cohort study)	548 000 women from 26 US states recruited by volunteers in 1959 for large population-based study; 93% followed to 1973. For those who died, copies of death certificates were obtained to determine cause of death	Self-reported interview data from 1959 served as baseline. Women divided into those performing BSE ($n = 177\ 602$) and those not ($n = 272\ 554$)	No difference in breast cancer mortality between groups based on BSE performance reported in 1959, even after adjustments for covariates	Large, prospective study. Poor measure of BSE performance; no objective assessment or evaluation of technique. Cause of death on death certificate accepted as cause of death
Harvey et al ³⁶ (case-control study nested in Canadian NBSS RCT of breast cancer screening)	Women aged 40–59 without breast cancer recruited in 1980–1985. <i>Cases:</i> 163 women who died of breast cancer and 57 with distant metastases; cases had to have been diagnosed 2 yr after study entry <i>Controls:</i> 10 per case randomly selected from NBSS and matched by 5-yr age group, screening centre and year of enrolment, and by randomized group in NBSS study	All participants given BSE instruction at entry. Annual measures of BSE frequency. Objective measure of BSE technique for subgroup analysis	Similar proportions of cases and controls practised BSE before study entry ($p = 0.10$). Frequency of BSE not associated with case status. Omission of specific components of BSE technique associated with increased risk of death from breast cancer among cases: for those who omitted 3 key manoeuvres at 2 yr before diagnosis, the OR was 2.95 (95% CI 1.19–7.30; $p = 0.02$); no difference between groups at 1 or 3 yr	Study designed to reduce recall, lead-time and length biases. Controls selected from same population as larger study. Objective measures of BSE performance and frequency. Multiple comparisons in post hoc analysis without statistical adjustment. High compliance with BSE in trial; thus, compliers with BSE may differ from noncompliers in other ways that affect breast cancer mortality
Muscat et al ³⁷	<i>Cases:</i> 453 women with newly diagnosed advanced breast cancer (axillary or distant metastases, or tumour > 2 cm in diameter) <i>Controls:</i> 887 age-matched women randomly selected from population	Self-reported BSE frequency before study entry	No difference in BSE frequency between groups	Study designed to avoid lead-time bias. Retrospective interview
Newcomb et al ³⁸	<i>Cases:</i> 209 women with advanced breast cancer (TNM stage III or IV) <i>Controls:</i> 433 age-matched women without advanced breast cancer	Self-reported BSE practice	No difference in BSE frequency between groups. Compared with cases, controls were more proficient at BSE (OR 0.54, $p = 0.003$) and more likely to have had clinical breast examination within 5 yr of reference date*	Study designed to avoid lead-time bias. Retrospective interview, self-reported BSE practice without confirmation, no standardized measure of proficiency. Multiple comparisons with no statistical adjustment. No adjustment in analysis for CBE
Gastrin et al ³⁹	56 177 Finnish women; 29 018 women returned BSE compliance calendars and were linked to the Finnish Cancer Registry	All women were enrolled in BSE information session and mammography self-referral system and asked to complete BSE compliance calendars annually	Lower breast cancer mortality (RR = 0.75) among women returning calendars than among women in general female population (excluding women diagnosed with breast cancer within the first 2 yr of the program)	Population-controlled cohort study. Designed to avoid lead-time bias, but not length or over-diagnosis bias. Appeared to be significant selection bias (twice as many subjects in cohort as in general population attended college)

Note: NBSS = National Breast Screening Study, OR = odds ratio, TNM = tumour-node-metastasis.

*Date of breast cancer diagnosis in a case subject was used as the reference date for both the case and matched control subject.

groups. A random sample of women from each group was tested for their ability to detect lumps in silicone breast models. Women from the BSE group found more lumps and demonstrated greater specificity than did those from the control group. Competency of BSE was assessed in subgroups of the intervention group and was judged to be good, with more than 90% of the women correctly palpating most of the breast even 1 year after reinforcement of BSE technique. The study's large size and its high participation and compliance rates are strengths. Although the methods used to classify tumours by size and stage may have been nonstandardized, any misclassification would not bias mortality outcomes; however, they could obscure any real differences between the groups for other comparisons.

The other RCT was conducted in St. Petersburg, Russia, and involved women aged 40–64 randomly assigned to BSE educational programs or to a control group.^{28–32} Five-year and 9-year follow-up data were published for 122 471 women;^{30–32} the 9-year follow-up report was published in Russian, and an English translation was obtained from the authors. Women in the BSE arm attended small-group sessions, run by trained nurses or physicians, that involved a demonstration of the BSE technique. Among 400 randomly selected women, the self-reported compliance rate for BSE 5 or more times per year was 82% at 1 year but decreased to 55.8% by 5 years. Medical personnel assessed the quality of BSE performed by this subset of women as good. After 9 years of follow-up 493 of the 57 712 women in the BSE group and 446 of the 64 759 women in the control group had breast cancer. There was no difference in tumour stage between the BSE and control groups, nor was there a difference in breast cancer mortality (0.27% [$n = 157$] and 0.26% [$n = 167$] respectively). Although a well-developed cancer registry was lacking in St. Petersburg, there is no evidence that any failure to find all cases would have biased the study in either direction. Inadequate information about the control group could theoretically mask a high rate of BSE (although unlikely in this population) and decrease the ability of the study to detect a benefit in the intervention group. Because of lower-than-expected compliance and cancer incidence,⁴⁰ there was inadequate power to detect a 20% difference in mortality between the 2 groups, and the study was extended until the year 2001. Although this study is unable to answer the question of the effect of mass teaching of BSE on mortality at this time, the failure to find any difference between the 2 groups in breast cancer stage decreases the likelihood of a positive study.

A quasi-randomized trial in the United Kingdom in a large population of women aged 45–64 years at 8 centres with little concomitant screening^{33,34} showed no reduction in breast cancer mortality between the BSE and control centres after 16 years of follow-up. However, significant differences existed between the centres in methods of recruitment for BSE teaching, breast cancer care and the pre-

trial breast cancer mortality rate, all of which may have confounded the results of the study. A case–control study at one of the centres demonstrated a significant reduction in deaths from breast cancer in those attending BSE classes;⁴¹ no adjustment for confounders was attempted. Because the same data were reported in the quasi-randomized controlled trial, a study of stronger design, the case–control study was not considered separately.

Cohort and case–control studies

A prospective cohort study in the United States involving 450 156 women over age 30 demonstrated no benefit of self-reported BSE practice in preventing death from breast cancer, regardless of age.³⁵ Self-reporting of BSE and unverified data from death certificates were potential limitations. The strengths of the study included its large sample, and the other breast cancer risk factors measured in the study significantly influenced risk of breast cancer mortality in the expected direction.

Three well-performed case–control studies evaluated the effectiveness of BSE.^{36–38} No difference in self-reported frequency was found between the cases and controls in any of these studies. One study showed that, although women who reported examining their underarms were at low risk of advanced breast cancer (odds ratio 0.48, 95% confidence interval [CI] 0.33–0.69), women who reported examining their nipples appeared to be at increased risk (relative risk 1.48, 95% CI 1.05–2.09). The fact that more women in the control group than in the case group had clinical breast examinations in the 5 years before the reference date was not controlled for in the analysis.³⁸ (The date of cancer diagnosis in a case subject was used as the reference date for both the case and matched control subject.)

The case–control study nested within the Canadian National Breast Screening Study eliminated lead-time, length and recall bias through prospective data collection.³⁶ No difference was found in self-reported BSE frequency between the case and control subjects. In a subgroup analysis, the performance of some components of BSE was found to differ between case and control subjects; however, these components were not selected a priori but based on a regression analysis, which increased the chance that the results may have been confounded.³⁶ Of note, one component of BSE in this study, the use of circular palpation, was associated with an increased risk of death from breast cancer or metastatic disease at 1 year preceding diagnosis. Women in this study were highly compliant with BSE, with over 74% usually performing visual examination, 71% using 3 digits for examination and 70% using the finger pads by the fifth year of the study.³² The possibility that compliers with these components of BSE differed significantly from noncompliers in ways other than BSE performance must therefore be entertained and may explain the results found.

Other studies

A Finnish cohort study³⁹ involving 56 177 women reported a breast cancer mortality ratio of 0.75 in the BSE group, lower than that in the general female population. However, methodological problems with this study, particularly selection bias, make it impossible to draw firm conclusions. A large number of cross-sectional studies examined the effect of BSE on various measures of cancer stage and survival.^{39,43-62} Because these have shown mixed results and are subject to lead-time, length and selection bias, they were not included in this analysis.

Effect of proficiency on breast cancer mortality

In 2 of the case-control studies described in Table 2^{36,38} and in an observational study,⁴⁹ secondary analyses were used to evaluate the effect of BSE technique. In the study by Newcomb and associates,³⁸ although BSE performance was not effective overall, in subgroup analysis more thorough BSE was associated with a decreased risk of advanced breast cancer.³⁸ However, no statistical adjustment was made for multiple comparisons. Also, subjects highly compliant with thorough BSE may differ significantly from noncompliant subjects in other ways (e.g., age,^{16,20,21,63} health motivation,⁶⁴ marital status,¹⁷ educational level,¹⁷ perceived barriers to BSE⁶⁴ and perceived susceptibility or family history of breast cancer⁶⁴), which may influence breast cancer mortality. In the secondary analyses, the effectiveness of some individual components of BSE was also evaluated, with conflicting results. Because of potential selection and other biases, and susceptibility to type I error, it is impossible to draw conclusions about BSE proficiency based on results of such studies.

Potential harms

Although considered a relatively minor procedure, breast biopsy causes permanent scarring and may cause significant breast deformity and emotional distress.⁶⁵⁻⁶⁷ In the UK trial the rate of benign breast biopsy results was significantly higher in the centres assigned to BSE than in the control centres (0.91% v. 0.61%).⁶⁸ Differences in benign biopsy rate were reported between the 2 BSE sites (0.71% and 1.28%); however, both sites had higher rates than those in the control sites.⁶⁸

The Russian trial reported a significant difference in the proportion of women who presented for assessment of signs or symptoms of breast disease (7.5% in the BSE group v. 3.8% in the control group at 9 years).³² After 5 years, there was a significantly higher rate of benign biopsy results among the BSE-trained women than among the control subjects (0.21% v. 0.14% respectively; relative risk 1.5; 95% CI 1.1-1.9). In addition, the benign needle biopsy rate was higher in the BSE group than in the control group (0.57% v. 0.32%). No significant dif-

ference in the rate of malignant breast biopsy results was found between the groups.²⁹ In the Shanghai trial, although the rate of benign breast biopsy results was not provided, many more benign lesions were detected by women in the BSE group than in the control group (1.09% v. 0.47%), with a nearly equal number of breast tumours diagnosed.²⁷

Negative psychological impacts related to BSE training include increased levels of worrying, anxiety and depression,^{15,69} and increased numbers of follow-up investigations because of false-positive findings.^{65,70,71}

No published studies provided a clear breakdown by age of the outcomes of investigating positive BSE findings. However, because the incidence of breast cancer is low among women under 30 and breast lumps are commonly benign in that age group, it would be expected that the false-positive rate would be much higher among younger than among older women.⁷²

Costs

Teaching and reinforcing BSE are costly activities and potentially divert resources from other preventive strategies. Although no Canadian data exist, a US cost-effectiveness analysis of 2 nursing-led BSE education programs estimated the cost to be between US\$574 and US\$848 per competent frequent self-examiner added.⁷³ A well-conducted trial showing no evidence of efficacy would justify utilization of limited funds and resources for other purposes. Some evidence exists about the effect of BSE programs on health care utilization: one study indicated that a hospital management organization (HMO)-based BSE program may increase utilization of health services by all women,⁷⁴ and another study showed that, 1 year after training, women who entered a trial of BSE education had similar health care use to those in the control groups.¹⁵

Summary

There were 7 studies that evaluated the effectiveness of BSE in preventing death from breast cancer. Although neither trial has reached maturity, 2 large RCTs have shown to date no difference in breast cancer mortality, or stage at diagnosis, between women taught BSE and control subjects.^{27,32} Although it is important that both trials continue to completion, these current findings make the possibility of a large impact of BSE on mortality unlikely. Political and social changes in China and Russia may jeopardize the completion of both studies.

After 16 years of follow-up in the UK quasi-randomized trial, no reduction in breast cancer mortality was found between the BSE and control centres. However, the significant differences between the centres in methods of recruitment for BSE teaching, breast cancer care and pretrial mortality may have confounded the results.³⁴

A large US cohort study of women over 30 demonstrated no effect of self-reported BSE practice on breast cancer mortality. No confirmation of BSE performance or adequacy was attempted, and this may have biased the study toward the null hypothesis.³⁵ Three case-control studies were properly performed to evaluate the effectiveness of BSE.³⁶⁻³⁸ Although they may have shown a benefit from more thorough BSE, no statistical adjustment was made for multiple comparisons. Also, because subjects highly compliant with thorough BSE may differ significantly from noncompliant subjects in other ways that might affect breast cancer mortality, this result should not be given undue weight. In summary, no appropriately designed study has shown a benefit from regular performance of BSE or BSE education over no BSE.

In contrast, there is good evidence of harm from BSE instruction. Both RCTs demonstrated a significant increase in the number of physician visits for the evaluation of benign breast lesions in the groups assigned to BSE education. The Russian study reported a benign breast biopsy rate that was significantly higher in the group assigned to BSE instruction than in the control group, whereas the number of biopsies showing cancer was virtually identical between the 2 groups. In the UK trial, the benign biopsy rate was also significantly higher in the centres assigned to BSE education than in the control centres.

To conclude, many breast tumours are discovered by women themselves, and although the evidence does not support routinely teaching BSE, women should be instructed to promptly report any breast changes or concerns. Any woman who wishes to practise BSE and who requests instruction should be counselled regarding the risks and benefits, and the health care professional should ensure that BSE instruction is thorough and that the woman is performing BSE in a proficient manner.

Recommendations

By the Canadian Task Force on Preventive Health Care

The recommendations for routine teaching of BSE to women in various age groups are summarized in Table 3.

Women aged 40-69 years

Women aged 40-49 years: In this age group, mammography and clinical breast examination are not of clear benefit, and studies evaluating the effectiveness of BSE have shown no benefit. In addition, the evidence for increased risk of benign biopsy and the lower incidence of breast cancer in this younger group indicates an increased potential for net harm. Thus, there is fair evidence to recommend that routine teaching of BSE be excluded from the periodic health examination of women aged 40-49 (grade D recommendation).

Women aged 50-69: There is fair evidence to conclude that screening with BSE is not effective in reducing breast cancer mortality in populations not receiving mammography or routine clinical breast examinations. Because mammography and clinical breast examinations reduce breast cancer mortality, they are currently recommended in Canada for this age group. It is highly unlikely that screening with BSE would confer additional benefits to screening of proven efficacy. In addition, there is good evidence that BSE education increases the number of physician visits for assessment of breast complaints and the rate of biopsies of benign breast lesions. Because there is good evidence of harm and fair evidence of no benefit, there is fair evidence to recommend that routine teaching of BSE be excluded from the periodic health examination of women aged 50-69 (grade D recommendation).

Table 3: Summary table of recommendations for the routine teaching of BSE to women

Manoeuvre	Effectiveness	Levels of evidence*	Recommendation*
Routine teaching of BSE to women aged 40-49 yr	Evidence of no benefit in terms of survival from breast cancer	RCTs (I), ^{27,31,32} nonrandomized trial (II-1), ³⁴ cohort study (II-3), ³⁵ case-control studies (II-3) ³⁶⁻³⁸	Because there is fair evidence of no benefit, and good evidence of harm, there is fair evidence to recommend that routine teaching of BSE be excluded from the periodic health examination of women aged 40-49 (grade D†)
	Evidence of increased no. of physician visits for breast problems and increased rate of benign biopsy results	RCTs (I), ^{27,31,32} nonrandomized trial (II-1) ³⁴	
Routine teaching of BSE to women aged 50-69 yr	Evidence of no benefit in terms of survival from breast cancer	RCTs (I), ^{27,31,32} nonrandomized trial (II-1), ³⁴ cohort study (II-3), ³⁵ case-control studies (II-3) ³⁶⁻³⁸	Because there is fair evidence of no benefit, and good evidence of harm, there is fair evidence to recommend that routine teaching of BSE be excluded from the periodic health examination of women aged 50-69 (grade D†)
	Evidence of increased no. of physician visits for breast problems and increased rate of benign biopsy results	RCTs (I), ^{27,31,32} nonrandomized trial (II-1) ³⁴	

*See Appendix 1 for definitions of the levels of evidence and grades of recommendations.

†Although the evidence indicates no benefit from routine instruction, some women will ask to be taught BSE. The potential benefits and harms should be discussed with the woman, and if BSE is taught, care must be taken to ensure that she performs BSE in a proficient manner.

Note: The lack of sufficient evidence to evaluate the effectiveness of the manoeuvre in women younger than 40 years and those 70 years and older precludes making recommendations for teaching BSE to women in these age groups. The following issues may be important to consider: *Women younger than 40 years:* There is little evidence for effectiveness specific to this group. Because the incidence of breast cancer is low in this age group, the risk of net harm from BSE and BSE instruction is even more likely. *Women 70 years and older:* Although the incidence of breast cancer is high in this group, there is insufficient evidence to make a recommendation concerning BSE for women 70 years and older.

Women younger than 40 and those 70 years and older

The lack of sufficient evidence to evaluate the effectiveness of the manoeuvre in women younger than 40 and those 70 years and older precludes making recommendations for teaching BSE to women in these age groups. The following issues may be important to consider.

Women under 40 years: There is little evidence for the effectiveness of routinely teaching BSE that is specific to this age group. Because the incidence of breast cancer is low in this age group, the risk of net harm from BSE and BSE instruction is even more likely.

Women 70 years and older: Although the incidence of breast cancer is high in this age group, there is insufficient evidence to make a recommendation concerning BSE for women in this age group.

Important note

Although the evidence indicates no benefit from routine instruction, some women will ask to be taught BSE. The potential benefits and harms should be discussed with the woman, and if BSE is taught, care must be taken to ensure that she performs the examinations in a proficient manner.

By other organizations

Organizations that currently recommend the routine teaching of BSE include the American Academy of Family Physicians,⁶³ the American College of Obstetricians and Gynecologists,⁶⁴ the American Cancer Society⁷⁵ and the Canadian Cancer Society.⁷⁶

In 1993 the Evaluation Committee of the European Society of Mastology concluded that there was no benefit from routine BSE and no support for public health programs for BSE education.⁷⁷

The US Preventive Services Task Force found insufficient evidence to recommend for or against teaching BSE and insufficient evidence to recommend changing current BSE practices.⁷⁸ This recommendation is currently under review.

Research agenda

The RCTs of BSE effectiveness should be continued until adequate power is achieved. A well-designed trial of BSE effectiveness in a population receiving screening techniques of proven effectiveness (mammography and clinical breast examination for women 50–69 years) would be more applicable to the Canadian population but is unlikely to occur. Research into BSE technique may be useful. Ways of minimizing the detection of benign lesions should also be examined. There is a need to determine the extent to which older women (70 years and older) are likely to benefit from any screening programs for breast cancer.

This paper is based on the full technical report available from the office of the Canadian Task Force on Preventive Health Care (see the contact information at the end of the bibliography).

Competing interests: None declared.

Contributors: Dr. Baxter, as primary author, was responsible for all aspects related to initiating the topic, reviewing the evidence, drafting the original manuscript for review by the Canadian Task Force on Preventive Health Care and making subsequent revisions following input from the task force and external reviewers. The task force had 2 main roles: first, each task force member thoroughly reviewed the draft systematic review at several meetings, provided feedback to the author on the evidence review and deliberated with the author to arrive at practice recommendations; second, the task force office managed the committee analytical process, arranged external expert review and supported the author in preparing literature searches, drafting tables or other supplementary materials, and revising the various drafts of the manuscript.

Acknowledgements: The Canadian Task Force on Preventive Health Care thanks Dr. Suzanne W. Fletcher and Larissa Nekhlyudov, Department of Ambulatory Care and Prevention, Harvard Medical School, Boston, Mass., Dr. Russell Harris, University of North Carolina at Chapel Hill, Chapel Hill, NC, and Dr. Kathleen I. Pritchard, Toronto–Sunnybrook Regional Cancer Centre, Toronto, Ont., for reviewing an earlier draft of this manuscript. The views expressed in this report are those of the author and the task force and do not necessarily reflect the positions of reviewers.

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Appendix 1: Canadian Task Force on Preventive Health Care levels of evidence and grades of recommendations**Levels of evidence**

I	Evidence from at least one well-designed randomized controlled trial
II-1	Evidence from well-designed controlled trials without randomization
II-2	Evidence from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group
II-3	Evidence from comparisons between times or places with or without the intervention; dramatic results from uncontrolled studies could be included here
III	Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees

Grades of recommendations

A	Good evidence to support the recommendation that the condition or manoeuvre be specifically considered in a periodic health examination (PHE)
B	Fair evidence to support the recommendation that the condition or manoeuvre be specifically considered in a PHE
C	Insufficient evidence regarding inclusion of the condition or manoeuvre in, or its exclusion from, a PHE, but recommendations may be made on other grounds
D	Fair evidence to support the recommendation that the condition or manoeuvre be specifically excluded from a PHE
E	Good evidence to support the recommendation that the condition or manoeuvre be specifically excluded from a PHE

HOLIDAY REVIEW 2001

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