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French college of gynecologists and obstetricians (CNGOF) recommendations for clinical practice: Place of breast self-examination in screening strategies

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ABSTRACT

Breast cancer is the most common female cancer in the world. Numerous studies have shown that the risk of metastatic disease increases with tumor volume. In this context, it is useful to assess whether the regular practice of formal breast self-examination (BSE) as opposed to breast awareness has an impact on the number of cancers diagnosed, their stage, the treatments used and mortality.

Design: The Commission of Senology (CS) of the Collège National de Gynécologie et Obstétrique Français (CNGOF) respected and followed the Grading of Recommendations Assessment, Development and Evaluation method to assess the quality of the evidence on which the recommendations were based.

Methods: The CS studied 16 questions individualizing four groups of women (general population, women aged over 75, high-risk women, and women previously treated for breast cancer). For each situation, it was determined whether the practice of BSE versus abstention from this examination led to detection of more breast cancers and/or recurrences and/or reduced treatment and/or increased survival.

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Results: BSE should not be recommended for women in the general population, who otherwise benefit from clinical breast examination by practitioners from the age of 25, and from organized screening from 50 to 74 (strong recommendation). In the absence of data on the benefits of BSE in patients aged over 75, for those at high risk and those previously treated for breast cancer, the CS was unable to issue recommendations. Thus, if women in these categories wish to undergo BSE, information on the benefits and risks observed in the general population must be given, notably that BSE is associated with a higher number of referrals, biopsies, and a reduced quality of life.

1. Introduction

The annual incidence of breast cancer in France continues to rise, from 29,934 new cases in 1990 to around 61,214 new cases by 2023 (+104 %). The median age at onset is now 64 [1]. It is estimated that 30 % of this increase is due to the growth of the French population, 23 % to aging, and 51 % to an increase in risk factors (the main ones being hormonal and reproductive factors, alcohol, overweight and sedentary lifestyle) [1]. According to the International Agency for Research on Cancer (IARC) [2], the estimated age-standardized breast cancer incidence rates in 2020 is 88.9/100,000 for women under the age of 70 and 213.6/100,000 for women over the age of 70 in France.

Nearly a million women are treated for breast cancer in France, and around 12,000 die from it every year, making it the most prevalent cancer and the leading cause of cancer-related death in women [3]. Given the high incidence of breast cancer, and even if the recommendations of the French National Authority for Health do not include scientific arguments to prove the value of clinical examination in reducing breast cancer mortality or promoting early diagnosis, clinical breast exam is recommended annually in France for all women, from the age of 25, by a general practitioner or a gynecologist [4].

In addition, given that 79.3 % (n = 46,357) of breast cancers are diagnosed after the age of 50 [5], organized screening is offered to women aged 50 to 74, based on a clinical breast examination and mammography (with double reading) every two years, possibly supplemented by ultrasound. The mammography is first interpreted in a medical imaging center and a second evaluation is performed in a centralized center. This double reading allows more cancers to be detected. Mammography has been the mainstay of organized screening in France since 2004, with the possibility of integrating tomosynthesis in the future. The development of dematerialization and the resolution of tomosynthesis image transfer (in the centralized center) problems will probably enable tomosynthesis to be used for both first and second readings of screening mammography [6]. In cases of high breast risk (genetic, histological, or personal), other screening modalities are proposed, starting earlier, and combining clinical examination, mammography and sometimes breast magnetic resonance imaging on an annual basis [7].

In addition to these screening methods (clinical or including imaging), other methods are recommended in some countries, such as breast awareness (BA) [8]. BA is defined as women's awareness of the appearance, feel and changes to their breasts, whether physiological (linked to pregnancy, menopause, weight variations, etc.) or abnormal (appearance of a lump, changes to the nipples, etc.), to identify pathological changes at an early stage. The BA, which in theory provides women with the knowledge, skills, and confidence to detect an abnormal change in their breasts and promptly consult a health professional, has been little evaluated [9]. Evidence of its effectiveness in terms of anticipating diagnosis and reducing breast cancer mortality is still limited [10].

BA must be distinguished from breast self-examination (BSE), which is a much more structured and regular method of breast analysis by women. BSE is a seemingly simple method involving inspection and palpation of the breasts and lymph nodes, which women are asked to repeat regularly (often monthly) to detect any abnormalities, and to consult a doctor if they do occur [11]. Several local, national, and international initiatives encourage women to undergo BSE as soon as they reach the age of majority, usually monthly, to encourage early diagnosis of breast cancer, in the hope of reducing the burden of treatment and improving breast cancer mortality [12]. Most of these initiatives do not involve any evaluation of the benefits or risks associated with the practice.

The Commission of Senology (CS) of the *Collège National des Gynécologues et Obstétriciens Français* (composed of 17 multidisciplinary experts and 5 invited members) therefore decided, based on an updated review of the international literature, to publish recommendations on the role of BSE in breast cancer screening in four groups of women: under 75, over 75, at high risk of breast cancer and previously treated for breast cancer.

2. Methods

Following the advice of the CNGOF's Scientific Advisory Board, the CS set up a working group to answer the questions, following the CNGOF's methodology [13]: a steering committee defined the questions to be addressed and designated the writers in charge of each one. The questions were formulated according to the PICO (Patients, Intervention, Comparison, Outcome) format.

An extensive bibliographical search in English or French was carried out using Medline/PubMed, Embase and Cochrane library. The CS has first identified randomized controlled clinical trials, systematic reviews, meta-analyses from 1992 to 2022 concerning women with no history of breast disease, women with history of breast cancer, elderly women, performing BSE or not, performing breast screening or not. The CS used the following "MeSH" and "non-MeSH" terms: "breast self-exam"; "breast self-examination"; "mammography"; "ultrasonography"; "survival"; "mortality"; "fine-needle aspiration"; "core-biopsy"; "palpable mass"; "benign breast disease"; "benign breast tumor"; "benign breast lump"; "fibroadenoma"; "macrobiopsy"; "breast cancer"; "cyst"; "breast carcinoma"; "incidence"; "sensitivity"; "specificity"; "elderly";."screening". Different combinations of items were used with the terms "humans"; "female" AND "Clinical Trial" [ptyp]; "Meta-Analysis" [ptyp]; "Randomized Controlled Trial" [ptyp]; "Comparative Study" [ptyp]; "Controlled Clinical Trial" [ptyp] OR "Multicenter Study" [ptyp]). The search of these databases was completed by reviewing the references contained in the meta-analyses, systematic reviews and original articles included (Fig. 1).

Our systematic review followed the recommendations of the PRISMA statement [14]. Five reviewers independently (VL, XF, CM, JS, KA) searched the relevant studies that assessed the accuracy of BSE to reduce breast cancer mortality and increase breast cancer diagnosis. They excluded articles that included only clinical breast examen and not BSE and articles published in languages other than French and English. The discrepancies were resolved by consensus with VL, XF, CM, JS, KA.

The CS used the GRADE method (Table 1). After a quantitative analysis of the literature, this method made it possible to determine for each question individually the quality of evidence, estimated confidence from quantitative analysis, and the level of recommendation. Quality of evidence is divided into four categories: High, Moderate, Low and Very Low. Analysis of the quality of evidence is carried out for each criterion, and an overall level of evidence is defined based on the quality of evidence for crucial criteria. The final formulation of recommendations is

always binary: either positive or negative, and either strong or weak [13]. Five reviewers independently (XF, VL, CM, JS, KA) scored the relevant studies according to the GRADE method. The discrepancies were resolved by consensus.

3. Results

3.1. Bibliographic search

From the three databases (Medline/PubMed, Embase and Cochrane library), 342,605 publications were screened. After exclusion, 7920 reports were sought for retrieval with a total of 136 reports assessed for

Table 1
GRADE method [14].

Grade of recommendation	
High	Research unlikely to change confidence in the estimated effect.
Moderate	Research is likely to change confidence in the estimated effect and may change the estimated of the effect.
Low	Research will surely have an impact on confidence in the estimated effect and will probably modify the estimate of the effect itself.
Very low	The estimated effect is highly uncertain.

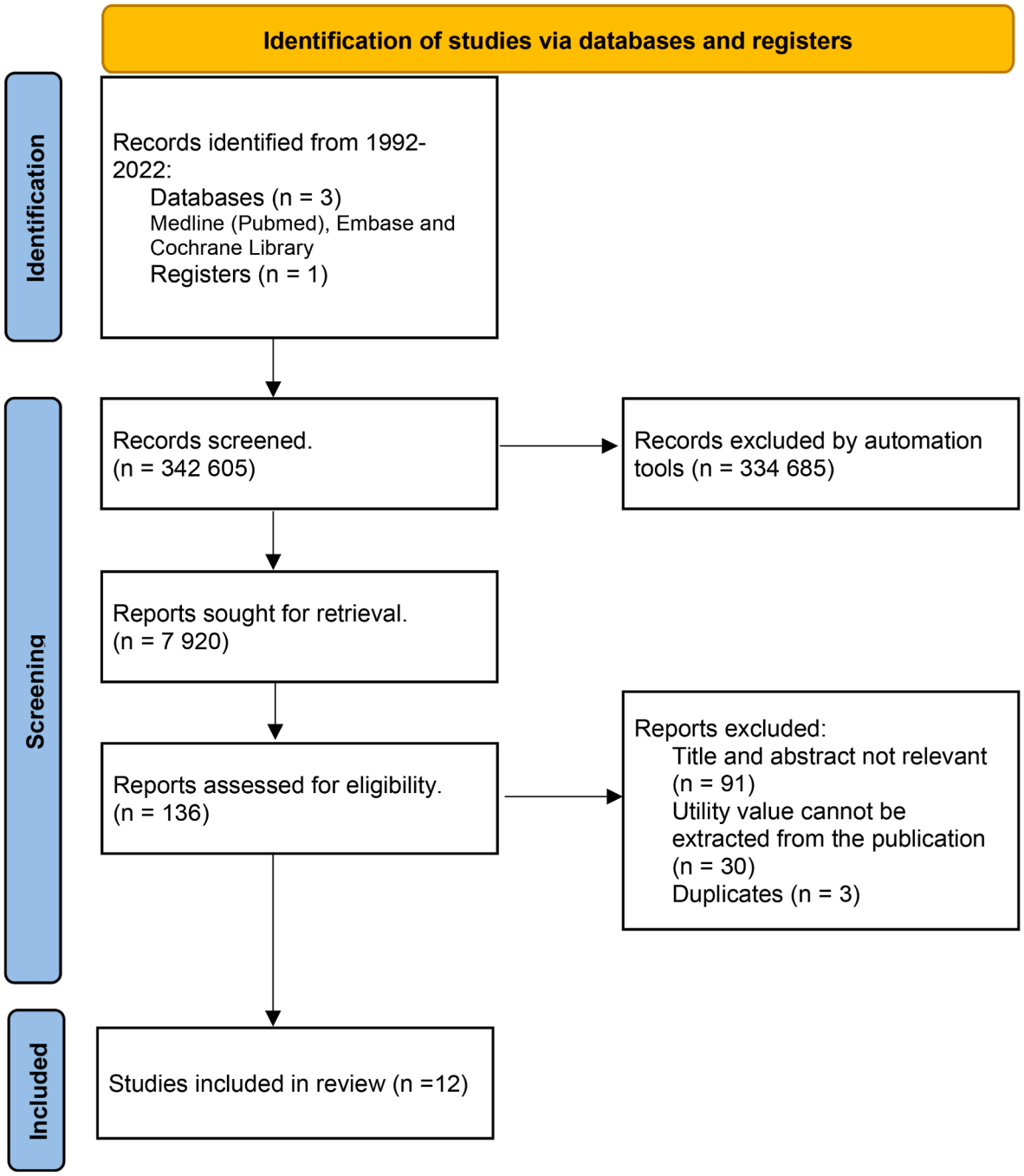

Fig. 1. The selection of randomized controlled trials, systematic reviews and meta-analyses covered the period from 1992 to 2022. Different groups of women were analyzed: with or without a history of breast disease, with or without a history of breast cancer, young or older, practicing or not practicing breast self-examination, or included or not in a breast cancer screening program.

eligibility using previously described MeSH and non MeSH terms. Exclusion was then done when title and abstract were irrelevant (n = 91), when utility value couldn't be extracted from the publication (n = 29) or when duplicated studies were found (n = 3). A total of 12 studies were included in the review (Fig. 1). Kappa coefficient was not used.

3.2. Recommendation fields

The members of the working group have chosen to address 16 questions concerning the use of BSE for breast cancer screening in four groups: the non-elderly general population, the general population over 75, women at high risk of breast cancer, and women previously treated for breast cancer (screening for breast cancer recurrence). A question was added on how BSE should be carried out, in terms of method, training, frequency, etc.

After synthesizing the arguments put forward by the authors and applying the GRADE method (Tables 1 and 2), the recommendations were formalized by the working group, submitted to the CNGOF Scientific Advisory Board, then to a reading group (independent of the working group) and to a patient association. The working group revised the recommendations considering comments made by these reviewers (Table 3).

3.3. Rationale, questions asked, summary of evidence and recommendations

3.3.1. Modalities of breast self-examination (BSE)

BSE is a systematic method of self-inspection and palpation of the breasts and axillary area. There is no conclusive evidence regarding the most effective technique, the best teaching and reinforcement methods, or the optimal frequency. In intervention studies [15–17], BSE was taught in groups of five to 15 people, usually in three stages: inspection in a mirror, circular palpation of the gland and axillary hollow by the contralateral arm, and then a search for nipple discharge. The frequency of BSE proposed varied from one study to another [18–21], ranging from once a month to five or six times a year, or without clear specification, the usual proposal being "several times a year".

1. Women in the general population under 70–75 years of age

To answer the question of the place of BSE in breast cancer screening in the non-elderly general population, several PICO questions were formulated on cancer diagnosis and impact on survival for women practicing BSE according to several screening contexts.

Question 1. In women under 70–75 years of age not participating in an individual or organized screening program (P), does regular BSE (I) versus no BSE (C) increase the amount of detected breast cancers (sensitivity, specificity)?

3.3.1.1. Argument. A Thai study published in 2019 [22] considered BSE as a screening tool. In Thailand, there is difficult access to mammography and no organized screening for breast cancer. A cohort study evaluated a BSE screening program involving 1,906,697 women aged 30 to 70 (61 % of women were under 50). The BSE training tool was based on a BSE follow-up booklet given to women with the support of health volunteers from the village. The booklet had to be filled in monthly by the women and was checked every month by the health volunteers. Follow-up took place from 2012 to 2017. In this study, the participants who reached the regularity (at least once in every 2 months) of BSE within 12 months before diagnosis were defined as regular BSE. The participation rate of women with regular BSE was 72 %. In case of an abnormality detected at BSE, the patient was referred to health personnel for a clinical examination, possibly followed by imaging and biopsy. During the study, 2956 breast cancers were diagnosed, 48 % of them stage II and 31 % stage III and IV. Breast cancer mortality was significantly higher in patients who underwent BSE irregularly than in those who underwent it regularly (OR = 1.702, 95 % CI = 1.235–2.347, $p < 0.05$), but a lead-time bias cannot be excluded and could be an explanation for these findings. Moreover, there was no control arm in this study, and no analysis by age subgroup (between 30 and 70 years). Another limitation of this study is the lack of data on breast cancer size, only available for 2031 patients (68.7 % of all patients with breast cancer).

As a screening tool for the general population, BSE was the subject of a large randomized controlled study in China (Shanghai) [17]. In this study, 266,064 women working in the textile industry who were not being screened by mammography were randomized to receive or not receive information about BSE (most of these women were aged between 30 and 60). BSE was initially taught to each woman in groups of 10 in three steps: inspection in front of a mirror, palpation with circular motion in standing and lying positions, axillary palpation, and finally pressure/expression of the nipples. Palpation on a silicone simulation tool was also performed as part of the training. A reminder of the BSE instructions was given at one and three years. After 10–11 years' follow-up, 864 breast cancers were found in the BSE group, compared with 896 in the control group (not statistically significant). The amount of benign breast lesions detected in the BSE group was higher than in the control group (3253 versus 2,189, $p < 0.05$). Population adherence to BSE was low, with only 41 % of the population attending BSE follow-up sessions.

A Russian study of 122,000 women aged between 40 and 64 followed the same pattern between 1985 and 1989 in Saint Petersburg [16]. BSE was taught in groups of 5–20 women, with a demonstration of the technique on one of the women by paramedical or medical staff. The women were given a follow-up schedule for the BSE. The BSE education sessions resulted in a higher frequency of visits to specialists by women complaining of breast "pathology" and a higher number of biopsies or excisions of benign lesions (RR = 1.5; 95 % CI = 1.1 to 1.9) compared with the control group (1138 vs. 797). In this prospective study, 190 breast cancers were diagnosed in the BSE group versus 192 in the control group, with no difference in terms of size, lymph node invasion or metastasis [16]. Adherence to BSE was 82 % after one year and 56 % after four years. This Russian study was included in 2003 in a meta-analysis [23], which surprisingly reported that at the end of the Russian study, more cancers were found in the BSE group than in the control group (RR 1.24, 95 % CI = 1.09 to 1.41). The authors highlighted the biases of the Russian study, with mammograms added over time in the BSE arm, explaining the increased number of cancer diagnoses in the intervention arm at the end of the study reported in their meta-analysis.

The retrospective cohort conducted by Tu et al. in 2006 [24] showed no association between stage of breast cancer at diagnosis and BSE. In total, 75 % of women performed BSE and 27 % performed adequate BSE. Women reporting higher duration, frequency and quality of BSE underwent more diagnostic mammograms. Participants diagnosed with breast cancer (n = 300) performed BSE less often. Breast cancer size and stage were not associated with BSE.

The 2019 retrospective cohort by Al-Gburi et al. [25] included 409 patients with a diagnosis of breast cancer in Baghdad. The strongest predictors of BSE were family history of breast cancer or other cancers (OR = 3.87, p = 0.018), followed by being a civil servant (OR = 1.87, p = 0.024), history of contraceptive use (OR = 1.80, p = 0.011) and high educational level (OR = 1.73, p = 0.004). On the other hand, there was no significant correlation between the practice of BSE and breast cancer stage at diagnosis. The CNGOF recommendation is summarized in Table 3.

Question 2. In a woman under 70–75 not participating in an individual or organized screening program (P), does the practice of regular BSE (I) versus no BSE (C) provide a survival benefit (0)?

Table 2
List of studies used for the GRADE Table with study description, Effect and Evidence.

Study description			Effect				Evidence	
Author (year of publication) Reference	**Study type**	**Study design Years of inclusion Countries Number of subjects**	**Intervention**	**Follow up in years**	**Criteria of analysis**	**Results (95%CI)**	**QoE**	**Downgrade**
Thomas (2002) (17)	RCT	Years: 1989–1991 Country: China 266,064	BSE (n = 132,979)	11 years	BC mortality	No mortality reduction No difference in tumors detection, more benign breast biopsies in BSE group	⊕⊕⊕⊕ High	
Thaineua (2020) (22)	Observational cohort	Years: 2012–2017 Country: Thailand Total = 1,906,697	non	follow-up 5 years	BC mortality + stage	2956 BC diagnosed, 48 % were stage III and IV. The mortality was more important in patient who did not practice BSE. (OR = 1,702, 95 % CI = 1235–2,347, p < 0,05).	⊕⊕◯◯ Low	No control group
Hackshaw (2003) (30)	Meta-analysis	Year: 2003 Total = 20 observational studies and 3 clinical trials	BSE		BC mortality	A lower risk of mortality or advanced BC was only found in studies of women with BC who reported practising BSE before diagnosis (mortality: pooled RR: 0.64, 95 % CI 0.56–0.73; advanced cancer, pooled RR 0.60, 95 % CI 0.46–0.80). None of the trials of BSE training (in which most women reported practising it regularly) showed lower mortality in the BSE group (pooled RR 1.01, 95 % CI 0.92–1.12). Regular BSE is not an effective method of reducing BC mortality.	⊕⊕⊕⊕ High	Bias and confounding
Philip (1984) (27)	RCT	Years: 1979 Country: UK Total = 22,514	BSE instruction (n = 6724)	follow-up 7 years	Incidence of BC and stage	No difference in terms of stage detection or mortality rate.	⊕⊕⊕⊕ High	
Semiglasov (1992) (16)	RCT	Years: 1985–1989 Country: Russia Total = 120,310	BSE instruction (n = 60,221)	follow-up 5 years	Incidence of BC	No mortality reduction More tumors diagnosed in BSE group	⊕⊕⊕⊕ High	
Harvey (1997) (26)	Case-control nested in a cohort	220 cases and 2200 controls aged 40–59 years. Matched by age, screening center, year of enrollment and randomization group Years: 1980–1985 Country: Canada	NA	NA	BC mortality	Patients examined their breasts visually, used finger pads for palpation and examined with their 3 middle fingers. The OR for women who omitted 1 of the 3 components was 1.82 (95 % CI 1.00–3.29, p = 0.05), for those who omitted 2 of the 3 components, 2.84 (95 % CI 1.44–5.59, p = 0.003), and for those who omitted all 3 components, 2.95 (95 % CI 1.19–7.30, p = 0.02).	⊕◯◯◯ Very low	Small sample Retrospective study Non-homogeneous groups after matching. Memory bias
Tu (2006) (24)	Retrospective cohort	USA Total = 27,421	NA	NA	BSE quality and subsequent screening and diagnostic efforts: mammograms, diagnosis of BC, BC size and stage	A total of 75 % of the women performed BSE, adequate in 27 %. Women reporting higher BSE duration, frequency, quality were more likely to have diagnostic mammograms. Participants ultimately diagnosed with BC (N = 300) were significantly less likely to report performing BSE. Tumor size and stage were	⊕⊕◯◯ Low	Observational study

(*continued on next page*)

Table 2 (*continued*)

Study description			Effect				Evidence	
Author (year of publication) Reference	**Study type**	**Study design Years of inclusion Countries Number of subjects**	**Intervention**	**Follow up in years**	**Criteria of analysis**	**Results (95%CI)**	**QoE**	**Downgrade**
						not associated with BSE behavior.		
Wilke (2009) (35)	Observational cohort	2004–2007 USA Total = 147	NA	Follow-up 3 years	BC detection	4 BC detected in 12 women. BSE detected 6/14 BC versus 6/14 detected by MRI and 2/14 by mammography. Sensitivity, specificity, and predictive value of BSE: 58.3 %, 87.4 %, and 29.2 %.	⊕⊕◯◯ Low	Observational study
Al-Gburi (2019) (25)	Retrospective cohort	Iraq Total = 409	NA	NA	BC stage	No association between BSE and BC stage	⊕⊕◯◯ Low	Observational study
Kösters (2003) (23)	Meta-analysis	Russia, China n = 388,535	BSE	NA	BC mortality and morbidity	There was no statistically significant difference in BC mortality, RR = 1.05 (95 % CI 0.90 to 1.24) (587 deaths in total). In Russia, more BC were found in the BSE group than in the control group (RR = 1.24, 95 % CI 1.09 to 1.41), while this was not the case in Shanghai (RR = 0.97, 95 % CI 0.88 to 1.06).	⊕⊕⊕⊕ High	
Neuman (2016) (42)	Cohort	Years: 2006–2007 USA Total: 4854	NA	Follow-up 5 years	Local-regional Breast events after Breast-conservation treatment in women with a personal history of high-risk BC	Local-regional events detected in 5.5 % (n = 265). 48 % of local-regional events were detected on asymptomatic breast imaging, 29 % by patients, and 10 % on clinical exam. Overall, 0.5 % of the 4854 patients had a local-regional event detected on exam. Clinical exams, as an adjunct to screening mammography, have a modest effect on local-regional event detection.	⊕◯◯◯ Very low	Observational study
Kontos (2013) (40)	Retrospective cohort	Years: 1990–1997 UK Total: 1143	NA	Follow-up up to 16 years	Contralateral relapse after surgery	23/1143 patients had isolated CR. The median probability of CR was a constant 0.24 % per year. Only one recurrence was found clinically at follow up, while the majority was detected through mammography and self-palpation.	⊕◯◯◯ Very low	Observational study

RCT: Randomized Control Trial; BSE: Breast Self Examination; BC: Breast Cancer; CI: Confidence Interval; QoE: Quality of Evidence; NA: Not Available; RR: Relative Risk, CR: Controlateral Relapse.

3.3.1.2. Argument. In the Chinese study evaluating BSE via a randomized controlled trial in China on 266,064 women [17], 135 breast cancer deaths were observed in the BSE-informed group and 131 in the control group after 10–11 years of follow-up. Cumulative breast cancer mortality rates were not significantly different between the two groups (relative risk (RR) 1.04; 95 % CI = 0.82–1.33; p = 0.72).

In the Russian study [16], there was no statistically significant difference between intervention (BSE) and control groups for breast cancer mortality (RR 1.05, 95 % CI = 0.90 to 1.24).

An English study [15] investigated three breast cancer screening strategies: clinical examination and mammography versus BSE versus no screening, recruiting 45,607, 63,373 and 127,123 women aged 45 to 64 in eight centers, respectively, with a 16-year follow-up. This study showed no benefit of BSE compared with no BSE in terms of mortality (RR: 1.01; 95 % CI = 0.89–1.16). It should be noted that women's adhesion to BSE was low, with only 47 % carrying out BSE after one year. The rate of benign biopsy was significantly higher in the BSE arm than in the control arm (0.91 % versus 0.61 %, $p < 0.05$). Harvey et al. [26] conducted a case-control study nested in a cohort concerning breast cancer screening in Canada, measuring the frequency of BSE and its impact on mortality. The subjects were 163 women who died of breast cancer and 57 women with metastatic disease. For each case-subject, the

Table 3
Synthesis of 10 recommendations of the French College of Gynecologist-Obstetricians.

N°	Synthesis	Recommendation	Quality of evidence
1	The three large trials investigating the place of BSE in BC screening (in women aged 30 to 70) showed no increase in the number of cancers screened compared with control groups (not practicing BSE), with however a significant increase in the number of breast biopsies for benign lesions.	It is recommended that BSE should not be encouraged in the general population to increase the number of cancers detected.	High quality of evidence, Strong recommendation
2	The three major trials and three meta-analyses on the role of BSE in BC screening show that there is no survival benefit from BSE	BSE should not be recommended in the general population to reduce BC mortality.	High quality of evidence, Strong recommendation
3	There is no evidence that in a woman aged 50 to 75 participating in an individual or organized screening program (P), regular BSE (I) versus no BSE (C) results in an increase in the number of BC screened (O).	It is not recommended to encourage BSE in the population participating in an organized screening program to increase the number of cancers detected.	Low quality of evidence, Weak recommendation
4	In women aged 50 to 75 participating in an individual or organized screening program (P), there is no evidence to show that regular BSE (I) versus no BSE (C) improves recurrence-free survival and/or overall survival in BC (O).	It is not recommended to advise BSE in the population participating in an organized screening program to increase overall or recurrence-free survival.	Low Quality of Evidence, Low Recommendation
5	There are no studies specifically addressing the impact of BSE on quality of life, but BSE induces an increase in the number of complementary breast examinations, which increases patient anxiety.	In the absence of data on the impact of BSE on quality of life, it is not possible to recommend BSE to increase women's quality of life.	Low quality of evidence, Low recommendation
6	No study has been found to specifically answer this question. In women over 75 not participating in a screening program (P), there is no evidence that regular BSE (I) versus no BSE (C) increases BC screening (O).	In the absence of data on the place of BSE in women over 75, it is not possible to recommend BSE to increase the number of BCs screened.	No evidence, no recommendation
7	The working group did not identify any study of BSE in women over 75. The 3 large prospective trials only looked at women under 70 or under 65. The meta-analysis by Baxter et al. (29) concluded that, in the absence of data on the place of BSE in women over 70, it is not possible to issue a recommendation.	In the absence of data on the role of BSE in women over 75, it is not possible to recommend BSE to reduce BC mortality.	No evidence, no recommendation
8	Data in the literature on the place of BSE in the diagnosis of BC in women at high risk of BC are therefore very poor, with only one study identified showing the place of BSE in the diagnosis of interval cancers without showing its impact on patient survival, with a false positive rate of 75 %.	Due to the lack of data on the role of BSE in BC screening in high-risk patients and its impact on overall and recurrence-free survival, it is not possible to issue a recommendation.	Very low quality of evidence, no recommendation
9	Data in the literature on the role of BSE in the diagnosis of recurrence of ipsilateral or contralateral BC after conservative or non-conservative treatment are very limited, with only 3 retrospective studies that focus more on the modalities of diagnosis of BC recurrence than on the role of BSE in the post-therapy follow-up strategy of a patient treated for BC.	In the absence of data on the place of BSE in a patient treated for BC to anticipate the diagnosis of cancer recurrence, it is not possible to issue a recommendation.	Very low quality of evidence, no recommendation
10	No data in the literature were identified to answer the question "In a woman with a history of BC and without individual screening by annual imaging (P), does regular BSE (I) versus no BSE (C) enable an improvement in recurrence-free survival and/or overall survival in BC (O)?"	In the absence of data on the benefit in terms of early diagnosis of recurrence or modification of survival by the practice of BSE in a patient treated for BC, it is not possible to issue recommendations.	Very low quality of evidence, no recommendation

authors selected 10 controls matched by age group, screening center and year of screening enrolment, with a total of 220 cases and 2200 controls aged 40–59 years. The BSE modalities were based on inspection, palpation, and a palpatory amplification system. The OR for women who omitted one of the three modalities was 1.82 (95 % CI 1.00–3.29, $p = 0.05$), for those who omitted two of the 3 modalities, 2.84 (95 % CI 1.44–5.59, $p = 0.003$), and for those who did not perform BSE, 2.95 (95 % CI 1.19–7.30, $p = 0.02$). This study was highly controversial due to its retrospective nature, possible recall bias associated with the questionnaire and, above all, the non-comparability of the two groups with different risk factors (smoking, marital status, lifestyle, hormonal risk factors).

J. Philip et al. [27] in 1984 studied breast cancer mortality in a three-year prospective cohort study. They included 22,484 women aged 45 to 64 and followed them for three years. Information meetings on BSE were organized, with a response rate of 30 % of women who accepted the invitation to these meetings. There was no statistically significant difference in incidence rates between those who attended the BSE information meetings and those who did not. Similarly, there was no difference in cancer stage between participants and non-participants in these meetings, nor between cancers identified in the first, second and third year.

The meta-analysis by Kosters JP et al. [23] showed no survival benefit from BSE. A second meta-analysis was identified [28] which included 20 observational studies, 2 randomized trials (Russian and

Chinese) and the English non-randomized trial (which compared 2-arm BSE: no screening and mammography screening). Only the observational studies were focused on patients with a breast cancer diagnosis, who were asked whether they practiced BSE, and showed benefits in terms of mortality linked to the practice of BSE. These observational studies are marked by several potential biases, notably of recall and inclusion, which make it impossible to validate the results. The meta-analysis by Baxter N et al., published in 2001, reached similar conclusions [29].

The CNGOF recommendation is summarized in Table 3.

Question 3. In a woman aged 50 to 75 participating in an individual or organized screening program (P), does regular BSE (I) versus no BSE (C) lead to an increase in the number of screened breast cancers (O)?

3.3.1.3. Argument. In the English study [15], women's adhesion to BSE was low, with only 47 % carrying out BSE after one year. The number of cancers detected in the non-mammography arms of the study over the follow-up period was not described (only the number of cancers in the mammography arm was reported, i.e., 575 cases of invasive or in situ cancers). The CNGOF recommendation is summarized in Table 3.

Question 4. In women aged 50 to 75 participating in an individual or organized screening program (P), does regular BSE (I) versus no BSE (C) improve recurrence-free survival and/or overall survival of women with breast cancer (O)?

3.3.1.4. Rationale. In the study from the UK [15], the RR of breast cancer death at 10 years was 1.01 (95 % CI = 0.89 to 1.16) in the BSE arm and 0.74 (95 % CI = 0.56 to 0.92) in the mammography arm, compared with no screening. No studies were identified on the addition of BSE to a screening strategy involving mammography and clinical examination in terms of interval cancer diagnosis or survival. Only the meta-analysis by Hackshaw AK and Paul EA [30] reported observational studies of self-diagnosed breast cancer (interval cancer), but these retrospective studies are marked by potential bias. In this meta-analysis, the authors concluded that none of the trials involving the practice of BSE (which most women reported performing regularly) had shown a reduction in mortality in the BSE group (RR 1.01, 95 % CI = 0.92–1.12). The CNGOF recommendation is summarized in Table 3.

Question 5. In the general population (P), does regular BSE (I) versus no BSE (C) modify women's quality of life (O)?

3.3.1.5. Rationale. Studies on the role of BSE in breast cancer screening have not analyzed the impact of BSE on quality of life. The working group was able to identify four studies, all of which found a significant negative emotional (psychological) impact when complementary breast examinations were carried out while waiting for mammogram or biopsy results [31–34]. Since BSE induces an increased rate of mammograms and biopsies compared with no BSE, it is conceivable that a BSE policy could induce a negative impact on quality of life. The CNGOF recommendation is summarized in Table 3.

2. General population women over 75 years of age

Question 6. In a woman over 75 not participating in a screening program (P), does regular BSE (I) versus no BSE (C) increase breast cancer screening (O)?

Question 7. In women over 75 not participating in a screening program (P), does regular BSE (I) versus no BSE (C) improve recurrence-free survival and/or overall survival of women with breast cancer (O)?

No study was found that could specifically answer this question. In women over 75 not participating in a screening program (P), there is no evidence that regular BSE (I) versus no BSE (C) increases breast cancer screening (O). The CNGOF recommendation is summarized in Table 3.

3. Population at high risk of breast cancer

The population at high genetic risk of breast cancer essentially concerns patients carrying a deleterious variant of a breast cancer predisposition gene (*BRCA1, BRCA2, PALB2, TP53, PTEN, CDH1, STK11* …) [7]. In the absence of risk-reducing surgery, patients should benefit from specific surveillance codified by the guidelines of the French National Cancer Institute (INCa) [7]. This recommended surveillance is based on a six-monthly clinical examination by a healthcare professional and annual imaging by breast MRI and mammography, possibly combined with breast ultrasound, from the age of 30 (or earlier in the case of a very early form in the family) up to the age of 65. From age 65, annual mammography replaces the rest of the imaging. BSE is not included in INCa recommendations as a breast cancer screening tool. In addition to proven genetic risk, women may also be considered at high risk when there are numerous cases of breast cancer in a family with no identified deleterious mutation, or when high-risk histological lesions have been diagnosed. Five questions in PICO format have been formulated to define the place of BSE in the high-risk breast cancer population.

Question 8. In a high-risk woman without individual screening by MRI/mammography/ultrasound (P), does regular BSE (I) versus no BSE (C) increase the number of breast cancers detected (sensitivity, specificity) (O)?

Question 9. In high-risk women without individual screening by MRI/mammography/ultrasound (P), does regular BSE (I) versus no BSE (C) improve recurrence-free survival and/or overall survival in breast cancer (O)?

Question 10. In a high-risk woman with individual screening by MRI/mammography/ultrasound and annual clinical examination (P), does regular BSE of the breasts (I) versus no BSE (C) lead to an increase in the number of breast cancers detected (sensitivity, specificity) (O)?

Question 11. In a high-risk woman with individual screening by MRI/mammography/ultrasound and annual clinical examination (P), does regular BSE (I) versus no BSE (C) improve recurrence-free survival and/or overall survival in breast cancer (O)?

Question 12. In the population at high risk of breast cancer (P), does regular BSE (I) versus no BSE (C) modify the quality of life of women at high risk of breast cancer (O)?

3.3.1.6. Argument. No publications were identified to answer questions 9, 11 and 12. The literature research on the role of BSE in breast cancer screening identified only one publication concerning the high-risk breast cancer population to answer questions 8 and 10: the 2009 study by Wilke et al. [35]. In this single-center study, 147 patients at risk of breast cancer were recruited between 2004 and 2007 for annual imaging surveillance (MRI and mammography) and biannual clinical examination. High risk was defined as being a carrier of a deleterious *BRCA* variant without having previously had breast cancer, having had a histological lesion at risk (borderline or atypical lesion) or having more than one first-degree family history of breast cancer diagnosed before menopause. BSE was taught 2 to 3 times a year with a healthcare professional at the time of the follow-up clinical examination. Modalities of BSE teaching were not described with details, but it took six to 15 min. BSE had to be performed once a month by the patient. In terms of adherence to BSE at one year from the start of the program, 60 % of patients practiced BSE monthly and 37 % practiced BSE but not regularly. Twenty-four masses were discovered in 22 patients by BSE. Of these 24 masses, imaging had considered 14 images to be benign (without histological confirmation) and 10 images had led to percutaneous biopsy, 6 of which corresponded to breast cancer and 4 to a benign anomaly. The sensitivity, specificity and positive predictive value of BSE were 58 %, 87 % and 29 %

respectively. Invasive cancers were discovered 6–12 months after follow-up MRI. During the study period, 14 patients were diagnosed with cancer by either BSE, clinical examination, or imaging, giving an interval cancer rate of 43 % (6/14). This study failed to show impact of BSE on survival in this high-risk population (not the focus of the study).

The study by Kaas et al. [36] has shown that among 151 high-risk breast cancer patients, 41 % of cancers were identified as interval cancers (between imaging examinations) among *BRCA1*-mutated patients. In this study, it was not possible to distinguish between BSE and clinical examination by a healthcare professional for the diagnosis of interval cancer. The CNGOF recommendation is summarized in Table 3.

4. Population previously treated for breast cancer

Surveillance after treatment for breast cancer is the subject of recommendations concerning the frequency of consultations with various doctors (with clinical examination) and imaging examinations. Current recommendations after breast cancer treatment include a clinical examination by a healthcare professional every six months for 5 years, then annually for life, and an annual mammogram [37]. The sensitivity of the clinical medical examination in detecting recurrence is assessed differently in the literature, especially as technological advances enable the detection of increasingly subtle images.

There is no consensus on patients' indication for BSE. Studies have investigated compliance of treated patients with regular BSE. Trask et al. [38] analyzed 345 questionnaires out of 1106 sent to patients treated for T1 or T2 in situ or invasive cancer between 1997 and 2004, with follow-up between 4 and 11 years (105 postal addresses were found to be inaccurate, so calculations were based on 1001 questionnaires). In this study, 89 % of patients reported performing BSE (40 % once/month, 39 % more than once/month, 21 % less than once/month). In these patients, anxiety levels were low, and confidence in the efficacy of their examination limited.

In a retrospective study of 352 treated patients, Tan et al. [39] have shown that information seeking by treated patients, from medical or non-medical sources (newspapers, internet …), was significantly associated with regular BSE (OR = 1.52, 95 % CI = 1.01 to 2.29, p = 0.046). The CNGOF recommendation is summarized in Table 3.

Question 13. For a woman with a history of breast cancer and with individual screening by annual imaging and biannual clinical examination (P), does regular BSE (I) versus no BSE (C) enable an increase in the diagnosis of the number of breast cancer recurrences detected (sensitivity, specificity)?

3.3.1.7. Rationale. Only four studies were identified to partially answer this question. Kontos et al. [40] have conducted a retrospective study on detection of contralateral recurrence, including 1143 patients treated between 1990 and 1997 (conservative treatment or mastectomy) with a median follow-up of 110 months by clinical examination 4 times a year for the first 3 years, then annually, and annual mammography. Among the 23 patients who developed contralateral recurrence, the method of diagnosis was known in 19 cases: 4 contralateral recurrences had been detected by BSE, one by clinical medical examination, and 14 by mammography. The authors recommended follow-up by BSE and mammography. This was a low level of evidence. Pivot et al. [41] conducted a retrospective study of initial indicators of recurrence (local, regional, or distant) in 1125 patients treated between 1973 and 1980. Breast surveillance included a clinical examination every 6 months for 5 years, then annually thereafter with an annual mammogram. In this cohort of 1125 patients, 254 locoregional or distant relapses (22.6 % of the study population) were detected during scheduled follow-up examinations, and of these, 64.6 % were detected by history or clinical examination. Scheduled follow-up visits detected an average of 25.9 % of locoregional or distant relapses during the first 36 months, whereas after 36 months, only 16.3 % were detected by routine surveillance. In this study, 23 patients presented with a local breast recurrence: 8 discovered on BSE (whose periodicity was not specified in the study), 10 on clinical medical examination and 5 on imaging.

The retrospective study by Neumann et al. [42] from 2006 to 2007 included patients with stage II or III breast cancer (excluding stage I), who had undergone conservative treatment and were followed for up to 5 years in the absence of intercurrent events. In this study, 11,099 files were randomly selected from a register of accredited centers. Clinical examination had been performed in 4854 patients (44 %) who were included in this study. Breast recurrence was detected in 220 patients (4.7 %) with a median delay of 2.9 years (for breast and ipsilateral lymph node recurrences). The patients themselves detected 43 recurrences in the ipsilateral breast and 17 in the contralateral breast, i.e., 27 % of all breast recurrences (versus 8.2 % for the clinical medical examination). It was not specified whether these recurrences were detected incidentally by the patient or during an BSE, as the aim of the study was to determine the usefulness of the clinical medical examination (effect considered modest).

The study by Yoo et al. [43] focused specifically on recurrence detection in a TRAM (Transverse Rectus Abdominis Myocutaneous flap) reconstructed breast with skin sparing mastectomy (SSM) or nipple-sparing mastectomy (NSM). This was a retrospective study of patients treated between 2001 and 2010, followed by annual mammography, possibly combined with ultrasound at the radiologist's discretion (and MRI in patients with a deleterious *BRCA* variant). Of the 964 patients in this study, 16 (1.7 %) had a local cancer recurrence. The mean follow-up period to detection was 31.1 months (range, 7–84 months). Fourteen (87.5 %) patients had recurrence in the skin or subcutaneous fat. Of the 16 patients, recurrence was detected by BSE in 13 (81.3 %) (11 palpable nodules, 2 nipple discharge/ulceration). In the other 3 patients, the recurrence was subclinical, detected by imaging. In addition, recurrence had a pseudo benign appearance on imaging in 50 % of cases. The authors concluded that patients should be trained for BSE, especially as recurrences were very often superficial and therefore palpable. The CNGOF recommendation is summarized in Table 3.

Question 14. For a woman with a history of breast cancer and with individual screening by annual imaging and biannual clinical examination (P), does regular BSE (I) versus no BSE (C) improve recurrence-free survival and/or overall survival in breast cancer (O)?

3.3.1.8. Argument. The literature search identified only one study that could partially answer the question: Montgomery's study [44] involved 1312 patients treated between 1991 and 1998 with conservative therapy (T1 and T2 tumors), followed by a clinical medical examination every 3–4 months for the first 2 years, then 6 months for 3 years, then annually and by annual mammography. Follow-up ranged from 1.5 to 15 years (median: 10 years). The BSE was taught to all patients, although the authors do not specify how this was done. In this study, 108 patients developed a recurrence, 23 of them self-discovered: 19 ipsilateral recurrences (breast and/or axillary) and 5 contralateral recurrences. Survival was reduced in women with a clinically diagnosed recurrence, compared with patients who consulted for an apparent or mammographically diagnosed nodule (p = 0.0002). The authors encourage regular BSE. It is not clear from this study whether taught BSE had an impact on the number of recurrence diagnoses or an impact on survival. The CNGOF recommendation is summarized in Table 3.

Question 15. In a woman with a history of breast cancer and without individual screening by annual imaging (P), does regular BSE (I) versus no BSE (C) enable an increase in the detection of the number of breast cancer recurrences screened (sensitivity, specificity)?

Question 16. In a woman with a history of breast cancer and without individual screening by annual imaging (P), does regular BSE (I) versus no BSE (C) enable an improvement in recurrence-free survival and/or overall survival in breast cancer (O)?

No study was found that could specifically answer these questions. In a woman with a history of breast cancer and without individual screening by annual imaging (P), there is no evidence that regular BSE (I) versus no BSE (C) increases the number of breast cancer recurrences screened (O) and/or recurrence-free survival and/or overall survival in breast cancer. The CNGOF recommendation is summarized in Table 3.

4. Discussion/conclusion

Following on from this work on drafting recommendations on the practice of BSE for breast cancer screening, we endorse the proposal made by the women members of the Parliamentary Assembly of the Council of Europe [45]: "there is no evidence that BSE reduces breast cancer mortality. Randomized controlled trials have shown that BSE increases the probability of breast biopsies showing no signs of cancer. On the other hand, BSE has its drawbacks, such as increased anxiety, discovery of benign abnormalities leading to excessive medical consultations for "re-assurance", or delayed diagnosis of cancer due to sub-optimal quality of BSE performance". Thus, following the example of various groups or societies, such as the Canadian Task Force on Preventive Healthcare [29] or the United States Preventive Services Task Force [46], the CS of the CNGOF states that no health policy (*i.e.* World Health Organization [12]) or information campaign should promote BSE for women in the general (non-elderly) population, who otherwise benefit from a clinical breast examination (by their general practitioner or gynecologist) from the age of 25, and from organized screening from 50 to 74. However, in the absence of data on the place of BSE in patients aged over 75, those at high risk of breast cancer and those previously treated for breast cancer, the CS of the CNGOF was unable to issue recommendations. Thus, if women in these three categories wish to undergo BSE, they must be given rigorous training in the technique and information on the benefits and risks observed in women in the general population, notably that BSE is associated with a higher number of referrals, biopsies, and a reduced quality of life.

In addition, BSE should not be performed as an exclusive screening method and can in no way replace the other follow-up modalities recommended in these three situations (clinical examination by a healthcare professional, imaging if necessary).

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Declaration of competing interest

The members of the steering committee, the redactors and the reviewers declare that they have no link of interest that could interfere with this work.

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