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Performance Indicators of Breast Cancer Screening program Based on National Screening Guideline in Rural area of Rudsar City in Gilan Province, Iran.

Fatemeh Pakdaman[1], Sareh Shakerian[2]

1. Departments of Community Based Education of Health Sciences, Virtual School of Medical Education and Management, Shahid Beheshti University of Medical Sciences, Valiasr Ave, Tehran, I.R. of Iran.
2. Department of Community Based Education of Health Sciences, Virtual School of Medical Education and Management, Shahid Beheshti University of Medical Sciences

***Corresponding Authors:**
Sareh Shakerian,
Assistant Professor, Departments of Community Based Education of Health Sciences, Virtual School of Medical Education and Management, Shahid Beheshti University of Medical Sciences, Valiasr Ave, Tehran, I.R. of Iran.
Postal Code: 19857-17443
Phone: (+98)21 26210092
Fax: (+98)21 26210093
Email: sarehshakerian@gmail.com

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ABSTRACT

Background: According to the World Health Organization (WHO), the high prevalence of breast cancer mortality in the least developed countries is due to the diagnosis at late phases. Accordingly, cost-effective breast cancer screening plans are the most effective methods to control this cancer and increase women's survival.

Methods: This study aimed to evaluate the performance of the breast cancer screening program based on the guidelines of the Iran Ministry of Health on 14,493 eligible women in rural areas of Rudsar city in 2018-19. We calculated performance indicators such as target coverage, identification of the at-risk population, early diagnosis, referral index, and other statistical using SPSS 22 software.

Results: Out of 14493 rural women aged 30-59 referred to health homes, 6992 women underwent breast cancer screening. Coverage of the program in the The target population coverage was estimated at 48%. Most high-risk cases were 46 years and older, and the lowest rate was in women of <35 years. We found Thethat results showed that 0.4% of the cases patients (n=27) were identified as the high-risk, and all (100%) referred to group according to the national guidelines with referral to a specialist for further evaluation. of 100%. All patients cases identified as high-risk groups atin the first phase of screening were found with BIRADS (Breast Imaging Reporting and Data System) 4 and 5 based on biopsy specimens.

Conclusion: The low target population coverage and the cases with advanced breast cancer indicated the need for more attention and consideration in implementing programs and policies for preventable cancer by all organizations. In this regard, there is a need for relevant interventions and follow-up by health authorities.

Keywords: Mass Screening, Breast Cancer, Guidelines, Evaluation

INTRODUCTION:

According to the World Health Organization, breast cancer is the most common cancer in women worldwide. In 2018, more than 627,000 women died from breast cancer. Studies on breast cancer indicated the increasing prevalence of this disease worldwide (1). Although the burden of breast cancer is higher in the developed world, 58% of the deaths occur in developing countries (2). The incidence rate of breast cancer in Western Europe and developing countries is 89.7 per 100,000 population and below 40%, respectively. The survival rate in North America is more than 80%. The survival rate in low-income countries is below 40% due to late diagnosis caused by a lack of knowledge and poor screening program implementation. At the same time, 30-50% of diseases are preventable. Therefore, early screening and diagnosis is the most cost-effective method in disease management (2,3,4). Accordingly, national screening programs in most countries are of particular importance in diagnosing many preventable cancers at an early phase (5). In this regard, the mortality of women participating in breast cancer screening is reduced by up to 40% (5,6). Cancer screening aims to detect tumors smaller than 1 cm, which are more likely to be treated with surgery (7). Screening breast cancer methods include self-examination, clinical breast examination (CBE), ultrasound, and mammography (7).

The mean age of patients with breast cancer in the Iranian population is 10 years younger than in other countries (8,9), and more than 30% of the patients are younger than 30 years (8). Also, approximately 70% of Iranian women are at the advanced phase of the disease at referral, making it difficult to treat (10). The first Iranian screening program was implemented in Shiraz in 1996-97. The plan was conducted on 10,000 women over 35 years and reported mammography as the most sensitive screening method. It was further recommended that, breast self-examination be included in the Iranian breast cancer screening program because mammography screening is not cost-effective among the Iranian population(10,11,12).Mammography screening has reduced the mortality rate of women with breast cancer by 22% in cases over 50 years and reduced the mortality rate by 15% among women aged 40-49 years (13). Therefore, the American Cancer Society (ASC) has suggested mammography as the selective screening method for breast cancer starting at age 40 (14). International studies have also highlighted the importance of different aspects of screening programs. Bawazir et al. (2019) showed that Yemeni women's knowledge about breast cancer was satisfactory. However, they had insufficient information on breast cancer screening and its methods (15). In a study aimed to ensure adherence to referral and treatment principles, Kulkarni et al. (2019) showed that the clinical breast examination CBE program could be achieved based on a breast cancer screening program and the community (16). Yurt et al. (2019) showed the impact of peer education on health beliefs about breast cancer screening. They also indicated that breast self-examination is a practical, cost-effective, and simple method (17). Nestram et al. (2017) in Malmö, Stockholm, and Gothenburg found a 15% relative decrease in breast cancer mortality due to mammography screening measures (18). The first Iranian cancer screening program was carried out in 2011, according to the Ministry of Health guidelines as the Iranian women's health services (19). Given the importance of cancer screening programs in Iran, the general policies of the Iranian Cancer Prevention and Control Program are as follows:

- Priority of the prevention programs and activities to treatment and the priority of outpatient treatment to outpatient treatment programs
- Reducing the costs imposed on the people
- Reducing inequality in health services
- Reducing inequality in the financing of the health system

- Maintaining and deepening achievements in the health system
- Attracting the support and cooperation of national policymakers
- Attracting public support and cooperation and charities

In this regard, the most important technical components of the program were the target group, screening using clinical examination and mammography, screening interval and follow-up process, and information resources.

In mammography screening and clinical breast examination, the target group was women examined based on the guideline in two high-risk and normal subjects. In this regard, the present study aimed at evaluating the performance of a screening program based on the guideline developed by the Ministry of Health to identify the program weaknesses for the most preventable cancer type using considered indicators.

METHODS:

The present study aimed to evaluate the breast cancer screening program conducted in 2018-19 following confirming by the ethics committee and making the subjects assure the confidentiality of the information. The statistical population included all eligible women aged 30-59 years living in the Rudsar city (14493 cases). This research was conducted on 14493 rural women aged 30-59, referring to the health houses subjected to breast cancer screening during 2015-16. From a total of 14493 target population, 6,992 women were screened by midwives. Health house (Khane Behdasht) is a primary healthcare setting for providing primary health services by community healthcare workers (Behvarz) in rural areas in Iran. The research objectives were based on the breast cancer screening program developed by the Ministry of Health guidelines designed and validated according to the research tool, including a breast screening checklist. The content and face validity were examined using the stakeholders and experts' viewpoints at the Rudsar Health Center (including a family health expert, two midwives of the headquarters, an expert in disease control at the office, and two midwifery trainers of the health & treatment center). Two experts completed the checklist at two health houses for 10 patients to determine the reliability, and the results showed a good agreement coefficient (90%). The checklist included four sections. According to the health assessment form for 30-59-year-old women (age, gender, marital status, education, occupation, etc.). Section 2 included questions regarding identifying high-risk and normal individuals in terms of clinical symptoms, signs, or risk factors, a history of breast cancer in themselves or their first-degree relatives. Those with no risk factors and no signs or symptoms in breast screening were considered normal (according to the recommendation provided by the ministry of health (MOH) guideline, clinical breast examination every three years from 30 to 50 years of age in women with no individual and family risk factors and every year in those with risk factors and women aged over 50 years). Section 3 included questions about the referral of high-risk people. According to the MOH guideline, patients with phase 2 breast cancer referred to the hospital to be examined by a breast surgeon or general surgeon to order ultrasound or mammography and more diagnostic measures, if needed. Section 4 included questions assessing the feedback of referral of high-risk individuals to advanced phases To analyze the population coverage, identifying high-risk women, early diagnosis, and the number of referrals (which is one of the most critical indicators in the implementation of screening programs) were determined based on the relevant formulas. The subjects' demographic characteristics and the relationship between screening and age and education level were calculated using the chi-square test and the Pearson correlation coefficient. Descriptive and inferential statistical indices were analyzed using SPSS 22 software.

RESULTS:

Table 1 reports the demographic characteristics of the subjects. The average age of the participants was 44.5(±6.5). Most of the cases aged 35-40 years 2248 (±32.2%) and a small number of subjects were in the age group of 30 to 35 years 171 (2.4%).

The population coverage since the program's implementation was calculated 48% in 483 people per 1,000 rural people, which includes less than half of the eligible population.

Table 2 presents the risk status of the studied population (high-risk or normal) at phase 1 breast screening by follow-up year and age groups. At the screening time, 27 cases (0.4%) were at risk for breast cancer, and 6965 patients (99.6%) had a normal condition. The high-risk cases were as follows: one patient (0.6%) in the age

Table 1. Frequency and percentage of the subjects' demographic characteristics

Variables	Frequency	Percent
Education		
Illiterate	878	12.6
Primary	909	13
Middle School	2610	37.3
Diploma	2301	32.9
Associate	128	1.8
Bachelor	146	2.1
Master	14	0.2
Ph.D.	6	0.1
Age		
≤35years	171	2.4
35-40	2248	32.2
41-45	1961	28
46- 50	1107	15.8
51≥ years	1505	21.5
Marital status		
Single	152	2.2
Married	6840	97.8
Total	6992	100

Table 2. The status of the studied population (high-risk and normal) after phase 1 breast screening by age in 2015-16

Age		≤35years		35-40		41-45		46- 50		51≥ years		Total	
Screening year	Screening Result	F*	P**	F*	P**	F*	P**	F*	P**	F*	P**	F*	P**
2015	High-risk	1	1.4	6	0.7	1	1	4	0.9	3	0.5	15	0.5
	Normal	69	98.6	910	99.3	797	99.9	446	99.1	609	99.5	2831	99.5
2016	High-risk	0	0	2	0.2	5	0.4	2	0.3	3	0.3	12	0.3
	Normal	101	100	1330	99.8	1158	99.6	655	99.7	890	99.7	4134	99.7
Total	High-risk	1	0.6	8	0.4	6	0.3	6	0.5	6	0.4	27	0.4
	Normal	170	170	2240	99.6	1955	99.7	1101	99.5	1499	99.6	6965	99.6

*Frequency ** percent

Table 3. Performance indicators

Screening performance indicator	Formula	value
The Number of target group per year	All women in the eligible target population	1446
Participation rate per 1000 (2015,2016)	$\frac{\text{eligible women who participated in the screening program}}{\text{All women in the eligible target population}} \times 1000$	480
Referrals rate per 100	$\frac{\text{women who detected as high} - \text{risk}}{\text{women who referred}} \times 100$	100
Detection rate per 1000	$\frac{\text{women who detected as high} - \text{risk}}{\text{eligible women who participated in the screening program}} \times 1000$	4.034
Percent of breast cancers detected by screening (early phase disease)	$\frac{\text{breast cancers detected by screening}}{\text{women who detected as high} - \text{risk}} \times 100$	0
Percent of breast cancers detected by screening (late phase disease)	$\frac{\text{breast cancers detected by screening}}{\text{women who detected as high} - \text{risk}} \times 100$	100

group of <35 years, 6 patients (0.4%) in the age group of 35-40 years, 6 patients (0.3) in the age group of 41 to 45 years, 6 cases (0.5) in the age group of 46 to 50 years, and 6 cases (0.4) in the age group of 51 years and older. The rate of high-risk people was more in the age group of <35 years. **Table 3** shows the performance indicators. As shown, all subjects with BIRAD 4 and 5 underwent surgery. BI-RADS is a numerical scale ranging between 0 and 6 used in the mammogram, breast ultrasound, and breast magnetic resonance imaging (MRI) reports (20). **Table 4** reports the follow-up measures for the high-risk people identified in the first phase of the screening. All cases identified in the first phase of screening were in advanced stages of cancer. All 27 patients showed breast mass on examination, and all were referred to step 2, which is the referral to the specialist doctor. Six cases had abnormal skin appearance, one patient had a family history of breast cancer, one had a history of hormone therapy, and one reported infertility. The relationship between demographic characteristics and family history of breast cancer with a 95% confidence level showed no significant relationship between family history risk of breast cancer and age in the subjects. However, there was a significant relationship with the level of education ($P<0.05$).

DISCUSSION

Based on the findings of the present study, the coverage population was 48%, which is a low level, considering the goals of the national screening program (21,22). The results show that 2846 and 4146 rural women aged 30-59 years were screened in 2015 and 2016, respectively, which shows an increase. However, it is still inadequate regarding the target population of 14,493 people. The underlying reasons may be inappropriate recall for screening or insufficient knowledge and attitude regarding breast cancer screening program. This rate is reported by 58% of women ages 40-49 and 72% of women ages 50-74 undergoing mammograms in the US (23). Among women ages 50–64, the rates ranged from 20.2 percent in Denmark to 70.0 percent in Austria (23). In Lithuania, The coverage rate of the screening program was from 20.0% in 2006 up to 65.8% in 2014 (24).

The findings of the present study are consistent with those of other studies conducted in Iran. The results of Naghibi's study indicated that Iranian women had a low level of awareness regarding diagnostic methods for diagnosing early-phase breast cancer. Using self-examination, clinical examination, and mammography was also low (25). Fouladi et al. showed that delays in breast cancer diagnosis caused by a lack of awareness of the disease, cultural factors, and fears could play a key role in late referral to a physician (26). Monfared et al. indicated that most women did not realize the need for regular breast screening (27). Kulkarni's study showed low compliance with screening, referral, and treatment and the fact that CBE is acceptable to the eligible population (16). Bawazir et al. (2019) showed inadequate awareness regarding breast cancer screening and screening methods in Yemeni women (15). The possible causes are the lack of awareness about free screening programs or unfavorable attitudes due to cultural restrictions.

Based on the principles of the screening program (principal 1), it is crucial to inform the covered and eligible women, since in the first phase of the screening program (self-examination), with the necessary training, women can identify most of the masses and other symptoms at an early phase. It can be achieved by providing the required awareness and knowledge to the covered population. On the other hand, women in the target group entered the screening program through verbal invitations by health workers and health professionals, public invitation through national media, and written media by health volunteers. Therefore, the target group's participation rate at this phase is entirely associated with the provided information and individual and social awareness. However, the population coverage is a measure of

Table 4. The results of follow-up measures of the people at risk identified in the first phase of screening

Number of High-risk Patients	Risk History (in First screening)	Symptom (in First screening)	Sign (in First screening)	Referral	Sonography	Mammography	MRI	Biopsy Report
1	-	Skin Change	lump	Yes	Yes	Yes	**No**	BIRAD4
2	-	No	lump	Yes	Yes	Yes	No	BIRAD4
3	-	Skin Change	-	Yes	Yes	Yes	No	BIRAD5
4	Taking hormonal drugs	Skin Change	Lump	Yes	Yes	Yes	No	BIRAD4
5	Family history	Discharge from the nipple	Lump	Yes	Yes	Yes	No	BIRAD4
6	Infertility	No	Lump	Yes	Yes	Yes	No	BIRAD5
7	-	Skin Change	Lump	Yes	Yes	Yes	No	BIRAD5
8	-	Skin Change	Lump	Yes	Yes	Yes	No	BIRAD5
9	-	Skin Change	Lump	Yes	Yes	Yes	No	BIRAD4
10	History of Biopsy	No	Lump	Yes	Yes	Yes	No	BIRAD5
11	-	No	Lump	Yes	Yes	Yes	No	BIRAD5
12	-	No	Lump	Yes	Yes	Yes	No	BIRAD5
13	-	No	Lump	Yes	Yes	Yes	No	BIRAD5
14	-	No	Lump	Yes	Yes	Yes	No	BIRAD5

Table 4. Continue...

Number of High-risk Patients	Risk History (in First screening)	Symptom (in First screening)	Sign (in First screening)	Referral	Sonography	Mammography	MRI	Biopsy Report
15	History of cancer	No	Lump	Yes	Yes	Yes	No	BIRAD5
16	-	Discharge from the nipple	Lump	Yes	Yes	Yes	No	BIRAD4
17	-	No	Lump	Yes	Yes	Yes	No	BIRAD4
18	-	Discharge from the nipple	Lump	Yes	Yes	Yes	No	BIRAD5
19	History of Biopsy	Discharge from the nipple	Lump	Yes	Yes	Yes	No	BIRAD4
20	Family history	Discharge from the nipple	Lump	Yes	Yes	Yes	No	BIRAD5
21	-	No	Lump	Yes	Yes	Yes	No	BIRAD5
22	-	No	Lump	Yes	Yes	Yes	No	BIRAD5
23	-	Skin Change	Lump	Yes	Yes	Yes	No	BIRAD5
24	Taking hormonal drugs	No	Lump	Yes	Yes	Yes	No	BIRAD5
25	-	No	Lump	Yes	Yes	Yes	No	BIRAD5
26	-	Skin Change	Lump	Yes	Yes	Yes	No	BIRAD5
27	-	Skin Change	Lump	Yes	Yes	Yes	No	BIRAD5

-No identified

success and should be fulfilled with local arrangements, including written invitations, group invitations, and informing using local facilities and other measures. No active implementation of the screening program was another reason for low population coverage. Based on the findings, all high-risk cases (100%) in the first screening phase were referred to a specialist (phase 2).

It is noteworthy that all identified cases 27 (0.4%) at the first phase, after examination of biopsy specimens, were found with BIRAD 4 and 5 (advanced phases of cancer), which indicates the detection rate of BIRAD 3 in the early phase of cancer. Early detection of diseases is one of the most important indicators to screening programs worldwide. According to the World Health Organization (WHO) report, the early detection rate is high in developed countries and low in less developed countries. This leads to lower incidence (40%) in these countries but higher mortality (58%) due to diagnosis at advanced phases because of the poor implementation of the screening program for many reasons, including lack of financial resources (1). Safai et al. showed that financial support by the government and measures are taken for early diagnosis are effective in improving the quality of life of patients (28).

Lakzaee's study showed that breast cancer survival is directly associated with age, which means that breast cancer in older cases reduces the survival rate and life with no disease and is consistent with our study (29). According to the WHO, the appropriate targeted age for screening can lead to the cost-effectiveness of the program. Considering the limited number of health care centers, it avoids unnecessary actions for low-risk age groups and reduces costs (2-3). Rejali reported that there is a statistically significant relationship between breast cancer screening methods and the level of education. Balvardi indicated that the level of knowledge and attitude of medical students is higher than that of non-medical students. However, both groups found poor performance (30, 31).

Since the implementation of screening programs requires the creation of expensive infrastructure, it is better to increase the effectiveness and cost-effectiveness of these programs to improve population coverage (22). It is suggested that volunteer health workers and health ambassadors be employed to recall breast screening women. Also, face-to-face training is effective in motivating and change attitudes. It is essential to improve the training programs and train health service packages in health workers and health teams. It is necessary to use theory-based interventions and behavior change models in addition to conventional information-based interventions to enhance the level of knowledge, attitude, and performance of the target groups (32). Providing facilities for mammography and services for phase III breast cancer can prevent patients' treatment by the private sector and avoid imposing high costs on low-income and vulnerable people.

This study faces some limitations. Since the present study assessed the recorded data of the target population history, the researcher could not control and monitor the data collection. There was also no accurate and complete data in some of the cases. No information was available about eligible women who had never been screened and why they have not been screened at that time. This issue is necessary to study in the future. It is also essential for all pilot centers to conduct similar studies for appropriate decisions and policymaking in Iran. Besides, due to the low population coverage of the screening program at phase 2, the combined cancer screening programs and the Iranian Women's Health (SABA) services should be comprehensively assessed for different aspects, particularly cost-effectiveness and cost-benefit.

CONCLUSION

The low population coverage index and advanced phases of cancer in all identified cases indicate more

attention and consideration in implementing the screening programs and policies for preventable cancer by all organizations. Therefore, health policymakers should consider that performing a breast cancer screening program requires the specialized sector (surgeons, hospitals, and pathologists) and the health network system. The specialized sector should also record the cancer cases and provide a long-term follow-up regarding their survival rate.

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