RESEARCH ARTICLE

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Evaluating the Impact of a Clinical Breast Examination Screening Program within the IraPEN Project

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Abstract

Purpose: Breast cancer is a prevalent global cancer and a leading cause of mortality in developed countries. In 2015, Iran introduced the Package of Essential Noncommunicable Diseases (IraPEN) as a pilot project to tackle prevalent noncommunicable diseases, including breast cancer. However, there is limited research evaluating the implementation, costs, and outcomes of breast cancer screening within IraPEN. Therefore, this study aims to investigate the costs and outcomes of the clinical breast examination screening program in Isfahan from 2017 to 2020. **Method:** This descriptive cost-outcome study utilized data from 450,876 individuals aged 30 to 69 who participated in clinical breast examination screening. The outcomes assessed in this program encompassed the number of participants, the number of individuals identified with symptoms, referrals to the next level of examination, the number of individuals undergoing mammography, recorded mammography results, and the number of cases of breast cancer identified. Direct costs were estimated, including personnel, infrastructure, equipment, and other related expenses. **Results:** The findings revealed that the direct costs of the breast cancer screening program in Isfahan between 2017 and 2020 were 310,514,608,558 Rials, equivalent to approximately 15,470,633 PPP$. These expenses led to the identification of 134,508 individuals with symptoms, referrals of 258,599 individuals to the subsequent level of examination, and approximately 55,974 individuals undergoing mammography tests. **Conclusion:** This study demonstrates that the breast cancer screening program provides a significant number of women in the target age group with breast self-examination education while raising public awareness about this disease.

Keywords: Breast Cancer- Screening- Direct costs- Outcomes

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Introduction

Breast cancer, the most common type of cancer, is the second leading cause of death in developed countries and the third leading cause of death in less developed nations [1]. In 2020, an estimated 19.2 million individuals worldwide were diagnosed with cancer, among these cases breast cancer had the highest prevalence rate at 11.7%. Tragically, Breast cancer led to the loss of 684,996 lives during that year coming as the fifth cause of death right after stomach cancer [2]. Breast Cancer imposes a significant economic burden on healthcare systems and households, even in developed countries [3]. In 2020 alone, breast cancer left 1 million maternal orphans in its wake [4]. Breast Cancer with 16,967 new cases found in 2020, has been identified as the most prevalent form of cancer [2]. There are no absolute preventive measures exist for stop this disease and early detection is the only way to reduce its death toll & economic burden [5]. Research has demonstrated that progress in breast cancer screening and treatment has led to a 40% decrease in mortality rates caused by this disease [6]. Breast cancer screening has diverse methods. While mammography-based screening has been proven cost-effective in developed and high-income countries. However, it remains a subject of debate and investigation in other regions especially low-income countries [7]. A common screening method is clinical breast examination (CBE), which has been cost-effective in some countries. For example, biennial clinical breast examination has identified cancer only 34% less than the mammography method [8]. In one study conducted by Ohnuki K and et al., the cost-effectiveness of breast cancer screening methods, specifically focusing on women aged 40 to 49, was examined. The study estimated the average cost of clinical breast examination screening at 2,276 yen, and annual clinical breast examination was

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found to save 815.5 lives and increase survival duration by 16,756.8 years [9]. Over the past few decades, despite significant advancements in the diagnosis and treatment of non-communicable diseases, their prevalence continues to grow. For this reason, the World Health Organization devised the Operational Plan 2002-2013 to tackle these diseases. The program was designed to address four main conditions: cardiovascular diseases, diabetes, cancer, and respiratory issues [10]. As part of these efforts, Iran's Essential Noncommunicable Diseases (IraPEN) was initiated as a pilot project in four cities in February 2015. Within the IraPEN program, specific attention was given to breast cancer. Detailed information, including symptoms and examination results, was recorded for women aged 30 to 69 in the E-integrated health system (SIB (in Persian)). Clinical breast examination screening played a vital role in this program. Because of its success, the program was extended to cover the entire province [11]. Despite the implementation of clinical breast examination screening as the primary comprehensive screening program, there has been a lack of investigation into its costs and outcomes. Therefore, this study aims to fill this research gap by examining the costs and outcomes of this program in Isfahan Province from 2017 to 2020.

Materials and Methods

This study employed a Cost-Consequence Analysis (CCA) to assess the Costs and outcomes of the Clinical Breast Examination (CBE) screening program in Isfahan from 2017 to 2020. CCA is an economic evaluation method that focuses on the costs and consequences of a program. CCA directly assesses program costs and outcomes, using descriptive tables to guide experts and policymakers in making informed decisions about whether the program is worthy or not [12].

Screening Program

The CBE screening program in Isfahan, Iran utilized a combination of active and non-active strategies for inviting eligible individuals to participate. Based on the last published population data, the target population for the clinical breast examination breast cancer screening program comprises approximately 1,266,099 women aged between 30 and 69 years.

To invite eligible individuals in urban areas, city-wide notifications were made through various media channels, including local radio, television, and banners. In addition, individuals visiting the health centers for other services were also invited to take part in the program. In rural areas, eligible individuals who did not initially participate were contacted up to three times via phone calls to encourage their participation in the screening.

The findings of the breast screening program emerged from interviews with professionals in the field of non-communicable diseases and active midwives, while also considering the official instructions regarding the invitation process. In this breast cancer screening program, women between the ages of 30 to 69 visit healthcare centers. Midwives conduct clinical examinations and obtain their medical history. If both the examination and medical condition are normal, women are provided with education on breast self-examination (BSE). Depending on their age range, they are advised to return for CBE every two years or annually. If any symptoms or abnormalities are detected during the examination or medical history assessment, individuals are referred to the next level of examination (level two). At this level, physicians at the facility may recommend further diagnostic procedures such as mammography or sonography. It is important to emphasize that, this study does not conclude level two. In Figure 1, the operational details of this project are illustrated.

Outcome

This study included all individuals registered in the E-integrated health system (SIB (in Persian)) in Isfahan Province, aged 30–69 years who had undergone the CBE test. The outcomes of interest in this study included adherence rate, the number of symptomatic cases identified, the number of cases referred to level two, the number of cases that underwent mammography, and the number of identified cases of breast cancer.

The required outcomes data were extracted from the Health Deputy of Isfahan Province. Screening outcomes were described via frequency and rates, and data analysis was conducted using Excel.

Cost

The direct costs associated with the CBE screening program were divided into nine categories: Personnel, buildings and space, Equipment, Utility (Carriers of Energy), Training, Consumable Equipment, Transportation, Social mobilization and publicity, and Others. For each category, estimates were considered to determine the portion of costs attributed to breast cancer screening [13]. These costs were assessed from a healthcare perspective. Detailed information regarding these cost categories can be found in the Supplemental Table.

All expenses for CBE were obtained from the Financial Department of Isfahan University of Medical Sciences, utilizing the financial documents of the health centers.

All costs are reported in Iranian Rials, with year-specific values (2017-2020). These values were adjusted using the Purchasing Power Parity (PPP) conversion factor for each respective year, as provided by the World Bank's International Comparisons Program indicators [14]. To calculate the program costs Excel software was used. Additionally, a multi-way sensitivity analysis was conducted to account for potential errors in the cost the CBE screening. This analysis aimed to assess how the results would be affected if the cost estimates were to increase or decrease by 20% [15]. This sensitivity analysis helps to evaluate the robustness of the findings and provides a range of potential cost outcomes.

Results

The results of the study indicate that a total of approximately 450,876 women participated in the Isfahan breast cancer screening program during the four years. Among the participants, there were around 753,686 total

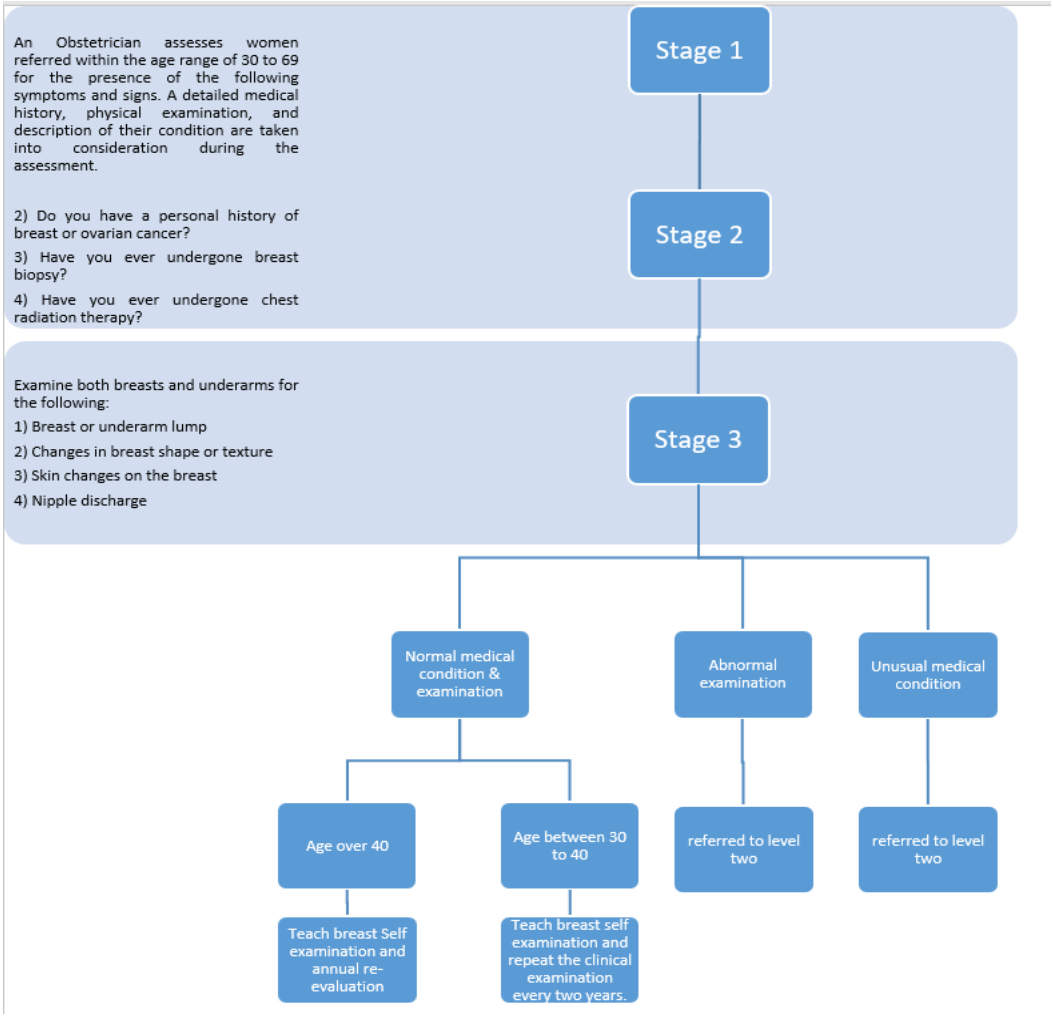

Figure 1. Early Diagnosis and Breast Cancer Screening Process

visits and about 302,810 individuals returned for the next round of screening. As it is shown in Table 1, 96.6% of the participants had Iranian nationality. The average age of participants was 47.25± 11.406. Among the participants, 87.7% were married and around 68.7% were housewives. Additionally, 61.3% of the participants were covered by social security insurance. More details presented in Tble 1:

Outcomes

From 2017 to 2020, a total of 753,686 CBE tests were conducted as part of the screening program. Among these tests, 134,508 individuals (17.85%) were diagnosed with symptoms. Out of the total participants, approximately 258,599 individuals (34.32%) were referred to level two for additional assessment. Among those referred to level two, 55,974 individuals underwent mammography tests. Out of these individuals, 713 cases were identified as having critical mammography results with Breast Imaging-Reporting and Data System (BIRAD) 4&5 classifications, indicating a higher likelihood of breast cancer. Finally, a total of 1,893 cases of breast cancer were detected during the screening program (See Figute 2). For a year-by-year breakdown of these outcomes, please refer to Table 2, which provides detailed information regarding the number of CBE tests, individuals with symptoms, referrals to level two, mammography tests, critical mammography results, and detected cases of breast cancer.

Table 1. Characteristics of the CBE Screening Participants

Variable		Number	Percentage
Nationality	Iranian	435,667	96.6
	Non-Iranian	15,209	3.4
Marital Status	Married	395,792	87.8
	Single	55,084	12.2
Number of participants (first visit)	2017	147,786	32.78
	2018	135,581	30.07
	2019	124,931	27.7
	2020	42,578	9.45

Costs

The total cost of breast cancer screening through clinical breast examination from 2017 to 2020 was estimated at around 310,514,608,558 Rials, which is equivalent to 15,470,633 PPP$ as shown in Table 3. Personnel costs accounted for the majority of the expenses, representing over 93% of the total costs. This amounted to around 291,427,886,907 Rials or 14,468,159 PPP$. The next cost categories were Consumable Equipment, and buildings and space accounted for the highest portion

Table 2. Outcome of the Breast Cancer Screening Program

Level	Consequences		2017	2018	2019	2020	Total
One	CBE tests	Number	147,786	135,581	124,931	42,578	450,876
		Ratio per target population	12%	11%	10%	3%	36%
	referred to level two	Number	50858	75220	91208	41313	258599
		Ratio per Visits	28.26%	36.01%	37.49%	34%	34.32%
	diagnosed with symptoms	Number	37574	36207	42791	17936	134508
		Ratio per Visits	20.87%	17.33%	17.59%	14.75%	17.85%
Two	mammography	Number	3033	20044	21906	10991	55974
	tests	Ratio per diagnosed Individuals	8.07%	55.36%	51.19%	61.28%	41.61%
	diagnosed with BIRAD 4&5	Number	25	261	289	139	714
		Ratio per mammography tests	0.83%	1.30%	1.32%	1.26%	1.28%
	diagnosed with Breast Cancer	Number	408	479	501	505	1893
		Cancer detection rate per visits	0.23%	0.23%	0.20%	0.41%	0.25%
		Cancer detection rate per symptomatic individuals	1.08%	1.32%	1.17%	2.81%	1.40%
		Cancer detection rate per mammography tests	13.47%	2.39%	2.29%	4.60%	3.39%

with 3.12% & 2% of the total costs.

Cost per outcome

The study findings indicate the cost per outcome measures for the breast cancer screening program through clinical breast examination. The cost per visit was calculated to be approximately 411,994 Rials which is equivalent to 20.53 PPP$. Additionally, the cost of screening per individual participant was estimated at around 688,691 Rials, equivalent to 34.31 PPP$.

Table 3. Direct Costs of the Breast Cancer Screening Program

Cost of	Value	2017	2018	2019	2020	Total
Personnel	Present Value (Rials)	52,970,712,878	59,836,597,041	66,041,830,408	112,578,746,579	291,427,886,907
	Present Value (PPP$)	3,798,572	3,724,755	2,991,641	3,953,189	14,468,159
	%					93.52%
buildings and space	Present Value (Rials)	1,784,212,022	1057079339,29	1,212,626,969	1,729,317,654	5,783,235,986
	Present Value (PPP$)	127,947	65,801	54,931	60,724	309,405
	%					2%
Equipment	Present Value (Rials)	978,684,964	97,868,496	97,868,496	97,868,496	1,272,290,454
	Present Value (PPP$)	70,182	6,092	4,433	3,436	84,144
	%					0.54%
Utility (Carriers of Energy)	Present Value (Rials)	77,025,214	89,219,595	130,184,607	144,162,205	440,591,624
	Present Value (PPP$)	5,523	5,553	5,897	5,062	22,036
	%					0.15%
Training	Present Value (Rials)	4,521,613	7,951,347	9,173,624	54,674,212	76,320,798
	Present Value (PPP$)	324	494	415	1,919	3,154
	%					0.02%
Consumable Equipment	Present Value (Rials)	1,300,569,994	2,797,313,200	2,389,512,200	3,039,546,827	9,526,942,222
	Present Value (PPP$)	93,264	174,129	108,242	106,733	482,370
	%					3.12%
Transportation	Present Value (Rials)	76,508,632	76,980,420	105,062,282	134,094,013	392,645,349
	Present Value (PPP$)	5,486	4,791	4,759	4,708	19,746
	%					0.13%
Social mobilization and publicity	Present Value (Rials)	12,816,709	15,381,814	10,074,727	12,255,755	50,529,006
	Present Value (PPP$)	919	957	456	430	2,763
	%					0.01%
Others	Present Value (Rials)	283,825,665	375,882,946	397,002,683	487,454,913	1,544,166,208
	Present Value (PPP$)	20,353	23,398	17,983	17,116	78,852
	%					0.51%
Total	Present Value (Rials)	57,488,877,696	64,354,274,201	70,393,336,000	118,278,120,660	310,514,608,558
	Present Value (PPP$)	4,122,573	4,005,975	3,188,761	4,153,322	15,470,633
	%					100%

Table 4. Cost and Outcome of the Breast Screening Program in Isfahan, Iran 2017 to 2020, Including Sensitivity Analysis

Cost (PPP$)	2017	2018	2019	2020	Total
Cost per Person	27.9	29.55	25.52	97.55	34.31
Sensitivity analysis	22.32 -33.47	23.64 -35.46	20.42-30.63	78.04-117.06	27.45-41.17
Cost per visit	22.9	19.18	13.11	34.17	20.53
Sensitivity analysis	18.32-27.49	15.34-23.02	10.49-15.73	27.34-41.01	16.42-24.63
Cost per symptom detected	109.72	110.64	74.52	231.56	115.02
Sensitivity analysis	87.78- 131.66	88.51- 132.77	59.62- 89.42	185.25- 277.88	92.01- 138.02

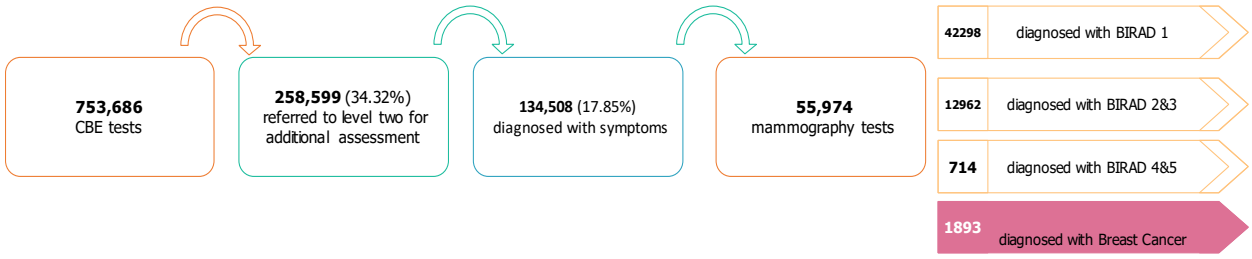

Figure 2. Outcome of Breast Cancer Screening Process from 2017 to 2020

Furthermore, sensitivity analysis demonstrated that the most influential variable in the results was personnel costs. Table 4 presents the findings of the sensitivity analysis, demonstrating the impact of a 20% increase or decrease in the variables. In the case of a 20% increase in the variables, the cost per test conducted would rise to 494,393 Rials, equivalent to 24.63 PPP$. Similarly, the cost per detected cancer case would be 196,839,688 Rials, equivalent to 9,807.06 PPP$. Additionally, the cost per participant would increase to 826,430 Rials, equivalent to 41.17 PPP$.

On the other hand, with a 20% reduction in the variables, the cost per test conducted would decrease to 329,595 Rials, equivalent to 16.42 PPP$. The cost per detected cancer case would be 131,226,458 Rials, equivalent to 6,538,04 PPP$. Furthermore, the cost per participant would reduce to 550,953 Rials, equivalent to 27.45 PPP$.

Discussion

This was a cost-outcome study that aimed to describe and analyze the costs and outcomes of the CBE Screening program which took place in Isfahan province from 2017 to 2020, this study focuses on what has been done in the CBE screening program rather than what should have been done. The results of this research indicate that in the buildings and space & Equipment sectors, the costs are higher at the beginning of the program (2017) compared to other years. This can be attributed to the allocation of space and purchase of equipment for the screening program.

Regarding personnel costs, the year 2020 experienced the highest increase due to the rise in the salary coefficient during that year. Clinical breast examination may identify some cancers that are not detected by mammography and can be valuable as an important screening tool for women who are not recommended for mammography or do not receive the recommended mammography. Furthermore, the reporting and documentation performance of clinical breast examinations is irregular and lacks standardization. Healthcare providers report a lack of confidence in their clinical breast examination skills, and the significant disparity between the number of referrals to level two and the number of cases identified with symptoms, confirming this issue.

In comparing the results of this research with previous studies, it should be noted that very few studies have meticulously examined the direct costs of a CBE screening program. Most studies have focused on the cost-effectiveness of mammography-based screening such as the study of Wong XY, et al. [16] And Alqahtani A. [17]. However, in the study run by Sun L et al. in 2019, which evaluated the cost-effectiveness of breast cancer programs for women in rural China, it was discovered that in low and middle-income countries, mammography-based cancer screening has higher cost and it might not be cost-effective with the accounting costs of mammography screening at $57 and clinical breast examination at $1.4 per individual [18].

In another study conducted by Denewer A, et al. in 2010, the cost-effectiveness of clinical breast examination in rural areas of Egypt was assessed. The target population consisted of women aged 25 to 65 in three cities in Egypt, with a total number of 50,057 individuals. The rate of cancer detection over two years in this program was estimated to be 30.5 per 100,000 individuals, and the cost of screening and treatment was about 415$ [19]. In a study by Zelle SG, et al. (2012), the cost-effectiveness, impact, and cost savings of breast cancer control in Ghana were examined. According to the results, biennial screening using CBE for women aged 40 to 69, along with treatment at all stages, is considered a cost-effective intervention. It prevents a DALY at the cost of 1,299$. In this study, the cost of biennial CBE was estimated to be approximately

40$ per person [20].

Additionally, Wu, T.-Y., et al. (2020) highlighted the beliefs, recommendations, and practices for breast cancer screening among physicians in China, emphasizing the need for improved outcomes through better screening practices [21]. Another study by MD Abu, B., & Arun K, A. (2020) presented a successful model of integrated cancer screening in low-resource settings in North India, which can serve as a valuable reference for implementing similar programs in other regions [22].

Regarding the cancer detection rate, it is steadily growing which means the program is getting better in terms of efficiency because the number of participants is decreasing each year. Given the higher allocation of costs to personnel expenses, the CBE screening program in Isfahan appears to be labor-intensive, and it seems that increasing the number of visits could make the program more cost-effective. However, further studies are needed for a more precise assessment of this matter.

Based on interviews with experts in non-communicable diseases in health deputy organizations and active obstetricians, it appears that there was more public advertising at the beginning of the program in 2017, and this advertising gradually dropped. This reduction could partly explain the decline in participant numbers in subsequent years. To enhance the CBE screening program's effectiveness, recommendations include increasing public awareness and education, enhancing training and capacity building, improving accessibility and participation, strengthening follow-up mechanisms, and continuously evaluating and adapting the program. These measures are crucial for improving early breast cancer detection and overall outcomes for women in Isfahan and similar regions.

The inability to conduct a full economic evaluation was due to the lack of effectiveness data for the CBE screening program in Isfahan. Therefore, this study was structured as a cost-consequence analysis. Our findings could serve as valuable inputs for future research that aims to assess the cost-effectiveness of the program.

Limitation

Data limitations and inaccuracies in information recording have made it impossible to determine the exact number of individuals invited to and participating in the program, and also it is not possible to measure the response rate to invitation letters. Additionally, the lack of a separate allocation for breast cancer screening program in financial records forced us to estimate its share in all cost categories, which is a complex, time-consuming process, and it may have reduced the precision of the study. Based on interviews, some women who were diagnosed with severe symptoms don't follow up with healthcare centers, and they may or may not have follow-up treatment in private healthcare facilities. Either way, the data of their status is not documented in the E-integrated health system. This study specifically focused on the cost analysis of the first level of breast cancer screening, which involves clinical breast examination. The costs associated with the second level of screening were not included in our estimation. Therefore, the findings and cost calculations presented in the study pertain solely to the expenses related to the initial screening stage.

In conclusion, based on this study, it is possible to identify approximately 1,893 cases of breast cancer at the cost of around 15.5 million dollars, prevent their progression to advanced stages, identify and prevent the progression of 713 cases of malignant breast cysts, and provide a significant number of women in the target age group with breast self-examination education while raising public awareness about this disease.

Author Contribution Statement

FMS and FR designed the study, ShT and ZR gathered data in terms of outcomes, cost data were gathered by ShT. FMS, FR, and ShT analyzed the data. FMS, FR, ZR, and ShT contributed in writing the manuscript. All authors have read and approved the final manuscript.

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Scientific approval

This manuscript is part of a master's thesis approved by the Isfahan University of Medical sciences with scientific code of 3400695.

Ethical approval

Research ethical approval was given by the research ethics committee of Isfahan University of Medical Sciences, Isfahan, Iran under the number (IR.MUI.NUREMA.REC.1400.178). This study has used the secondary data of CBE screening outcomes; all data was anonymized and all identifying information was removed.

Availability of data

All data generated and analyzed during this study are included in this published article.

Conflict of Interest

The authors have no conflicts of interest to declare.

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