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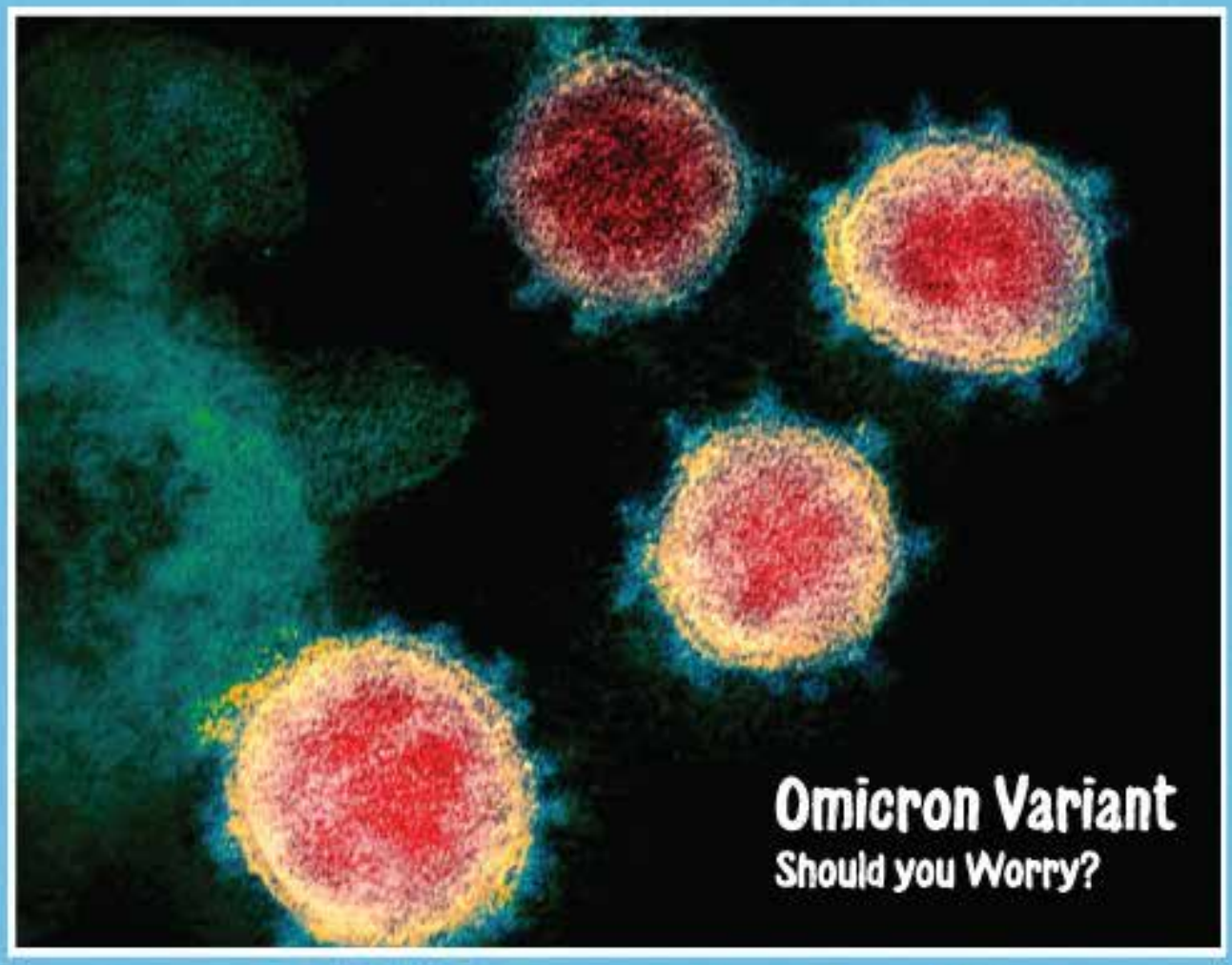


The Official Journal of the Gulf Federation For Cancer Control

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Original Article

# Impact of Screening Programs on Stage Migration in Breast Cancer

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## Abstract

**Introduction:** Breast cancer (BC) is the leading malignancy globally with consequent morbidity, mortality and burden on health care resources when diagnosed at an advance stage. Early–stage diagnosis is crucial to the better outcome. Screening is pivotal to early detection at an early stage. It is understood to reduce mortality, improve outcome, and is cost effective.

**Objective:** The objective of the study was to see the impact of screening program on Breast cancer stage in Oman. In this study we looked into the trends in stage–specific breast cancer incidence during two pre–specified time periods 2006–2010 and 2015–2017, before and after the introduction of a national screening programme in Oman.

**Patients and Methods:** It is a retrospective analysis, where breast cancer patient's data was retrieved from Oman national cancer Registry ministry of health Sultanate of Oman, for two pre–specified time periods 2006–2010 before the introduction of cancer screening programs and 2015–2017. The cases included were those who had confirmed histopathology diagnosis and where a composite stage, based on TNM stage, was available to be analysed and compared in these two pre–specified time periods to find out the difference between these two time periods. The statistical analysis was carried out and p values were determined. Ethical approval obtained from Royal Hospital medical ethics and scientific research committee.

**Results:** There was a 41% reduction in stage IV breast cancer from 23.01% to 13.58 %, and 86.15% increase in stage 0–1 from 6.86 % to 16.98%. (p Value <001). The stage 0 cases increased from 0% to 4.26 %. With regard to tumour size, T0–1 tumours increased from 14.16% to 26.03%, while T4 tumours decreased from 16.59% to 7.69%. There was increase in node negative breast cancer cases in Oman. The N0 increased from 28.43% to 37.64%. The diagnosis as Non–metastatic M0 disease increased from 39.77% to 60.23%, while diagnosis as metastatic M1 disease decreased from 55.32% to 44.68%.

**Discussion and Conclusions:** The introduction of national screening programme in Oman resulted in a continued increase in localized cancers and a decline in advanced disease. Screening programmes should be evaluated continuously and systematically to ensure their targeted objectives. The causal link between stage distribution and mortality needs to be investigated further in the context of screening. Health planners, policymakers, and other stakeholders; including clinicians, educators, community members, and advocates, should be aware of the health system requirements, as well as overall costs of these approaches to breast cancer early detection, to make effective investments, plans, and policies.

**Key Words:** Breast Cancer, Screening, Oman, Royal hospital, early detection, early stage, OCA

## Introduction

Breast cancer is the leading malignancy globally with ensuing morbidity, mortality, and burden on health care resources[1, 2]. The risk of developing breast cancer has increased in both developed and developing countries by 1%–2% annually[3]. The impact of breast cancer is

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more pronounced if it is diagnosed at a higher stage, as witnessed in the developing World. Primary prevention is desirable, but in practice frequently not feasible due to the inconsistency of risk factors, many associated with changing lifestyle. As a component of secondary prevention, breast cancer screening is anticipated to achieve an early–stage diagnosis and enhance prognosis. Treating the cancer at a more curable early localised stage eventually lead to a better outcome and cost effectiveness[4]. It is suggested that population–based screening may reduce breast cancer related mortality by 25–31%[5]. Whether screening benefit outweighs the potential over–diagnosis (cancer that would not have been diagnosed in a lifetime, had she not been screened) is questionable[6]. A decrease in advanced stage cancers is the early marker of effectiveness of screening, in a given population[5]. As stage distribution is a surrogate for improved survival, shifting trends in the stage distribution (increase in the incidence of localized cancers and decrease in the incidence of more advanced stages) may encourage screening as an effective prevention[4].

The principal objective of breast cancer screening is to decrease breast cancer mortality through early detection, diminish morbidity, and confer reassurance by a normal screen result[7]. Potential harms include pain and discomfort during mammography examination and anxiety about screening[6]. Breast cancer screening with mammography has been recommended for many decades for women over the age of 40 years in United States[8]. New screening modalities (magnetic resonance imaging, ultrasound, computerized tomography, positron emission tomography and biopsy.) have been gradually integrated into practice, but none of these has been evaluated for their impact on breast cancer outcome or mortality[9]. However, these techniques have limitations being expensive, time consuming and not suitable for young women. Developing a highly sensitive and swift breast cancer diagnostic method for early–stage diagnosis is important. Screening may yield both false positive and false–negative results as well. It is estimated that 1 in 2 women will have at least 1 false–positive mammogram result, and False–negative mammography examinations occur in approximately 20% to 40% of women with breast cancer. One in 5 women is also likely to have at least 1 false–positive clinical breast examination. False–positive results cause anxiety, added outlays, and morbidity. Over diagnosis and overtreatment of clinically insignificant disease is possible, of these cases was also available as per radiologic assessment (Ultrasound particularly ductal carcinoma in situ observed by mammogram. There are also apprehensions regarding radiation–induced breast cancer from repeated mammography, but the potential benefits outweigh the risks. Tumour dissemination after needle biopsy has also been suggested though the clinical significance is uncertain. Observer inconsistency among radiologists who interpret mammogram has been mentioned, which guides decision to perform a breast biopsy and can directly affect patient management. The benefit–to–harm ratio of screening enhances with women age because screening accuracy improves, and prevalence of breast cancer increases.

The efficacy of a breast cancer screening programme is assessed by compliance rate, cancer detection rate, rate of detection of advanced cancers (T and N status), follow–up rates, cost–effectiveness, public perception, and follow–through on screening recommendations, and change in provider and health care worker perception[3].

Community breast screening programs afford their expected benefit by diminishing the risk of breast cancer death amongst women and mammography is a principal tool[10]. A persistent follow–up is needed to assess the impact of mammography screening program on breast cancer mortality. The advanced breast cancer incidence rate (ABCR) can possibly be used as an early indicator of the efficacy of a screening program. The relationship between declines in breast cancer mortality and ABCR has been decisively established from screening trials. In a pooled analysis from eight trials, decrease in the risk of advanced breast cancer and the decrease in the risk of death from disease were approximately proportional.

When breast cancer is diagnosed and treated early, the outcomes and odds of survival are very high. Women often confront multifarious barriers to early detection, including social, economic, geographic, and other interrelated factors[4]. These can restrict their access to timely, affordable, and effective breast detection amenities[11]. The World Health Organization (WHO) has defined two distinct but related approaches to boost the early detection of cancer: early diagnosis (the recognition of symptomatic cancer at an early stage), and screening (the identification of asymptomatic disease in a healthy population)[28]. In low and middle–income countries (LMICs), a substantial proportion of breast cancer patients present late and are diagnosed at an advanced or metastatic stage[11,4], often due to barriers to screening[27]. Less than 50% of breast cancers are screen–diagnosed even in the most effective screening programs. Resource–stratified guidelines for early detection of breast cancer were developed by the Breast Health Global Initiative (BHGI). Delays in breast cancer treatment >3 months are linked with more advanced disease stage at diagnosis and inferior survival[4]. The training of primary care providers to recognize early signs and symptoms of breast cancer is compulsory for early referral through the health care system. Barriers to prompt health care should be recognized and rectified.

If the health system is fragmented through the entire care pathway, a diagnostic delay will ensue. Once high–quality, accessible services are in place to diagnose and manage clinical disease, early detection by screening programs is desirable[4]. If a screening program, though well intentioned, is commenced in a health care system that is not equipped to refer, diagnose, and treat the abnormalities it detects; then the program will not succeed. It may actually reinforce the pre–existing beliefs that cancer cannot be cured, maintaining a cycle of late presentation. There is limited evidence for the efficacy of Clinical Breast Examination only as a population–based screening modality where mammography is not routinely performed[11].

Despite screening mammography, the incidence of Stage IV breast cancer (BC) at diagnosis is not decreased in USA over the past four decades as projected. The reasons underlying this problem are still unknown. Stage I and Stage IV breast cancers may represent very different biologic tumour types. This may explain why the incidence of Stage IV cancer has not decreased with screening. The de novo Stage IV breast cancer may have a uniquely aggressive biology versus early–stage tumours commonly found on mammography, granting it growth properties that allow it to escape detection by screening. Aggressive tumour biology accounts for nearly 40% of advanced–stage tumours, versus only 5% of tiny early–stage tumours. Conversely, indolent biology is rarely associated with advanced disease[12].

Recommended screening in High risk from 40 years annually or biennially, from 50–74 years annually[13, 14, 15] American association of family Medicine 2016 –13, US Preventive services Task Force 2016 –14, American cancer society and IACR 2015, American college of Physicians)[30]. Oman follows a locally developed operational guideline for early detection and screening of breast cancer by department of family and community health, directorate general of health affairs ministry of health[19].

This study evaluates the impact of screening programs in the Sultanate of Oman (Clinical Breast Examination (CBE) and mammography) on Breast cancer stage at diagnosis in Oman, and its impact on practice and outcome.

## Patients And Methods:

Oman has a well organised national cancer registry operating under the auspices of the ministry of health since 1996, much earlier than other regional countries. It collects data on all cancers from all over the Sultanate of Oman, systematically analyse this data and publish its annual report on cancer incidence in Oman annually since 1996. The collected data undergo quality assurance and is well kept since its inception[26].

Ethical approval obtained from Royal Hospital medical ethics and scientific research committee. This study is a retrospective analysis where we estimated the trends in stage–specific breast cancer incidence during two pre–specified time periods 2006–2010 and 2015–2017, before and after the introduction of a Ministry of Health National screening programme and the Oman cancer association (OCA) mobile screening mammography in Sultanate of Oman.

The confirmed Omani female breast cancer cases data was retrieved from Oman cancer registry of Ministry of health, for 2006–2010 and 2015–2017[26]. The cases included in the analysis were those who had confirmed histopathology diagnosis and where a pathology stage data of Tumour stage and lymph node stage was available. The M stage (distant metastasis), CT scan, PET scan, MRI, bone scan) or biopsy from a metastatic site. A composite stage of disease was therefore available in all these cases, included in the analysis. The cases which have incomplete information on record, with respect to these parameters, were excluded.

The composite stage, T stage, N stage and M stage were analysed in these two pre–specified time periods to find out the difference between these two time periods. The statistical analysis was carried out and p values were determined.

## Results:

There was a 41% reduction in stage IV breast cancer from 23.01% to 13.58 %, and 86.15% increase in stage 0–1 from 6.86 % to 16.98% (p Value <001). The stage 0 cases increase from 0% to 4.26 %. There was 83.83 % increase in small size tumours < 2 cm (T0–1 tumour). In 2006–2010 there were 64 (14.6%) cases diagnosed with T0–1 tumour which has increased to 159 cases (26.03) in 2015–2017, which was statistically significant (P –value= <0.001) {table 2}. The late T4 tumour and size > 4 cm cases in 2006–2010 were 75 (16.59 %), while in 2015–2017 the number of these cases reduced to 47 (7.69 %), a reduction of 53.56 % which was statistically significant (P –value= <0.001) (table 2).

The percentage of tumour stage (based on pathologic tumour size) T0 –T1, T2, T3 and T4, for time periods 2006–2010 and 2015–2017 were 14.16%, 39.38%, 18.58%, and 16.59% vs. 26.03%, 45.66%, 17.35%, and 7.69% respectively (Figure 1 and Table 2). The percentage of early stage (T0 and T1) cases were increased by 11.87%, while advanced stage T4 tumours decreased

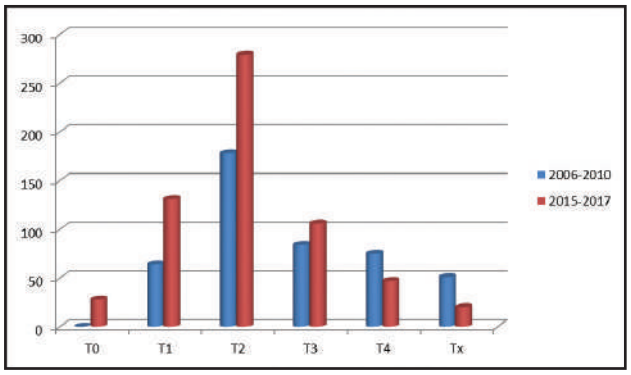


**Figure 1: T stage in 2006–2010 and 2015–2017**

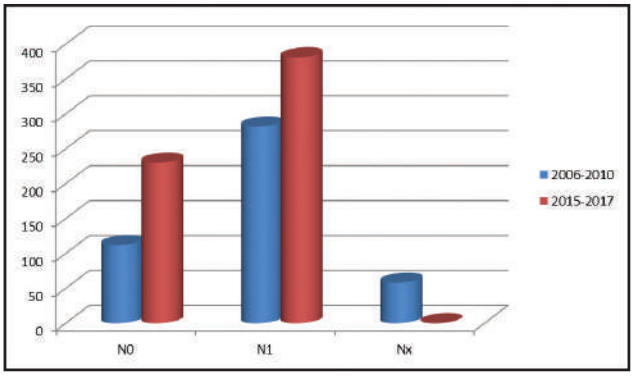


**Figure 2: Nodal status 2006–2010 and 2015–2017**

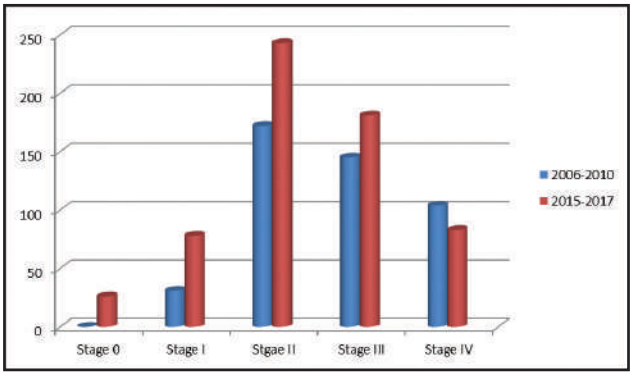


**Figure 3: Composite tumour stage 2006–2010 and 2015–2017**

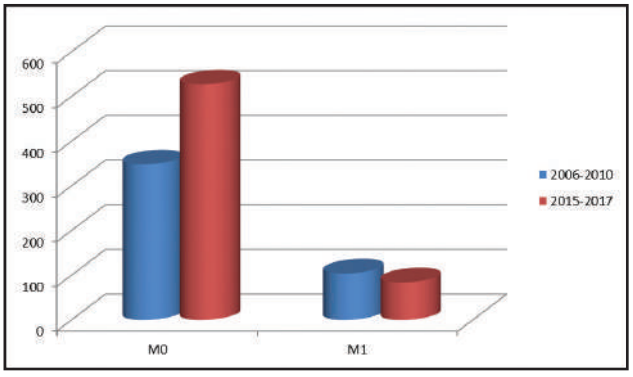


**Figure 4: M0 and M1 stage in 2006–2010 and 2015–2017**

from 16.59% to 7.69%. The undetermined Tx tumours decreased from 11.29% to 3.27% in these time periods.

| Tumour Stage | | | | |
|---|---|---|---|---|
| | 2006–2010 | 2015–2017 | Total | P –value |
| T1 | 64 | 159 | 223 | <0.001 |
| T4 | 75 | 47 | 122 | |
| Total | 139 | 206 | 345 | |
| | | | | |
| **Nodal Stage** | | | | |
| | 2006–2010 | 2015–2017 | Total | P –value |
| N0 | 112 | 232 | 344 | 0.002 |
| N1–3 | 282 | 345 | 627 | |
| Total | 394 | 577 | 971 | |

**Table 1: The T and N stage in 2006–2010 and 2015–2017**

| Tumour Size | 2006–2010 | 2015–2017 | Total | P Value |
|---|---|---|---|---|
| T0 | 0 | 28 | 28 | <0.001 |
| T1 | 64 (14.16%) | 131 (26.03%) | 195 | |
| T2 | 178 (39.38%) | 279 (45.66%) | 457 | |
| T3 | 84 (18.58%) | 106 (17.35%) | 190 | |
| T4 | 75 (16.59%) | 47 (7.69%) | 122 | |
| Tx | 51 (11.29%) | 20 (3.27%) | 71 | |
| Total | 452 | 611 | 1063 | |

**Table 2: T stage in 2006–2010 and 2015–2017**

| Lymph Node Status | 2006–2010 | 2015–2017 | Total | P Value |
|---|---|---|---|---|
| N0 | 112 (24.78%) | 232(37.97%) | 344 | <0.001 |
| N1–3 | 282 (62.39%) | 345 (56.46%) | 627 | |
| Nx | 58 (12.83) | 34 (5.57%) | 92 | |
| Total | 452 | 611 | 1063 | |

**Table 3: N stage in 2006–2010 and 2015–2017**

The percentage of Lymph Node status N (based on clinical and pathologic numbers, size, and involvement) Node negative tumour (N0) and node positive tumours (N1–3) for time periods 2006–2010 and 2015–2017

| Tumour Composite Stage | 2006–2010 | 2015–2017 | Total | P Value |
|---|---|---|---|---|
| 0 | 0 | 26 (4.26%) | 26 | <0.001 |
| I | 31 (6.86%) | 78 (12.77%) | 109 | |
| II | 172 (38.05%) | 243 (39.77%) | 415 | |
| III | 145 (32.08%) | 181 (29.62%) | 326 | |
| IV | 104 (23.01%) | 83 (13.58%) | 187 | |
| Total | 452 | 611 | 1063 | |

**Table 4: Composite tumour stage in 2006–2010 and 2015–2017**

| Metastatic Disease Status | 2006–2010 | 2015–2017 | Total | P Value |
|---|---|---|---|---|
| M0 | 348 (76.00%) | 527 (86.25%) | 875 | <0.001 |
| M1 | 104 (24.00%) | 84 (13.75%) | 188 | |
| Total | 452 | 611 | 1063 | |

**Table 5: Metastatic M0 and M1 stage in 2006–2010 and 2015–2017**

were 24.78%, and 62.39% Vs. 37.97% and 56.46% respectively (Figure 2 and Table 3). The N0 cases were increased by 13.19%, while N1 cases decreased by 5.93% as well during these time period.

The results also suggest that decrease in Nx and improved early stages at diagnosis, may well be a result of improved surgical skills and pathologic diagnostic accuracy.

The ratio of composite tumour stage (based on pathologic extent of involvement) 0, I, II, III, and IV for time periods 2006–2010 and 2015–2017 were 0, 6.86%, 38.05%, 32.08%, and 23.01% Vs. 4.26%, 12.77%, 39.77%, 29.62% and 13.58% respectively (Figure 3 and Table 4). After screening strategy in place now we have started to see stage 0 disease. The early stage (0 and I) disease increased by 10.17%, while stage IV disease decreased by 9.43%.

The percentage of M0 and metastatic M1 stage (based on pathologic extent of involvement) for time periods 2006–2010 and 2015–2017 were 76% and 24% Vs. 86.25% and 13.75% respectively (Figure 4 and Table 5). The M0 stage were increased by 10.25%, while M1 cases decreased by 10.25% during these time periods.

## Discussion:

Population–based screening programs are distinguished by central screening invitations to a well–defined target population, systematic invite, recall for screening, well–timed delivery of test results, diagnostic investigations, treatment, and follow–up care[18]. In the population, mammography remains the main standard screening tool while the value of clinical breast examination (CBE) and self–Breast examination (BSE) are less established. New screening modalities are questionable to replace mammography in near future for screening. The only breast screening test with sufficient evidence of a reduction in breast cancer mortality in population–based programs is mammography. IARC though, in 2015 showed evidence that screening with clinical breast examination alone can identify tumours at an early stage, a primary step to reduced mortality[20, 7].

Investigators have studied many breasts diagnostic approaches including mammography, magnetic resonance imaging, ultrasound, computerized tomography, positron emission tomography and biopsy. However, each of these techniques has some limitations such as being expensive, time consuming and not suitable for young women. There is an urgent need to develop a highly sensitive and quick early–stage breast cancer diagnostic method.

A retrospective study evaluated One hundred fifty–two breast cancer patients diagnosed between January 1996 and June 2002, from Oman. The mean tumour size was 4.6 cm, and 34.9% and 15.8% of patients had stage III or IV disease, respectively[21]). Another retrospective study of 122 breast cancer from January 2003 to December 2008 in Oman, presented mostly as advanced stages with stage III (41.2%) and IV (18.2%)[22]. Breast cancer data from 2006–2010 at National Oncology Centre – the Royal hospital Oman of 542 breast cancer, showed 19.7% of patients diagnosed as stage IV, and 30% diagnosed as stage III[23]. Early diagnosis in asymptomatic patients is a critical in improving the outcome of Breast cancer. Diagnosis of breast cancer at an early stage can increase the survival rate and reduce the cost of treatment by more than 70%[23].

In Norway, reported annual incidence of screen detected localized breast cancer among women doubled from 63.9 per 100 000 to 141.2 per 100 000, after the national cancer screening program. Before screening was nationally introduced 42% of all screen–detected breast cancers were of localized stage rising to 55% in the age group eligible for screening. This surge was seen despite the concurrent increase in the number of more advanced stages. The stage–specific incidence may also be influenced by public awareness and advances in mammographic imaging[5].

In a 10 years period 2003–2004 to 2013–2014 in Germany, BC incidence exhibited a distinctive prevalence peak with the introduction of the mammography

screening, mainly steered by an increase of early-stage BC. The stage III and IV BC incidence in 2013–2014 was 23.0% – 28.3% lower than in the pre–screening period. From 2003/2004 to 2015/2016 BC mortality was decreased by 25.8 %. The decline of late-stage BC incidence and BC mortality in the screening subjected groups in Germany is most probably attributed to the initiation of national mammography screening program. These encouraging effects are attained at the cost of a moderate over–diagnosis of in situ cancers[16].

The projected stage distribution in USA, when matched between 1982 and 1998 (Screening in USA was introduced in 1983), the proportion of localized stage increased between these two periods. The incidence of early–stage breast cancer including ductal carcinoma in situ doubled, while the rate of late-stage cancers only decreased by 8%, an imbalance suggestive of substantial over–diagnosis[5]. In a meta–analysis of 22 European studies the trend, though inconsistent, does support a reduction in advanced breast cancer incidence following the introduction of mammography screening programs.

A new screening policy and enhanced mammography in Netherlands have improved the detection of an early carcinoma and reduced the risk of interval carcinoma[17]. Women need balanced, high–quality information to make an informed decision on the benefits and harms of breast screening. Audit and evaluation of screening programmes on the advantages and detriments of long–term repetitive screening, is always justified to improve it. The high risk for repeat screening at initial assessment is acceptable because of the prevalent cases detected at initial examination and the absence of a previous mammogram for comparison. Younger women have comparably dense breast tissue, which diminishes with age, and causes more false–positive impressions and need for reassessments at the beginning of the series than at the end. The incidence of breast cancer increases with age, with subsequent increased chances for screen–detected breast cancer. The incidence of interval cancer is stable over 13 examinations, and the cumulative risk was lower in this study (2.9% versus 3.7%). Based on the long–term data after 13 consecutive screening examinations, the chance of a false–positive recall in the Netherlands is relatively low (4.2%), and screen detection of early breast cancer has improved to 5.3%. In this Dutch study the probability of false positive results is relatively low, while a new screening policy with improved mammography have increased the detection of early carcinoma and lowered the risk of interval carcinoma[17].

Most national programs endorse screening with mammography, with or without clinical breast examination, commencing at the age of 40 years[7]. Community based data on clinical breast examination suggest a lower cancer detection rate than suggested from clinical trials. Breast self–examination is no longer recommended by most expert groups. Limitations and potential harms have been identified for all existing screening tools[6,7]. Quality control needs to be emphasized for established screening methods.

Mammogram equipment is expensive, and their only utilization is in breast imaging, thus restricting their accessibility in LMICs[29]. The health system must support structured training of radiologists and radiographers, endure quality control, patient tracking, effective communication for patient follow–up, and service provider feedback; to make mammography optimally effective in screening and diagnosis. All this have substantial initial and continuing operational costs[11]. Human development in a country is based on national income or GDP, life expectancy, education, fertility rates, strength of the health system, life expectancy, and long–term survival from disease including cancer. Disease stage at diagnosis can be taken as a starting locus as the first measurable factor that most directly influences survival.

A recent review of cancer control priorities and policies in 158 countries illustrated that there are fewer breast cancer early detection programs in LMICs compared with high–income countries. Even in high–income countries, there are significant health care inequalities, involving access to early detection, diagnosis, and treatment for women with breast cancer. Ineffective and redundant referral pathways spark system delays and contribute major cancer care disparities worldwide[29]. Delays from onset of symptom to diagnosis vary from weeks to many months in different parts of the World, due to ineffective role of primary care physicians and redundant referral pathways. Unqualified and inexperienced health workers are more prone to misdiagnose cancer. The impact of both system and patient–related delays cannot be underestimated[11].

There is no well organised comprehensive national breast cancer screening program in Oman. There are two screening programs in Oman, the Oman cancer association mammogram screening and Clinical breast examination by the Department of Family & Community Health, MOH. Oman Cancer Association's Mobile Mammography Unit (MMU), provides free breast cancer screening for women over the age of 40, touring around Oman twice a year. Since its establishment in 2009, the MMU has offered over 22,000 mammograms. OCA opened in 2013 a Clinical Breast Examination (CBE) unit that provides free screening services to all women regardless of their nationality or age. This service is facilitated with ultra–sound equipment that allows the health specialist

a more in–depth exploration when required. Further, OCA created the Self Breast Examination (SBE) program to t9ain women to perform a self–exploration, thus empowering them to take care of their health[24, 25]. The MoH piloted a regional early detection program in 2009 in two governorates, North Sharqia and Dahirah. Gradually it expanded regionally to six of the eleven governorates in 2015, including Dohfar, Buraimi, Dakilyia, and Muscat. The program provides CBE and teaches breast self–examination (BSE) to 40–59–year–old Omani women. Any woman with demonstrated risk factors or suspicious results is referred to as the closest hospital for evaluation by a surgeon. Cases suspected to be positive by the surgeon also referred to receive a mammogram, usually in the same facility[19].

## Conclusions:

The introduction of the national screening programme resulted in a consistent increase in localized cancers and a decline in advanced disease, with an over–diagnosis of localized cancers[4]. The underlying link between stage distribution and mortality requires to be investigated further in the perspective of screening. Screening programmes should be appraised continuously and systematically to ensure that they are sustaining their targeted objectives. Any potential areas for improvement should be ascertained and managed in an appropriate and effective manner with defined interventions and furtherance.

Early diagnosis endeavours primarily should be prioritized over organized population–based screening until infrastructure and organizational prerequisites for screening are in place to contemplate this additional pursuit. Health planners, policymakers, and other stakeholders; including clinicians, educators, community members, and advocates, should be conscious of the health system requirements. They should apply balanced approach in consideration with overall costs of breast cancer early detection to make effective investments, strategies, and policies. Regardless of screening modality, the development of a population–based screening program should be considered in any national cancer control plan and national health financing strategy. The financial costs, at both national and societal levels, are extensive and should be weighed against competing health priorities[29].

All countries are challenged to meet the ambitious objectives of the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases (NCDs) and to achieve the related Sustainable Development Goals target, a one–third reduction in mortality from NCDs by the year 2030[26, 29]. Breast cancer is the most common cancer in women globally; and its survival depends essentially on access to timely, effective, and affordable cancer care. Early detection is decisive to breast cancer outcome and survival. When combined with prompt access to treatment, appropriate follow–up, and survivorship care; there can be considerable and sustainable declines in breast cancer mortality[29]. A strong and efficient health system is a prerequisite for providing state of the art management for breast cancers that are diagnosed through the early detection programs, whether with symptomatic breast cancer or through screening. Although patient and health provider education may shorten the patient interval, to achieve a diagnostic interval target of less than 60 days requires coordination of the diagnostic pathway, components of clinical evaluation, radiologic imaging, tissue sampling, and pathologic assessment[11].

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