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An Audit of Clinically Triaged Women at Low Risk for Breast Cancer Presenting to the Helen Joseph Mammography Unit, Johannesburg

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A research report submitted in format of a submissible article to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Diagnostic Radiology

Johannesburg, 21st May 2022

Declaration

I, Lavandhra Rajendran Naidu, declare that this research report is my own work. It is being submitted for the degree of MMed (Diagnostic Radiology) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Dr LR Naidu
On this 21st Day of May 2022

Publications and presentations

This article has been submitted and accepted for publication in the June 2022 edition of the South African Journal of Surgery.
It has never been presented at a congress.

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Research Ethics Committee Approval: Ethics clearance certificate was obtained from The University of the Witwatersrand, Johannesburg. Ethics number: M201025, Appendix A.

Declaration of Conflict of Interest: The author declares no conflict of interest.

Abstract

BACKGROUND

The Helen Joseph Hospital (HJH) Breast Clinic utilises a clinical triage system to stratify patients based on their risk of breast cancer into high, medium, or low risk profiles. This allows for timeous imaging and subsequent management of those patients at increased risk for breast cancer.

OBJECTIVES

The primary objective was to determine the cancer detection rate (CDR). The secondary objective was to correlate biopsy results with the Breast Imaging – Reporting and Data System (BI-RADS) risk-assessment.

METHODS

A retrospective audit of the patients at low risk for breast cancer who were referred to the Breast Imaging Unit (BIU) in 2019 at HJH. Patients were clinically assessed as low risk based on a triage form (Figure 4) and were identified using the imaging files stored in the BIU. Results were recorded on Microsoft Excel and calculated as per the American College of Radiology guidelines.

RESULTS

The total population sample consisted of 398 patients. Two patients were characterised as BI-RADS 4 and underwent breast biopsies. One patient was diagnosed with histologically proven breast cancer.

The CDR was 2.51% and the most representative age group was the 60 to 69 years one. The most common BI-RADS breast density assessment was group B while the most common BI-RADS risk assessment was category 2.

CONCLUSION

Amongst the low-risk population, both the CDR and spectrum of disease was comparable that of a screening population. This may be due to the use of a triage system prior to imaging, as well as an increase in clinical awareness of breast cancer within a tertiary institution.

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C. List of Abbreviations and Terminology

ACR	American College of Radiology
BCSC	Breast Cancer Screening Consortium
BIU	Breast Imaging Unit
BI-RADS	Breast Imaging – Reporting and Data System
CDR	Cancer Detection Rate
HJH	Helen Joseph Hospital
GLOBOCAN	Global Cancer Observatory
CANSA	The Cancer Association of South Africa
RSSA	The Radiological Society of South Africa
BISSA	The Breast Imaging Society of South African
USPTF	United States Preventative Task Force
MMG	Mammogram
USS	Ultrasound
NA	Not applicable

1 Rationale

Helen Joseph Hospital (HJH) is a tertiary-level hospital, within Johannesburg, South Africa, which offers an open access breast clinic to members of the public. Patients who are concerned about breast pathology of either benign or malignant origin present to the breast clinic where they are colour triaged into green (low risk), yellow (medium risk) or red cases (high risk). This reflects their overall risk for breast cancer. Low risk females are defined as individuals over the age of 40 who present with bilateral typical breast pain from no other medical cause or those who are asymptomatic and present for breast evaluation.

The purpose of this study was to conduct a retrospective audit of the HJH Breast Imaging Unit (BIU), to describe the spectrum of disease and the radiological findings within a low-risk triage group, and to correlate this with the histology when appropriate.

2 Introduction

2.1 Epidemiology of Breast Cancer

A global increase in population, compounded by an increase in life-expectancy and westernization of lifestyle has seen an increase in cancer as a major cause of morbidity and mortality.(1) Breast cancer remains the foremost cancer in females in both high and middle-to-low income countries.(2) In 2018 it accounted for 11.6% of all newly diagnosed cancers and 6.6% of all cancer-related mortalities globally.(2) Predictions estimate that it will reach up to 22 million new cases within the next two decades.(3) According to GLOBOCAN 2018, the incidence of breast cancer is highest in the first world, but its mortality is greatest in a third world setting.(4) The pooled crude incidence of breast cancer was 24.5 per 100 000 person years across the African continent.(5) The 2018 Ekurhuleni Population Based Cancer Registry demonstrated that breast cancer was the most common cancer amongst the female population within this Johannesburg district.(6)

2.2 Screening Mammography

Breast screening is the process whereby radiological imaging is utilised within a population of asymptomatic patients. The primary aim is to improve the detection of breast cancer.(7) Mammography is the only screening tool proven to decrease

mortality and as such, it remains the gold standard and the corner stone of all screening programs.[8]

2.2.1 Southern African Recommendations

South Africa does not have a formalised national screening programme.[9] Multiple institutions have different recommendations.

Cancer Association of South Africa (CANSA) recommends annual screening mammogram for all females over the age of 40 who are asymptomatic.[10]

The Radiological Society of South Africa (RSSA) and The Breast Imaging Society of South African (BISSA) both advise self-care examination in combination with annual screening between ages 40-70.[9]

2.2.2 Rationale of Screening Mammography

There is much debate as to the role that breast screening plays in reducing the overall mortality rate.[11] Individuals who attended screening programs have a 41% decrease in their 10-year breast cancer mortality rate as well as a 25% decrease in the incidence of advanced breast cancer.[12]

The Canadian National Breast Screening Study follow up published in 2014 demonstrated that in females aged 40-59, annual mammography is equivalent to that of a physical examination in decreasing breast cancer mortality.[13] It stated that there was no statistical difference in the mortality of patients who underwent screening versus those that did not and that the screening group was at increased risk of over-diagnosing cancer.[13]

The United States Preventative Services Task Force (USPSTF) has recommended that screening begin from the age of 50, biennial, in order to reduce the rate of over-diagnosis.[14] The National Health Service in England, offers screening mammography once every three years to individuals between the age 50-70.[15]

3 Primary Objective

To calculate the cancer detection rate in low-risk women who present for mammography at the breast imaging unit at HJH.

4 Secondary Objectives

1. To assess the spectrum of disease found at mammography and sonography in low-risk women triaged and referred to the BIU.
2. Where biopsied, to correlate BI-RADS classification with the histology results.

5 Methodology

5.1 Research Paradigm

This is a retrospective, observational, cross-sectional study – an internal audit.

5.2 Sample

Low-risk females who present for imaging at the BIU at HJH for the first six months during 2019.

5.2.1 Inclusion Criteria

1. Women triaged as low risk in the HJH breast clinic and subsequently referred to the HJH breast imaging unit.

5.2.2 Exclusion Criteria

1. A history of prior breast cancer.
2. Yellow and red coded patients.

5.2.3 Triage System

Patients are colour triaged according to an algorithm used in the HJH breast clinic. This is based on their history, examination and age of presentation as illustrated in Figure 1. High risk females were those who are colour coded as red, and intermediate risk females were those who are colour coded as yellow. Low risk females were classified as following: those over fourty years of age, are asymptomatic, with bilateral mastalgia not related to an underlying medical condition and who require imaging for a non-surgical reason. These patients were classified as Green.

(Figure 1, Table 1).

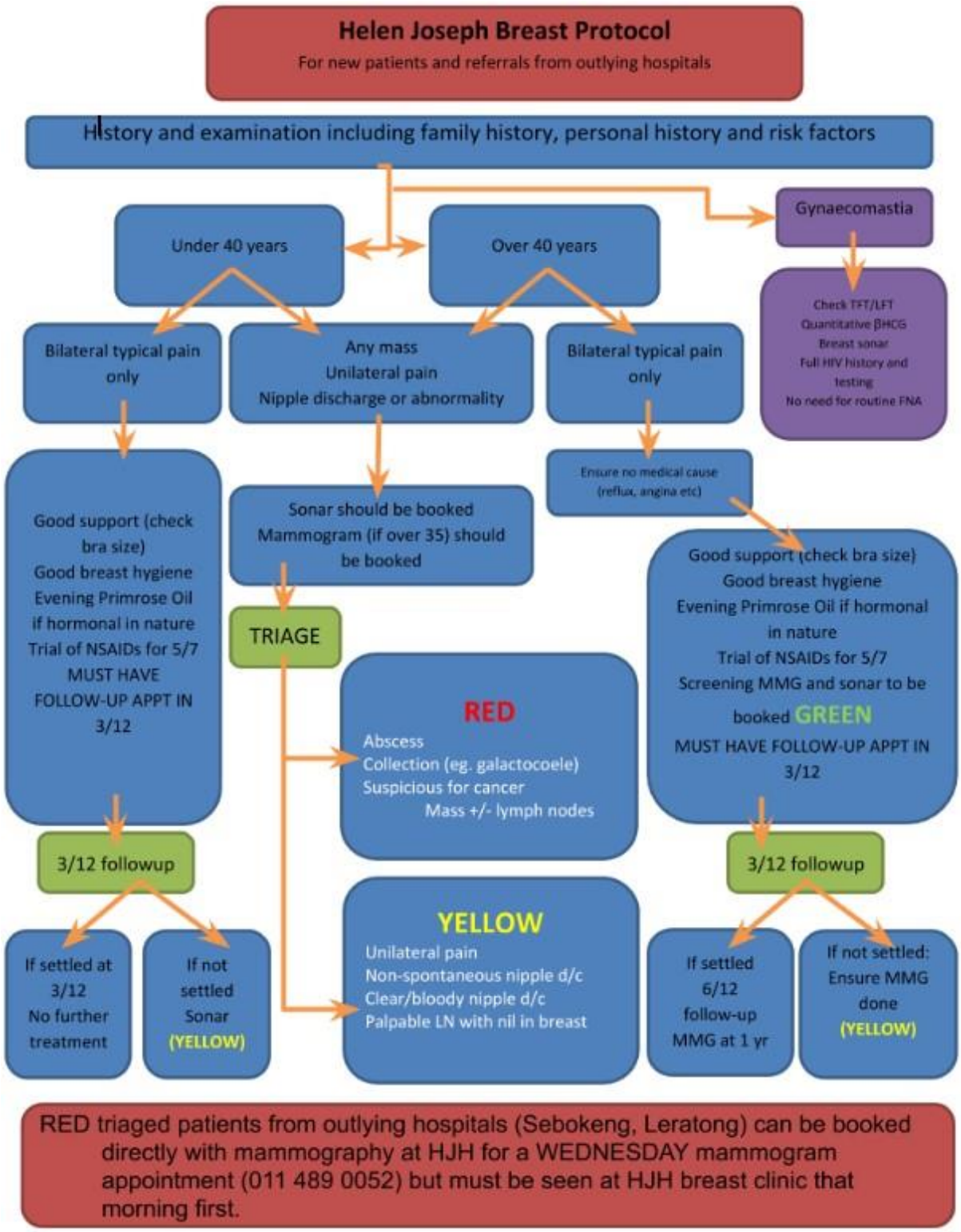


Figure 1: The HJH Breast Clinic Triage Form.

Figure 1 describes the Triage Form currently in use at the HJH Breast Clinic and provides a flow diagram on how patients were assessed and their basic management plan.

Table 1: Triage criteria

Colour	Green	Yellow	Red
Criteria	Over 40 years: • Bilateral typical pain (no other medical cause) • Asymptomatic patients • Do not meet the criteria for yellow or red • Breast examination prior to initiation for hormonal replacement therapy.	Any age: • Unilateral pain • Nipple discharge- clear, bloody, or non-spontaneous • Palpable lymph node without any palpable mass • Soft mobile mass <35years	Any age: • Any abscess, collection, or mass suspicious for cancer • Mass +/- lymph nodes
Imaging Plan	Screening MMG and ultrasound booked as a green case. Follow up at clinic in 3 months. If pain has resolved, to have a follow up MMG in 1 year. If not settled-become yellow	MMG and Ultrasound (if >35 yr.) to be booked as a yellow case	MMG and Ultrasound (if >35 yr.) to be booked as a red case

Table 1 describes the HJH Breast Clinic Triage system, describing the criteria for green, yellow, and red patients and their imaging plan.

5.3 Time Period

Data were collected in a retrospective manner for the period of 6 months from 01/01/2019 to 30/06/2019.

5.4 Materials and Methods

All images were captured using the below machinery:

1. Mammogram: Hologic Linear Dimensions (tomosynthesis)
2. Stereotactic Biopsy: StereoBiopsyMulticare Platinum
3. Sonogram: Siemens Aplio 300 and Acuson NX3 Elite

Mammogram images were captured using the automatic exposure control setting. Ultrasonography images have been captured using a dedicated 14-megahertz handheld breast-probe.

5.5 Data Collection

Gathered data includes:

1. Age
2. Final BI-RADS risk assessment (Table 2)
3. BI-RADS breast density assessment
4. Mammographic imaging features
5. Ultrasound imaging features
6. Cases biopsied and their histology result

Table 2: BI-RADS Classification

BI-RADS Category	Definition
0	Incomplete imaging data
1	Negative
2	Benign
3	Probably benign
4	Suspicious for malignancy
5	Highly suggestive of malignancy
6	Known biopsy-proven malignancy

Table 2 describes the ACR BIRADS-Risk Assessment Classification.[16]

The following were calculated as per Breast Cancer Screening Consortium (BCSC) and American College of Radiology (ACR) calculation guidelines, as explained in Appendix A:[16]

1. Cancer Detection Rate
2. False Positive Rate
3. Specificity
4. Abnormal interpretation Rate

6 Data Analysis and Statistics

Statistical data was captured using Microsoft Excel. Calculations were done using the equations as per the ACR guidelines.[17]

7 Ethics

The study was approved by the Human Research Ethics Committee of the University of the Witwatersrand, approval number M201025 (appendix A).

8 Results

8.1 Figures and Tables

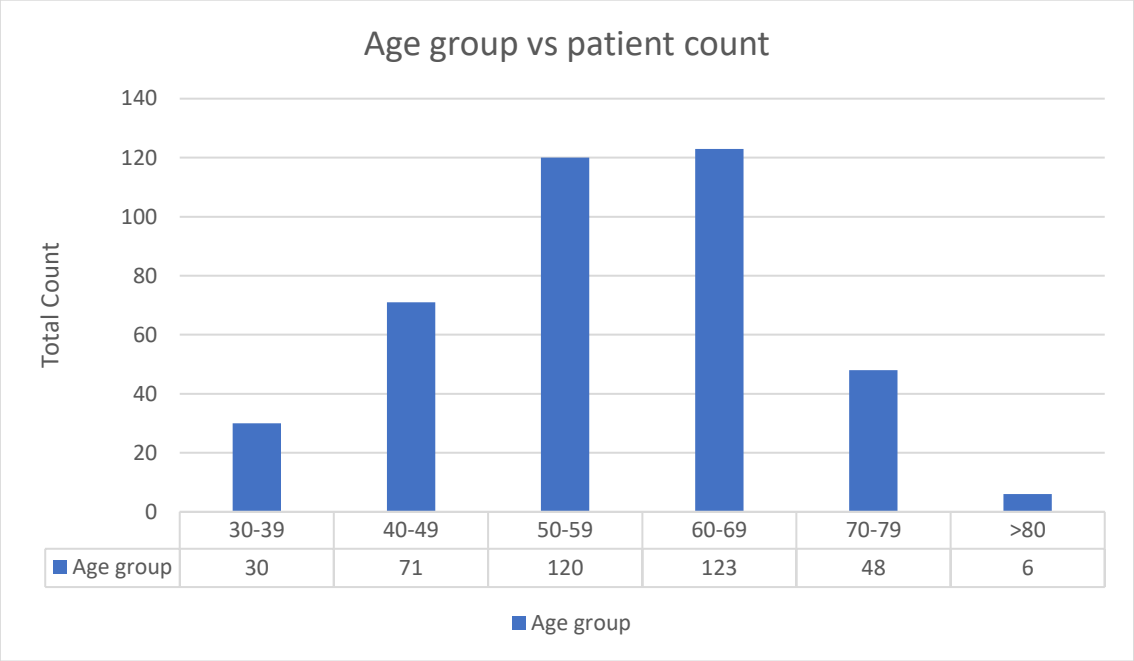


Figure 2: Age group versus patient count

Figure 2 totals the number of patients in each age-group.

The most common age group was 60-69 years totalling123.

Table 3: BIRADS Risk Assessment

BIRADS Risk Assessment	**Total**
1	36
2	326
3	34
4	2
5	0

Table 3 gives the total of each BIRADS Risk assessment (1-4). BIRADS 0 and 6 were omitted.

BI-RADS 2 was the most common assessment totalling 326 (81.91%)

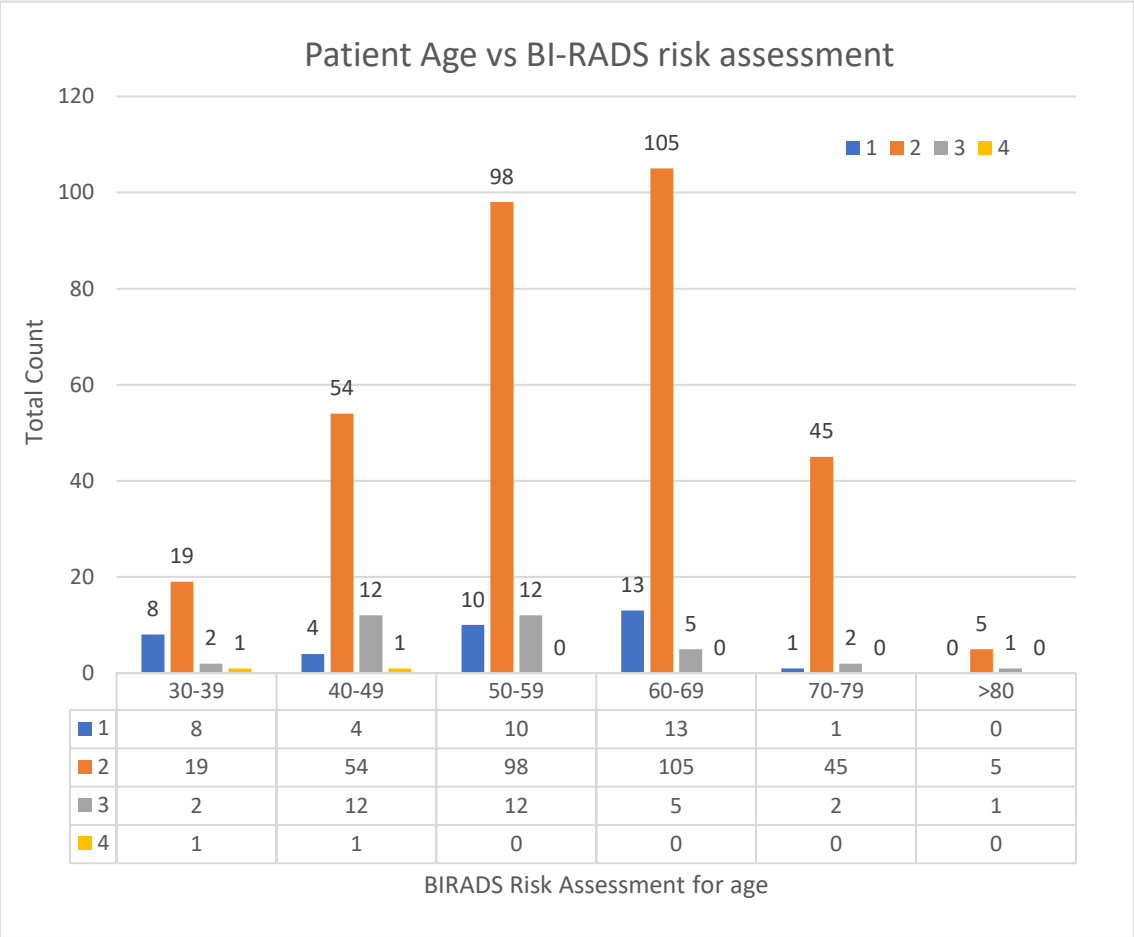


Figure 3: Patient Age versus BI-RADS Risk Assessment

Figure 3 describes the total count of the individual BIRADS Risk Assessment (1-4) in relation to each age group.

No patients were assessed as BIRADS 5.

Table 4: BIRADS Breast Density

BIRADS Breast Density	Total
A	166
B	178
C	47
D	7

Table 4 gives a total count of the individual BIRADS Breast Density (A-D). BIRADS Breast density B was the most common totalling 178 (44.72%).

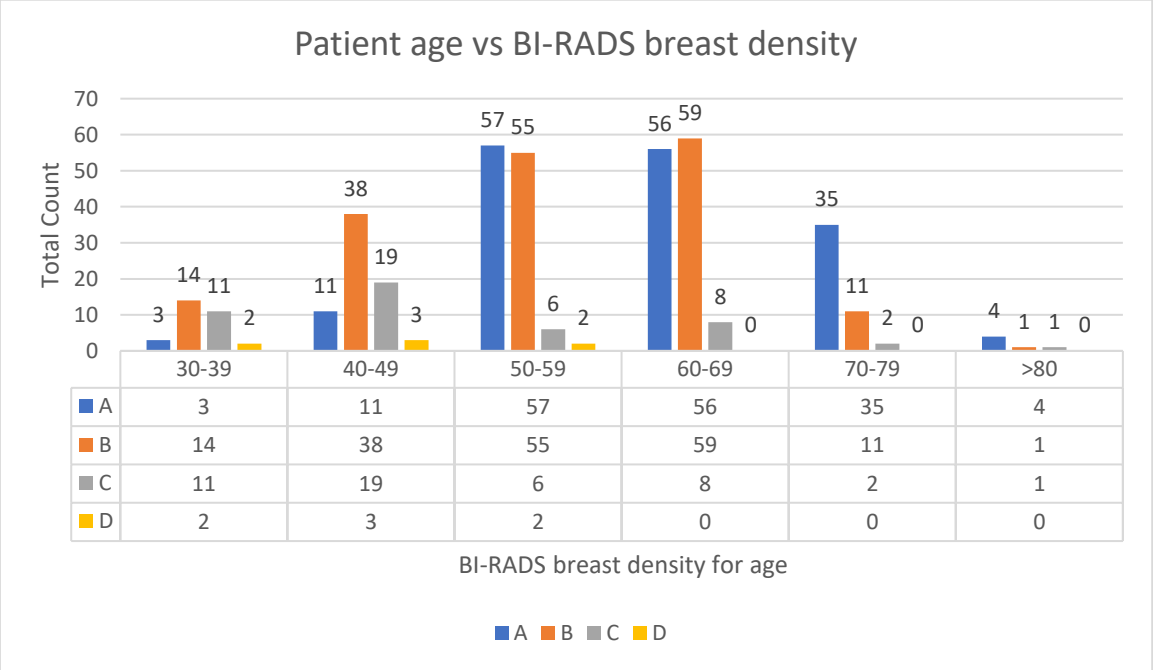


Figure 4: Patient age versus BI-RADS breast density

Figure 4 describes the total count of the individual BIRADS Breast Density (A to D) in relation to each age group.

Table 5: Features of Mammographically Detected Masses

BIRADS Risk Assessment	**1**	**2**	**3**	**4**	**Grand Total**
1. Multiple Masses	0	18	6	0	24
• **Bilateral Masses**	**0**	**14**	**4**	**0**	**18**
▪ Mass Shape					
o Oval	0	8	1	0	9
o Round	0	6	3	0	9
o Irregular	0	0	0	0	0
• **Unilateral Masses**	**0**	**4**	**2**	**0**	**6**
▪ Mass Shape					
o Oval	0	0	0	0	0
o Round	0	4	2	0	6
o Irregular	0	0	0	0	0
2. No Masses	36	266	20	1	323
3. Solitary Masses	0	42	8	1	51
• **Unilateral**	**0**	**42**	**8**	**1**	**51**
▪ Mass Shape					
o Oval	0	17	2	0	19
o Round	0	24	3	0	27
o Irregular		1	3	1	5
Grand Total	**36**	**326**	**34**	**2**	**398**

Table 5 documents the mammographic description of masses found, in relation to their overall BIRADS Risk Assessment (1-4). The mass descriptors are multiplicity and shape (oval, round or irregular).

Table 6: Features of Sonographically Detected Masses

	BIRADS Risk Assessment				**Grand Total**
	1	**2**	**3**	**4**	
1. Mass	1	17	8	2	28
• **Decreased Echo transmission**	**0**	**2**	**1**	**0**	**3**
▪ Mass Shape					
○ Irregular	0	0	0	0	0
○ Oval	0	2	0	0	2
○ Round	0	0	1	0	1
• **Increased Echo transmission**	**0**	**2**	**1**	**0**	**3**
▪ Mass Shape					
○ Irregular	0	0	0	0	0
○ Oval	0	2	0	0	2
○ Round	0	0	1	0	1
• **No Echo transmission**	**1**	**13**	**6**	**2**	**22**
▪ Mass Shape					
○ Irregular	0	0	1	2	3
○ Oval	1	11	2	0	14
○ Round	0	2	3	0	5
2. No Mass	35	309	26	0	370
Grand Total	**36**	**326**	**34**	**2**	**398**

Table 6 documents the ultrasound description of masses found in relation to their BIRADS Risk Assessment (1-4). The descriptors are-the presence or absence of a mass, their echo transmission (increase, decreased or non) and the mass shape (oval, round or irregular).

Table 7: Other Sonographic Findings

BIRADS Risk Assessment		**1**	**2**	**3**	**4**	**Total**
USS Cysts	Yes	0	34	5	0	39
	No	36	292	29	2	359
USS collections	Yes	0	0	1	0	1
	No	36	326	33	2	397
USS Duct dilation	Yes	0	18	5	0	23
	No	36	308	29	2	375

Table 7 documents the ultrasound findings (presence or absence of cysts, collections, duct dilation) in relation to the BIRADS Risk Assessment (1-4).

Table 8: Calcifications

	Frequency	**Percentage**
1. Calcification	42	10.55%
• Non-suspicious	42	10.55%
• Suspicious	0	0.00%
2. No calcification	356	89.45%
Grand Total	**398**	**100%**

Table 8 totals the number of patients found with calcifications on mammogram and the number of suspicious versus non-suspicious calcifications.

Table 9: Characteristics of Masses That Were Biopsied

Imaging Characteristics	**Patient 1**	**Patient 2**
Age group	40-49	30-39
BI-RADS breast density	B	C
BI-RADS risk assessment	4	4
MMG: mass number	Solitary	None
MMG: laterality of mass	Unilateral	NA
MMG: mass borders	Ill defined	NA
MMG: mass calcifications	None	NA
USS: mass	Yes	Yes
USS: shape	Ill defined	Ill defined
USS: echo through transmission	None	None
USS: axillary nodes	Multiple	None
USS laterality of nodes	Unilateral	NA
USS: duct dilation	No	No
Histology	Not malignant	Malignant

Table 9 documents the individual characteristics of the BIRADS 4 masses that underwent biopsy.

Patient 2 had a malignant mass demonstrating Ductal Carcinoma.
Patient 1 had a non-malignant biopsy that did not demonstrate any malignant cells.

Table 10: Confusion Matrix

		Biopsy Results	
		Positive (malignant)	**Negative (non-malignant)**
Screening Results	Positive (BIRADS 4)	True Positive (TP): 1	False Positive (FP): 1
	Negative (BIRADS 1, 2, 3)	False Negative (FN): 0	True Negative (TN): 396

Table 10 documents the confusion matrix in relation to screening results versus the biopsy results.

8.2 Calculations

The CDR was 2.51 per 1000. ACR recommended CDR ≥2.5.[17]
CDR=1000x1/ (1+1+0+396) or CDR 1000x (1/398)
CDR=1000 * TP / (TP + FP + FN + TN).

The false positive rate (FPR) was 0.25%. North American False Positive Rate 10.2-14.4%.[18]
FPR=1/ (1+396).
False Positive Rate (FPR)=FP / (FP + TN).

The specificity was 99.75%. ACR reference range of 88.00-95.00%.[17]
Specificity=396/ (1 + 396).
Specificity=TN / (FP + TN).

The abnormal interpretation rate was 0.50%. ACR (5.00-12.00%)[17] and the BCSC (11.6%).[19]
Abnormal interpretation rate = 2/398
Abnormal interpretation rate = Total positive exams / Total number of exams

9 Discussion

The CDR was 2.51 per 1000 people (1/398) which is within the ACR reference range.[17] The one patient who had a biopsy proven malignancy, fell below the age of 40 years and did not meet the age requirement for screening mammography. 30 out of 398 females (7.5%) were under the age of 40 and of this subset, 3 out of 30 (10%) were assessed as BIRADS 3 or higher, requiring short term follow up imaging. Screening mammography is not indicated below 40 years, except in high-risk individuals. Further research can assess as to whether patients are aware of a positive family history and/or genetic factors that may put them at a higher risk of breast cancer.

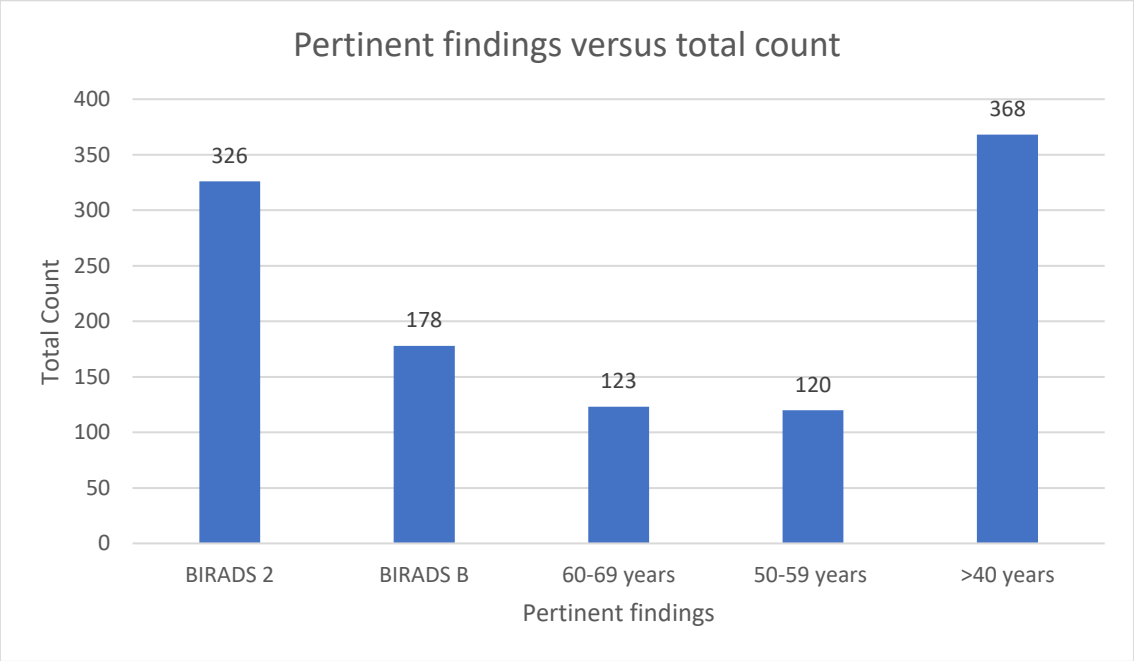


Figure 5: Pertinent findings versus total count

The most populous age group was 60-69 years (123 females, 30.90%) and the second most populous was 50-59 years (120 females, 30.15%). The BCSC reported the age group 50-59 year as their highest (30%) and 60-69 year old as the second highest (23.3%) patient count.[19] This discrepancy may be due to the limited period of the study and a late age of patient presentation for breast assessment. Further research into the age of initial presentation and a knowledge of primary prevention of breast cancer can be undertaken.

BIRADS Breast Density B was the most common tally (178, 44.72%). It remains the most common, however the overall percentage is low (44.47% versus 80%).[20] BIRADS Risk Assessment 2 represent 326 females (81.91%). This was not in keeping with other studies, in which BIRADS 1 was the most. [21, 22] These discrepancies may be due to a low patient number and a short study period.

The overwhelming majority of females were over the age of fourty (92.46%), as recommended by both the RSSA and CANSA. This suggests that female of the correct age and risk profile are being referred as 'low risk' from the HJH breast clinic through to the BIU. Most of our patients fell in the age group 60-69 which was above international reference ranges.[19] Further research may explore the presenting complaint of females who present directly to either the HJH breast clinic or the BIU to ascertain the clinical stage at which females first seek breast screening practices.

6 out of 398 (1.5%) females were over the age of 80 years. From this subset, 1 patient (16.66%) was assessed as BIRADS 3. The ACR does not have an upper age limit, however the recommendation is that screening should take place if the patient's life-expectancy is estimated to be greater than 5-7 years.[16] This is not currently performed at HJH, and further studies could use modelling criteria to estimate the life-expectancy of low-risk females over the age of 75 years who underwent mammography at HJH BIU.

The low False Positive Rate, high specificity, and the abnormal interpretation rate in the study may in part be due to the lack of follow-up data. Follow up imaging results e.g., in females who were classified as BIRADS 3. Further study could explore the results in the subset of patients in which short term follow up imaging in advised.

In its current form, the study adds to the body of literature supporting the role of breast screening programs in detecting at-risk females. 36 out of 398 (9%) females were classified as BIRADS 3 or higher which require short term follow up. In all females >40 years (92.46%), follow-up imaging was recommended – this allows continued screening and promotes an increased awareness of breast health. The findings of this study support the ongoing use of the clinical triage

system in the HJH Breast Clinic. It may help to motivate for the use of a similar clinical triage system in a South African setting where there are insufficient resources to perform screening mammography.

10 Study Limitations

The study was conducted over a short duration (6months) due to time constraints and this resulted in a low number of patients (total 398). Further research over a prolonged period may be undertaken in future.
Due to the lack of formalised screening programs within the public health sector, a low-risk patient population was used.

A single hospital with a specified drainage area was used for this study. Further research may make use of multiple sites across different regions.
Data from short term follow up imaging was omitted. due to time constraints. Further research could analyse this data and assess the shortcoming in terms of sensitivity, recall rate, the ongoing false positive and false negative rate.

11 Conclusion

There is lack of data related to screening mammography within a Southern African context. This retrospective study assessed the CDR and spectrum of disease at the HJH BIU within Johannesburg, South Africa. The CDR was 2.51%, most females were between 60 to 69 years of age, BI-RADS A or B in density and BI-RADS 2. The above findings are within the recommended reference ranges by ACR and BCSC and will help to advocate for the use of similar triage systems in hospitals where resources do not allow for the implementation of breast screening programs.

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13 **Appendix**

Appendix A: Ethic Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Dr LR Naidu

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M201025

NAME: (Principal Investigator)	Dr LR Naidu
DEPARTMENT:	School of Clinical Medicine Department of Radiation Sciences Division of Diagnostic Radiology Medical School University
PROJECT TITLE:	*An audit of clinically triaged women at low risk for breast cancer presenting to the Helen Joseph Hospital Mammography Unit, Johannesburg*
DATE CONSIDERED:	2020/10/30
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Drs P Naidoo and G Rubin
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2021/01/26

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **October** and therefore reports and re-certification will be due in the month of **October** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

31/01/2021.
Date