

MASTER OF PUBLIC HEALTH

Johns Hopkins Bloomberg School of Public Health & IIHMR University

PRACTICUM REPORT

By

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Cohort-6

2018-2020

Under the Guidance of

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TO WHOMSOEVER IT MAY CONCERN

This is to certify that ***Dr Madhura Nitin Wasnik***, student of Master of Public Health Program offered by IIHMR University, Jaipur in cooperation with Johns Hopkins Bloomberg School of Public Health, Baltimore has undergone Practicum Training at IIHMR University from ***9th January 2020 to 2nd April 2020.***

The candidate has successfully carried out the study designated to her during practicum training and her approach to the study has been sincere, logical, scientific and analytical.

The practicum Training is in fulfilment of the course requirements.

I wish her success in all her future endeavours.

Sd-

Dr Monika Chaudhary

Practicum advisor

CERTIFICATE BY SCHOLAR

This is to certify that the Practicum Project **VARIOUS RISK FACTORS FOR BREAST CANCER: A CASE CONTROL STUDY** submitted by **MADHURA NITIN WASNIK** with enrolment No. **IIHMR- U/07/2018-2020/0035** under the supervision of **Dr Monika Chaudhary and Dr Shilpa Hajare** for the award of Master of public health carried out during the period **9th January 2020 to 2nd April 2020** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institution or other similar institution of higher learning.

Dr Madhura Nitin Wasnik

MPH Cohort- 6

2018- 2020



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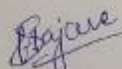
Date : 8/04/2020

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr. Madhura Nitin Wasnik IIHMR University 2018-2020 is a student of Master of Public Health program offered by IIHMR University, Jaipur in cooperation with the Johns Hopkins Bloomberg School of Public Health, USA. She has undergone practicum training under "Various risk factors for Breast Cancer: A case control study" conducted by NKP Salve institute of medical sciences & research centre and Lata Mangeshkar hospital. Her assignment project was from 9th January 2020 to 2nd April 2020.

Dr. Madhura has successfully carried out the statistical analysis of the above study designated to her during practicum training under the guidance of Dr. Shilpa Hajare (Assistant professor at NKP Salve institute, Nagpur, Maharashtra) and Dr. Monika Chaudhary (Professor at IIHMR University, Jaipur, Rajasthan). Lastly, through her integrity and resilience during the project, she has proven herself as a valuable researcher and Public Health Leader. A person like Dr. Madhura Wasnik would be a great asset for any institution she will join in the future.

I wish her a prosperous academic and professional journey.


Dr. Shilpa Hajare

Assistant professor at NKP Salve institute, Nagpur

INCHARGE
UHTC, JAITALA

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About IIHMR University

Indian Institute of Health Management Research (IIHMR) University established in 1984 is an institution focusing on health systems management to improve the standards of health. To achieve this, it is engaged in academics, research, training and consultancy in public health and primary health care, hospital and health management, pharmaceutical management, population and reproductive health, health economics and finance, NGO management and networking, rural development policy and program management research and related areas. It has set up collaborations in India and abroad in various national and international organizations and universities. It is a collaborating centre with the World Health Organization (WHO) for strengthening Health Systems based on Primary Care. It has conducted evidence-based research projects and studies related to health, well-being, social and developmental systems and policies in India and South East Asia to promote sustainable human development. It also has centres for injury research, gender studies, health economics, health systems and policies.

VARIOUS RISK FACTORS FOR BREAST CANCER: A CASE CONTROL STUDY

STUDENT: DR MADHURA NITIN WASNIK

GUIDE: DR SHILPA HAJARE

INTRODUCTION:

Breast cancer (BC) is the most common cancer found in the women of South East Asian Region (SEAR) countries like India. 25.8 cases per 100,000 women being the age adjusted rate women and a mortality rate of 12.7 per 100,000 women (1). In 2016 the estimated number of incident for breast cancer struck people in India was 118,000 out of which 98.1% were women and the prevalent cases were 526,000 (1). Over the span of years the age-standardised incident rate has seen a rise of 39.1% from 1990 to 2016, with increase observed in every state. Metastatic breast cancer incidence has been reported to be 5 to 25% in India (2).

Anything that increases the probability of developing breast Ca is defined as a risk factor.

But not every risk factor can be controlled or tackled like sex, age group, ethnicity, exposure to X-rays, genetic history or predisposition, past history of breast carcinoma, number of pregnancies and the breastfeeding practices followed by lactating mothers.

But there are some modifiable factors that can be controlled and could lead to significant difference like weight check, diet check, physical activity in ample amount, smoking and alcohol reduction, minimal use of oral contraceptives, reducing stress and anxiety levels (3).

In various studies and articles it is spotted that late childbearing, low [parity and minimal breastfeeding habits cause a rise in the chances of developing breast carcinoma in the future

Also, other studies have stated that excess and long term exposure to hormone oestrogen causing early menarche, other factors like child bearing at late age, long term reproductive period leading to late menopause and hormone replacement therapy leads to rise in breast cancer possibilities (4).

In the era of easy access to over the counter hormonal pills and easy access to induced abortions the women today are more prone to developing breast cancer. But a rise in medical awareness the survival rates have also seen a rise. As compared to the 1990s, women are more medically equipped and manage to survive the breast cancer if they remain vigilant. Two in three women are likely to overcome this cancer. Survival rate post treatment of breast cancer is seen to be 10 years or more. All credit goes to the field of research which made this possible (5).

PRACTICUM PROJECT BRIEF:

NKP Salve institute of medical sciences and research centre in association with Rashtra Sant Tukdoji hospital, Nagpur Maharashtra conducted a study in Nagpur, Maharashtra from January to April 2020, entitled, “**VARIOUS RISK FACTORS FOR BREAST CANCER: A CASE CONTROL STUDY**” in Nagpur, Maharashtra.

As a research intern at NKP Salve institute of medical sciences and research intern, Nagpur, Maharashtra, I was engaged in the project, for the duration of 3 months (9th January 2020 to 2nd April 2020) and my practicum activity was directly supervised by Dr Shilpa Hajare, Assistant professor (NKP Salve institute, PSM department, Nagpur, Maharashtra), who was the principal investigator of this study.

PRACTICUM LEARNING OBJECTIVES AND RESPONSIBILITIES:

- 1) **ANALYTICAL SKILLS:** by analysing the status of risk factors in causation of BC and identifying the key determinants of BC in the study population, by performing review of literature and analysing primary data generated through research activities under the study. Analysing the data using Chi-square technique.
- 2) **RESULT ORIENTED:** application of knowledge of clinical epidemiology in the surgery department of Rashtra Sant Tukdoji Cancer research centre, Nagpur, Maharashtra, to measure the association of various risk factors for BC, to measure if the association of various risk factors for breast cancer is statistically significant or insignificant, formulation and validation of questionnaire. And record maintenance.
- 3) **BEHAVIOUR AND COMMUNICATION:** communicating with the patient with questionnaire containing the particulars like social and demographic factors.
- 4) **RELATIONSHIP BUILDING:** rapport building with the patients, performing interviews with the patients coming to the surgery department.
- 5) **TIME MANAGEMENT:** appropriate share of time given to each patient participating in the questionnaire.

MY SPECIFIC TASKS AND RESPONSIBILITIES UNDER THE PROJECT:

- 1) To assess and determine the various risk factors leading to breast cancer.
- 2) To formulate and validate a questionnaire encompassing all the risk factors.
- 3) To create a patient information sheet which will cover all the vitals of the participants.
- 4) To collect data until desired sample size is achieved.

- 5) To understand and apply the relevant systematic review and meta analysis to help perform this study.
- 6) Measure the participant's knowledge on breast cancer, its causes, risk factors, treatment outcomes, signs and symptoms.

RESEARCH QUESTION:

Primary research question-

- 1) Is there any association of various risk factors with breast cancer?

HYPOTHESIS:

Null hypothesis: There is statistically no significant association of various risk factors with Breast Cancer.

Alternate hypothesis: There is statistically significant association of various risk factors with Breast Cancer.

PRIMARY OBJECTIVES:

1. To identify women with breast cancer and to evaluate them
2. To study the various risk factors associated with Breast Ca
Both the factors known (modifiable as well as the non modifiable factors)
Example age, parity, hormone replacement therapy (HRT) menstrual factors etc.
3. To provide guidance and proper counselling to such at-risk patients

METHODOLOGY:

Study Area - The study was conducted at Surgery Out Patient department (OPD) at RST Regional cancer hospital, Nagpur, Maharashtra.

Study Subjects -Study subjects consisted of female diagnosed cases of BC in age group of 20-70 years of age.

Study Design – Hospital based case control study.

Study Period-The study was done over a period of 8 weeks

Sample Size -250 women (125 cases and 125 controls) calculated with the help of Open Epi Calculator with percentage of exposure among controls and cases as 40 and 57.75 respectively and odds ratio as 2.08 as per the study conducted by Vishwakarma G et al(6)

$$n = Z (1 - \alpha/2) \times \left\{ \frac{1}{p_1(1-p_1)} + \frac{1}{p_2(1-p_2)} \right\} / \{ \log_e (1-d_1) \}^2$$

Statistical Analysis- Statistical software, Epi.Info. Version 7.2.2.2 using Chi-Square and Proportion; value less than 0.05 will be considered significant.

Cases – All females positive with BC belonging to age bracket of 20 – 70 years attending the Surgery Out Patient department (OPD)

Controls – All females belonging to age bracket of 20 – 70 years attending the Surgery Out Patient department (OPD) with similar risk factors were randomly selected as controls

Matching – One control was selected per case belonging to similar age group.

Study instrument – Ethical approval was taken before the study was initiated and enacted.

After the informed consent was taken, patients were interviewed after they gave their informed consent to the interviewer. After a thorough literature review and meta analysis a questionnaire was drafted with the identified risk factors associated with the ailment. Example body mass index, weight of the female, reproductive history, history of any breast diseases, menstrual history, lifestyle and physical activity, alcohol and smoking, diet, exposure to hormones to name a few.

Data collection method – it was a hospital based case control study was conducted among BC cases as well as age matched controls in RST research centre. Data were collected by interviewing the participants.

Data collection tool - Validated/ pre-tested questionnaire.

Gantt chart–

Activities	Weeks												
	1	2	3	4	5	6	7	8	9	10	11	12	13
1. Formulation of Protocol and questionnaire.													
2. Formulation of learning objectives, core competencies and responsibilities.													
3. Preparation, submission and approval of the required													

documents and other necessary materials.													
4. Conduction of pre-tested questionnaire													
5. Data documentation and confirmation. Arranging the documents and patient information sheets.													
6. Analysis of the procured data													

RESULTS:

Table 1 – Age wise distribution of women (n = 250)

AGE	FREQUENCY		PERCENTAGE (%)		p-value
	CASES	CONTROLS	CASES	CONTROLS	
20-29	11	13	4.4	5.2	0.3377
30-39	30	27	12	10.8	0.3275
40-49	41	42	16.4	16.8	0.4471
50-59	28	26	11.2	10.4	0.3807
60-70	15	17	6	6.8	0.3552
TOTAL	125	125	50	50	

Table 1 shows the age profile of the 250 women. Their age ranged from 20-70 years with a majority 16.4% cases and majority of 16.8 controls belonging to the age group of 40-49 years.

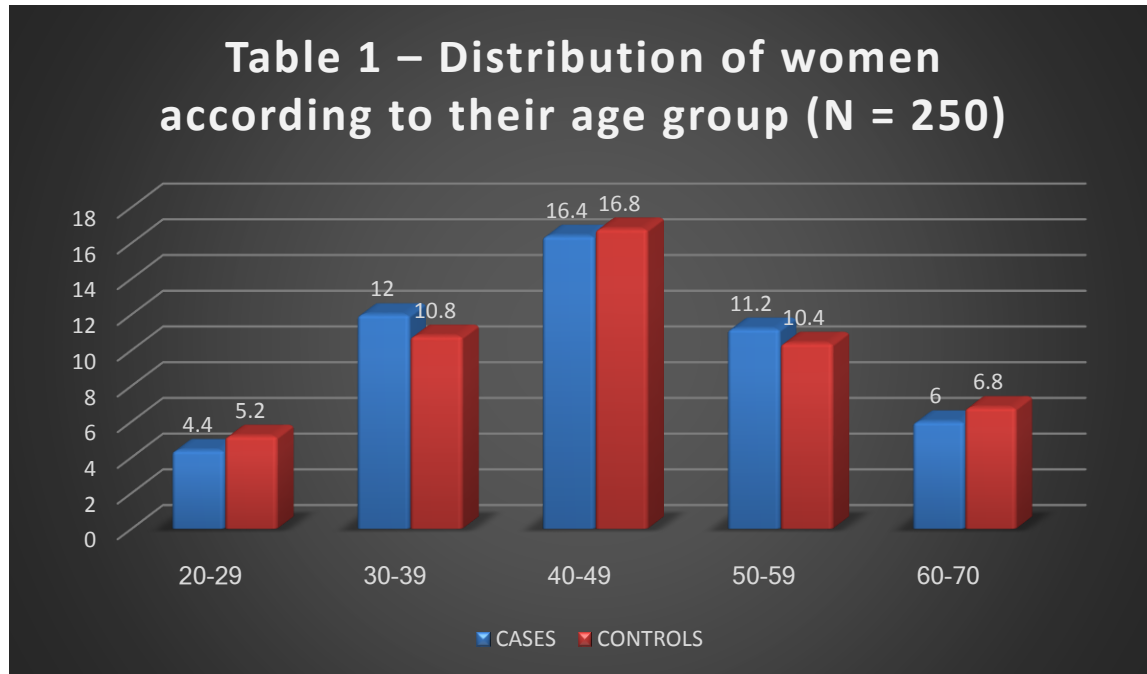


Table 2 – Distribution of women according to their literacy status

EDUCATION	FREQUENCY		PERCENTAGE (%)		p-value
	CASES	CONTROLS	CASES	CONTROLS	
Illiterate	13	14	5.2	5.6	0.4211
Primary school	6	5	2.4	2	0.3849
Middle school	27	24	10.8	9.6	0.3211
High school	51	45	20.4	18	0.2196
Graduate	24	31	9.6	12.4	0.1454
Post-graduate	4	6	1.6	2.4	0.2706
Total	125	125	50	50	

Table 2 shows the educational qualification of the women. As far as education is concerned, majority 20.4% cases and 18% controls were high school pass outs, 9.6% cases and 12.4% controls were graduates and 1.6% cases and 2.4% controls were post-graduates. Only 5.2% cases and 5.6% controls were completely illiterate having undergone negligible education.

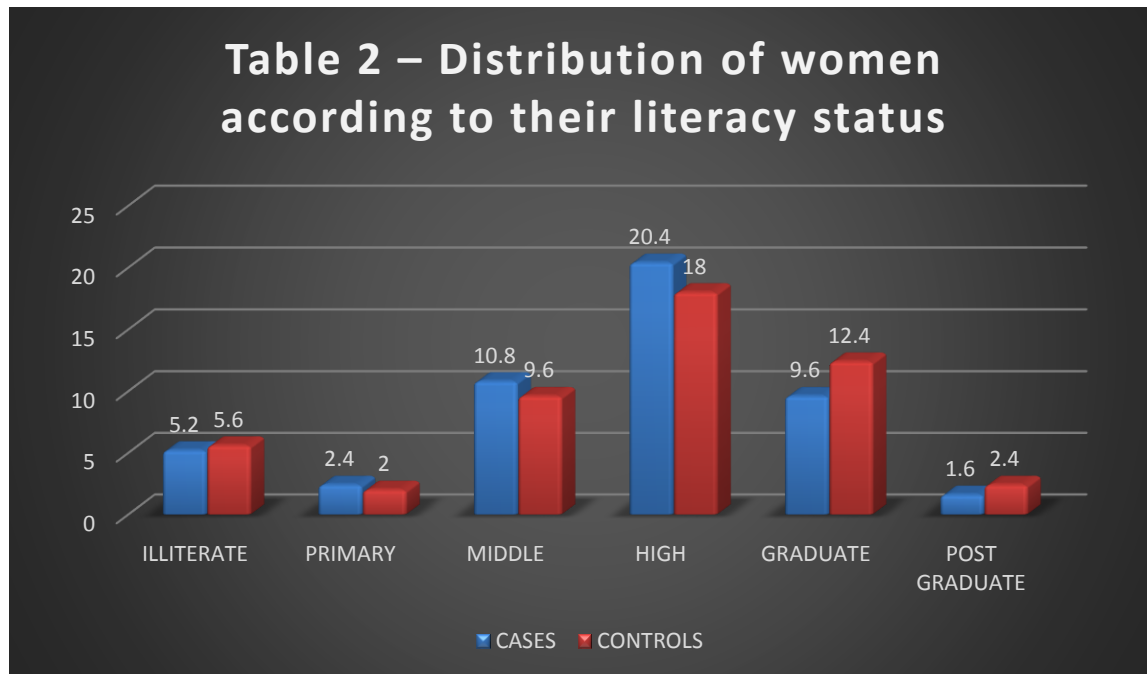


Table 3 – Parity wise distribution of women

PARITY	FREQUENCY		PERCENTAGE (%)		p-value
	CASES	CONTROLS	CASES	CONTROLS	
Nulliparous	19	21	7.6	8.4	0.3671
Primiparous	57	53	22.8	21.2	0.3066
Multiparous	49	51	19.6	20.4	0.3990
Total	125	125	50	50	

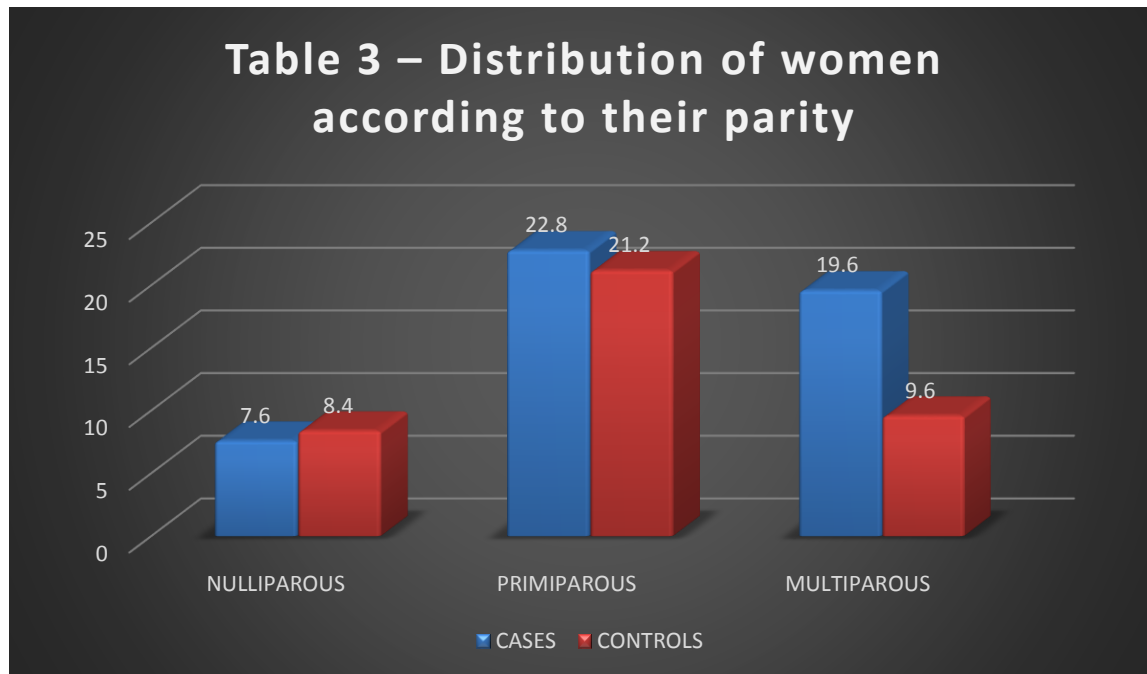


Table 3 shows the distribution of women according to parity. 5.9% cases and 8.4 controls were nulliparous, 22.8% cases and 21.2% controls were primiparous and 19.6% cases and 20.4% controls were multiparous.

Table 4 – Risk factors for Breast cancer

RISK FACTORS	FREQUENCY		PERCENTAGE (%)	
	CASES	CONTROLS	CASES	CONTROLS
Early menarche (before 12 years)	41	20	32.8	16
Late menopause (after 55 years)	35	17	28	13.6
Family history of breast cancer	66	49	52.8	39.2
Nulliparity	19	21	15.2	16.8
Personal history of breast cancer	4	2	3.2	1.6
History of radiation exposure	24	13	19.2	10.4
Age at first live birth (FTP)	23	16	18.4	12.8

after 30 years)				
Lack of breast feeding	7	2	5.6	1.6
Obesity (BMI > 30)	49	31	39.2	24.8
Alcohol consumption	21	9	16.8	7.2
Tobacco smoking	53	39	42.4	31.2
Use of hormone replacement therapy	19	15	15.2	12

Table 4 lists the risk factors associated with breast cancer. 32.8% cases and 16% cases had menarche before 12 years whereas 28% cases and 13.6% controls had menopause after 55 years. 52.8% cases had family history amongst first and second degree relatives whereas 3.2% of cases had personal history of previous breast malignancy. 15.2% cases were nulliparous. 19.2% cases and 10.4 controls were exposed to radiation beforehand. 18.4% cases and 12.8% controls had their first full term pregnancy after the age of 30 years. 5.6% cases complained of lack of breast feeding. 39.2% cases and 24.8% controls were obese with BMI more than 30 kg/m². 16.8% and 42.4% of cases consumed alcohol and tobacco respectively. 15.2% cases admitted to use of hormone replacement therapy in the past.

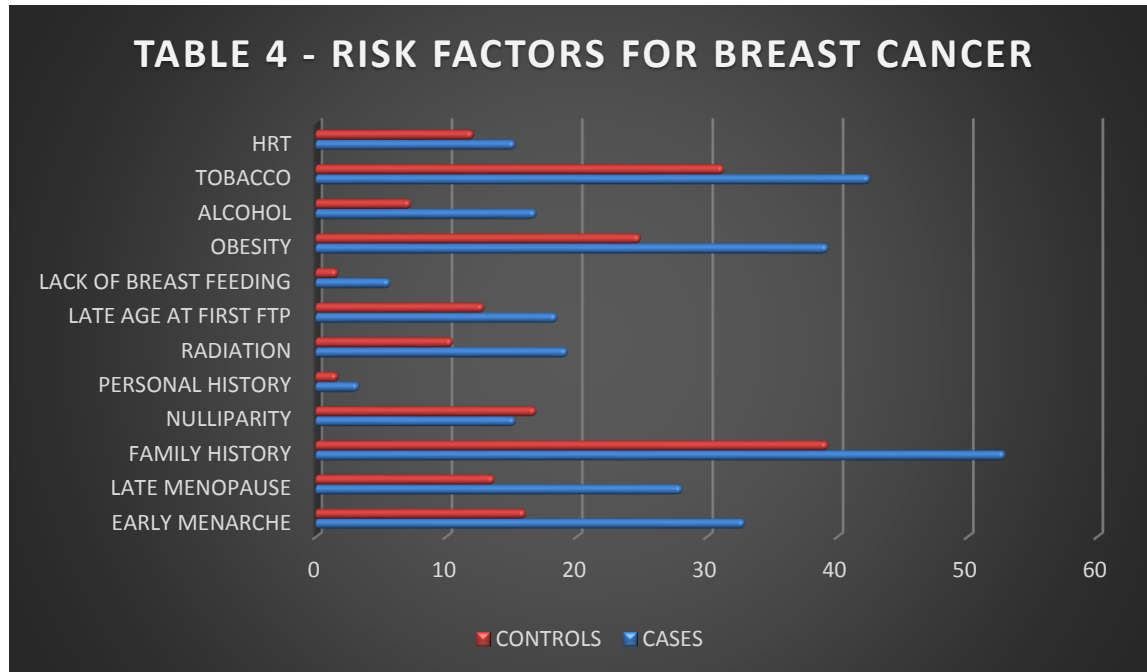


Table 5 – Association of breast cancer with risk factors

RISK FACTOR	CASES	CONTROLS	CHI-SQUARE	P-VALUE	ODDS RATIO	CONFIDENCE LIMITS
EARLY MENARCHE						
<12 YEARS	41	20	9.563	0.001032	2.553	1.398, 4.756
>12 YEARS	84	105				
LATE MENOPAUSE						
>55 YEARS	35	17	7.867	0.002628	2.462	1.301, 4.776
<55 YEARS	90	108				
FAMILY HISTORY OF BREAST CANCER						
PRESENT	66	49	0.01607	<0.001	1.731	1.048, 2.873
ABSENT	59	76				
NULLIPARITY						
PRESENT	19	21	0.119	0.3671	-	0.4466, 1.758
ABSENT	106	104				
PERSONAL HISTORY OF BREAST CANCER						

PRESENT	4	2	0.6831	0.2242	-	0.3533, 16.08
ABSENT	121	123				
HISTORY OF RADIATION						
EXPOSED	24	13	3.838	0.02635	2.041	0.9919, 4.335
NOT EXPOSED	101	112				
AGE AT FIRST LIVE BIRTH						
FTP >30	23	16	1.489	0.1146	-	0.7664, 3.12
FTP <30	102	109				
OBESITY						
BMI >30	49	31	5.956	0.007661	1.95	1.135, 3.378
BMI <30	76	94				
ALCOHOL CONSUMPTION						
PRESENT	21	9	5.455	0.01034	2.593	1.151, 6.198
ABSENT	104	116				
TOBACCO CONSUMPTION						
PRESENT	53	39	3.371	0.03421	1.62	0.9644, 2.735
ABSENT	72	86				
HORMONE REPLACEMENT THERAPY						
USED	19	15	0.5447	0.2342	-	0.6313, 2.765
NOT USED	106	110				

Table 10 showed that a statistically significant association was found between breast cancer and early menarche, late menopause, family history, radiation exposure, obesity, alcohol and tobacco consumption of the women ($p < 0.05$)

Women with menarche after 12 years had 2.553 times higher risk than those with menarche before 12 years. Women with menopause after 55 years had 2.462 times higher risk of developing breast cancer. Family history of breast cancer had risk of 1.731 times and personal history had risk of 2.027 times more than those who had none. Exposure to radiation lead to a risk of 2.041 than those not exposed. Females who consumed alcohol and tobacco had risk of 2.593 and 1.62 times than those who did not.

DISCUSSION:

The study was conducted at a hospital-based research centre of Nagpur. The study consisted of all women in the age group of 20-70 years. It was a hospital-based case control study. The data was collected by face to face interview of the women with the help of pre-tested questionnaire. Every effort was made to establish good rapport with them. The results of the study can be generalised only to population of women attending the selected hospital of Nagpur. Any generalisation to a wider population should be done with caution as it may not share similar socio-demographic profile as the current study population.

Maximum number of cases were in age bracket of 40-49 years. Risk is seen with increasing age and is rare before 20 years. 25% cases below 30 years are due to a dominant gene mutation as compared to the 1% seen above 70 years.

Majority of the cases had undergone education above middle school while only 5.2% of the total cases were totally illiterate. Lack of knowledge and awareness regarding identification of risk factors for breast cancer can be deemed responsible for late detection of malignant cases. It is important to identify these cases as early as possible for prompt treatment.

Amongst all the risk factors studied for breast cancer, the highest was found to be family history of breast cancer (52.8%). Many studies have been done exploring the connection between breast malignancy and family history. Closely related people like siblings, mother and daughter had more risk of developing BC. This can be identified by construction of family pedigree tree. Higher risk is seen in first degree relatives with disease onset before menopause and those with bilateral breasts affected. Risk is less with distant affected relatives but genetic predisposition

may be present. In the remaining sporadic cases, hereditary factors are more likely to be responsible (6)

Increased risk of breast cancer and increased density of breasts is seen in nulliparous females. History of breast malignancy in one breast leads to increased likelihood of development of another primary in the contralateral breast. In the present study, it was seen twice as likely. Females who had their first full term pregnancy after the age of 30 years had 1.5 times risk of developing breast malignancy. Other studies have also shown similar results. (7,8).

The second highest risk factor was seen with tobacco consumption (42.4%) while association of breast cancer with alcohol consumption was found to be 16.8%. Females who consumed alcohol and tobacco had risk of 2.593 and 1.62 times than those who did not. Exposure to radiation was also associated with a risk of 2 times than those with no exposure. Obese females with BMI more than 30 had 1.9 times risk than those who were overweight or moderately built (9)

Females undertaking hormone replacement therapy has risk of 1.3 times in our current study. Anti-estrogen therapy reduce risk whereas estrogen- progestin replacement therapy increases risk of cancer malignancy. Studies have shown that risk increases by 20% in women taking oral contraceptive pills. (9) In a study conducted by Boyd et al, HRT was found to have increased risk with OR 1.26, 95% CI. Similar results were found in our study as well. (10) More than 10 years of HRT usage is associated with significantly higher risk. (11)

Competencies acquired during the practicum as per learning objectives

S. No.	Practicum Training Achievement	Public Health Competencies developed

1	Using EPI info software assessed various risk factors for causing BC.	Analytical skills
2	Determining the risk factors for BC	Public health science skills
3	Critically analysed and identified the socio demographic, reproductive factors etc that were significantly associated with breast cancer.	Analytical skills, Critical thinking skills
4	Formulation and validation of questionnaire	Analytical skills
5	Conducting face to face interviews with the participants	Communication and behavioural skills Relationship building
6	Performing thorough review of literature to support the study	Result oriented
7	Giving every participant enough time to document their response and achieving the required sample size	Time management Relationship building

CONCLUSION:

The aim of the current study is to evaluate the association of risk factors of breast cancer. The risk factors included in the present study were classified as modifiable and non-modifiable. Modifiable risk factors were reproductive factors, age at first live birth, parity, lack of breast feeding, obesity, alcohol and tobacco consumption, use of hormone replacement therapy. Non

modifiable risk factors were used such as increasing age, menstrual factors, early menarche, late menopause, nulliparity, family history, past history, radiation exposure.

Identification of women with these risk factors will lead to early diagnosis. Delayed diagnosis due to illiteracy, financial problems, lack of awareness results in increased mortality rate. Lack of screening programs, paucity of diagnostic aids and female health overall indifference increases incidence of breast cancer. Therefore, females presenting in OPD often show advanced presentation. Therefore, it can be concluded by this present study that the risk factors associated with breast cancer are early menarche, late menopause, family history, personal history of past disease, radiation exposure, obesity, alcohol and tobacco consumption.

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