AN ASSESSMENT OF THE AWARENESS LEVEL AMONG GENERAL PUBLIC ABOUT BREAST CANCER

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ABSTRACT

The aim of the present work is to assess the awareness level of the general public about breast cancer, which is the leading cause of cancer deaths among women in India & many parts of the world. The study was performed amongst women who were admitted at a reputed cancer institute at Kolkata and have been residing in different parts of West Bengal. While examining the level of awareness among women, it has been found that only 4% of them were aware about BSE, 79% were unaware of safe diet, 22% were unaware of the demerits of addiction, 83% population were not aware about harmful effects of using contraceptives & Hormone Replacement Therapy [HRT] which might be responsible for breast cancer.

Key words: Breast Self Examination [BSE]. Hormone Replacement Therapy [HRT], Addiction, malignant tumor, Clinical Breast Examination [CBE], Mammography, Estrogen, Melatonin.

INTRODUCTION

Breast cancer is a malignant tumor that starts in the cells of the breast. A malignant tumor is a group of cancer cells that can grow into [invade] surrounding tissues or spread [metastasize] to distant areas of the body. The disease occurs almost entirely in women, but men can get it, too.

The aim of the present work is to assess the awareness level of the general public about breast cancer. It is the leading cause of cancer in women worldwide with 1.05 million new cases every year. It represents over 20 % of all malignancies among females [1].

Over 50 % of breast cancer incidence occurs in the developed world. High – risk areas include Europe and North America. The lowest rates are reported from Africa and Asia. Incidence of breast cancer is increasing in most of the countries, including the areas, which have had previously low rates [2-4]. It is estimated that in 2001 there were approximately 80,000 new breast cancer cases in India [5].

The population based cancer registry data from the various parts of the country, has revealed that the breast cancer is the commonest cancer among women in Delhi, Mumbai, Ahmadabad, Kolkata and Trivandrum. In the rest of the other Indian registries, breast cancer is listed as the second leading site among women [6-7].

An increasing trend in the incidence rates of the breast cancer has been reported from the various registries of National Cancer Registry project [7]. In Chennai, with the crude incidence rate [CIR] being 30.1/100,000 in the Madras Metropolitan Tumor Registry [MMTR], a significant increasing trend in the incidence of breast cancer was seen during 1982-2005 with an average annual increase of 0.72 cases per 100,000 [8].

The trend of rising incidence is likely to continue due to further changes in life style factors, such as age of first childbirth and dietary habits [9].

Moreover, increase over the past several decades in breast cancer incidence have been observed in Bangalore, Chennai, Mumbai, Nagpur and Pune registries. These changes may reflect the effects of rapid transition towards industrialization and urbanization as well as adoption of semi – Western diets and lifestyle, including childbearing patterns, among higher socioeconomic urban subgroups [10-12].

Increasing awareness about breast cancer would go a long way in the cure of this disease, since breast cancer is a progressive disease having a predilection of early dissemination and consequently detection of small tumors are more likely to be early stage disease, which would have a better prognosis and higher probability of getting effectively treated. BSE is an important tool for early detection of breast cancer. Unsafe diet, addiction to nicotine and alcohol, irregular work schedule like night shift duty regular flight attendance, availing contraceptives or HRT etc are risk factors for causing breast cancer.

Women, in general, and especially those over the age of 35 years are required to be more educated about the many available screening modalities for breast cancer and also need to be encouraged to adopt these measures as efficiently as they can.

Screening for breast cancer includes BSE, mammography, clinical breast examination (CBE) by a physician. Although mammography has been established as an effective technique for early detection of breast pathologies, mammographic screening of an outsized population cannot be supported as a priority in India owing to its high cost.

A. BREAST SELF EXAMINATION [BSE]

BSE on the other hand is simple, self generated, repeatable at monthly intervals and cost free. BSE involves regular monthly systematic examination of the breasts and axillary area, both visually and by palpation, for any signs of abnormality. It has been observed that how a woman learns about BSE can determine the frequency with which she performs it, and therefore it is important for every woman to adopt the correct method of performing BSE as demonstrated by a nurse or physician.

B. AWARENESS OF SAFE DIET

Food has been the centre of focus around every disease and that is true with breast cancer too. Patients should consume a balanced healthy diet that includes at least five portions of fresh fruits and vegetables every day. This will have all nutrients and fibre required daily.

Some research has been done to look at the effect of both diet and exercise on survival after breast cancer. Pierce, Director of the Cancer Prevention and control program at the Moores UCSD Cancer center, in La Jolla, California, and his team looked at the combined effects of diet and exercise on breast cancer survivors [13].

C. AWARENESS OF ADDICTION

Nicotine and alcohol are mostly used for addiction. Nicotine may spur the spread of breast cancer, pushing cells from the original tumor to other parts of the body [14]. Alcohol may change the way the body metabolizes estrogen. Many breast cancers are fuelled by the hormone estrogen. Therefore, regular use of alcohol is thought to increase the risk of breast cancer by increasing blood estrogen levels. Drinking as little as half a glass of wine a day may raise a women's risk of developing breast cancer [15].

D. AWARENESS OF IRREGULAR WORK SCHEDULE

Night shift worker and flight attendants are prone to breast cancer risk. Exposure to light at night and power frequency [50-60 Hz] magnetic fields may increase the risk of breast cancer by suppressing the normal nocturnal production of melatonin by the pineal gland, which, could increase the release of estrogen by the ovaries [16]. The increased risk of breast cancer and malignant melanoma among cabin attendants seem to be occupationally related. Cosmic radiation, disturbance of the circadian rhythm, and electromagnetic fields or combination of these factors may be the etiologic factors [17].

E. AWARENESS OF AVAILING CONTRACEPTIVE/HRT

Combined hormone replacement therapy in Women's Health Initiative trial has shown the risk of breast cancer to increase [18-19].

MATERIALS & METHODS

Materials

The report of indoor patients containing name, date of admission, name of guardian, age, sex, religion, address, phone number, duration of stay, marital status, education, occupation, mother tongue, no of dependants, income per month were collected.

The report also contains diagnosis including histology, stage & Tumor Board Decision in details with sequence. Surgery [s], chemotherapy [CT], Palliative [PAL], Radiotherapy [RT] & Immunotherapy [I] columns are there in the report. It also contains Admission, discharge dates along with clinical history containing symptoms & duration. In the next part of the report past history / previous treatment are found. Relevant family history along with relationship and disease are recorded.

In personal habits column-none, cigarette, bidi, snuff, chewing tobacco, betel nut, gutka, khaini, hormonal contraception & others boxes are there.

Menstrual and obstetric history is available in the report. In relevant medical history area of the report diabetes, hypertension, heart disease, jaundice, & others columns are given.

General examination portion of the report includes case histories of patients having edema, pallor, clubbing, obesity, cyanosis, surface area, height, weight, pulse, B.P. etc. cervical, axillary, inguinal and other columns maintain information about lymph nodes. Systemic examination includes cardiovascular, respiratory, abdomen& neurological reports. Report of local examination is also kept in it.

Investigation part of the report includes biopsy or cytology, slides, block- submitted or be submitted, routine blood examination, X-ray chest, E.C.G., blood biochemistry, urine R/E, Urine C/S, Stool R/E &OPC, complete hemogram, barium swallow, barium meal follow through, USG- pelvis/ whole abdomen/neck USG-FNAC, CT scan, bone marrow, bone scan/ typhoid scan, MRI.

In addition to the above report contains tumor markers, endoscopy, final diagnosis, operative note, radiotherapy note, concommitant chemotherapy note mentioning CT Regime-1, drug used , cycle date.

Palliative treatment note, anaesthasia / ITU note, death note, comments/referral note/ follow up remarks are given in the report.

Records of the Institute [CNCI] , personal interview with the caregivers & patients, reports from NGO like Hitoishini, & Kalpana Dutta Foundation Cancer care, different books, research papers and journals are the source of data.

Methodology of Patient Analysis

1. Awareness of Breast Self Examination: In this method, 50 women breast cancer patients were enquired about their past experience about BSE before diagnosis as breast cancer patient. They were asked whether they would practice BSE beginning from age 20 yrs or not. They also were asked whether they would know that early detection of the disease with this tool could help to increase the life span.

2. Awareness of safe diet: To assess awareness of safe food habit 47 women patients from CNCI were asked about their past food habit before diagnosed as breast cancer patient. They were asked whether they would know about the role of diet high in fats, red meat, highly processed food associated with breast cancer. They also were asked whether they knew that fruits, vegetables, nuts, grains fish. Chicken meat moderate quantity, sweet potatoes ,pumpkin, mango , spinach, tomatoes, watermelon guava, papaya carrots, milk, vitamin c containing fruits can prevent or slow the oxidative damage to the body and thereby prevent breast cancer.

3. Awareness of addiction: To assess awareness of addiction, 45 women breast cancer patients were enquired about their consciousness about consumption of alcohol or nicotine. They also were asked about awareness of passive smoking.

4. Awareness of irregular work schedule: To assess awareness of irregular work schedule like nightshift duty, regular flight attendants, exposed to radiation, 47 breast cancer patients were asked about their consciousness.

5. Awareness of contraindication for availing contraceptives or HRT: To assess awareness of availing contraceptives or HRT, 48 women breast cancer patients were enquired for their consciousness about contraindications of contraceptives/HRT.

RESULTS & DISCUSSIONS

1. Awareness of Breast Self Examination

Awareness of 50 subjects about Breast Self Examination was studied and the following results were obtained. The results are depicted in Table1-2 and Fig 1-2. Table 1 shows out of 50 women breast cancer patients 48 were unaware of usefulness of BSE which could have helped them for earlier diagnosis and better prognosis.

Table 1: Awareness regarding various parameters assessed amongst the patients

SI No:	Awareness related to	Total number of patient studied	Aware Population (AP)	Unaware population (UP)
1.	Breast Self Examination	50	2	48
2.	Safe Diet	47	10	37
3.	Alcohol & Nicotine addiction	45	35	10
4.	Irregular work schedule	47	1	46
5.	Contraindication in having contraceptives/HRT	48	8	40

Fig.1 shows 96 % population was unaware of the proper technique and utilities of BSE and thereby loosing the opportunities of early detection and increasing life span.

Table: 2 Age wise distribution regarding the various parameters amongst the patients participating in the study.

SI No:	Parameter Assessed	Total number of patient studied	Distribution of Age (years)						
			16-25	26-35	36-45	46-55	56-65	66-75	> 75
1.	Breast Self Examination	48 (UP)	1	13	15	6	8	5	0
2.	Safe Diet	37 (UP)	1	6	17	11	1	1	0
3.	Alcohol & Nicotine addiction	35 (AP)	1	7	12	13	2	0	0
4.	Irregular work schedule	46 (UP)	1	8	15	13	6	3	0
5	Contraindication in having contraceptives/HRT	40 (UP)	0	7	15	12	6	0	0

As depicted in Table 2 the age wise distribution of unaware subjects where 36-45 age groups of subjects are major in number [15] that means affected mostly.

Table 2 & Fig 2 also show 26-35 age group being 13 nos. out of 48 subjects which is closer to the above. 16- 25 years of age group is least sufferer.

BREAST SELF EXAMINATION
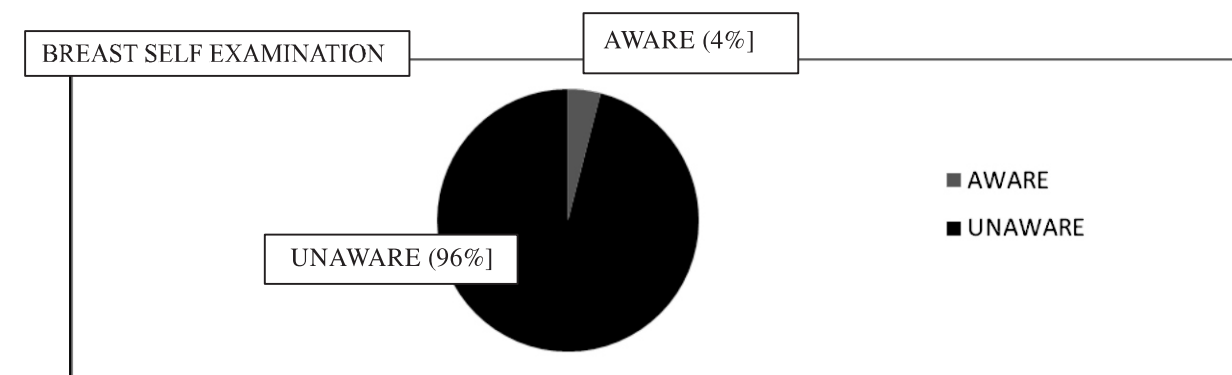AWARE (4%]
UNAWARE (96%]
■ AWARE
■ UNAWARE

Figure 1 : Percentage of awareness amongst studied population regarding breast self examination
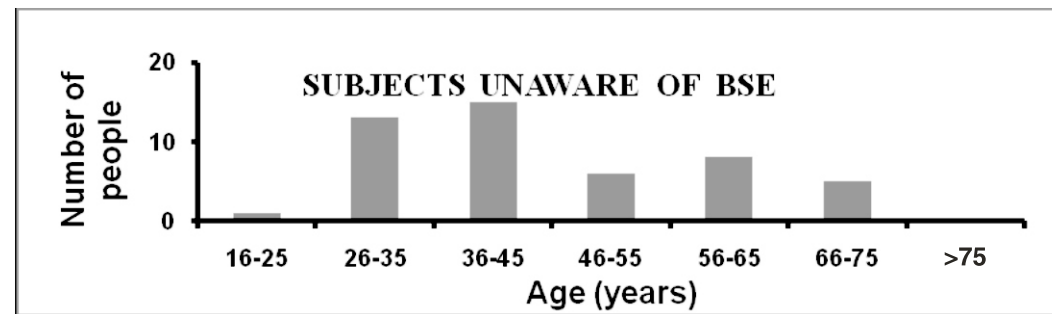
Figure 2 : Bar-chart of age wise distribution subjects unaware of breast self examination

2   Awareness of safe diet

High fat diet, Red meat, fiber & antioxidant lacking diet, diet without fruits, too much fried food has been considered as unsafe diet. Soya, moderate amount of chicken meat, fish, fruits, vegetables, vitamin C containing fruits are considered safe diet. Table 1 shows out of 47 subjects, 37 took unsafe diet. Fig. 3 shows 79 % of population took unsafe food. Table 2 shows age wise distribution of unsafe diet consuming subjects, where 36-45 age group of population are major in number. No. of people vs. age [years]   bar chart shows result of un-safe diet consumers vide Fig.4.
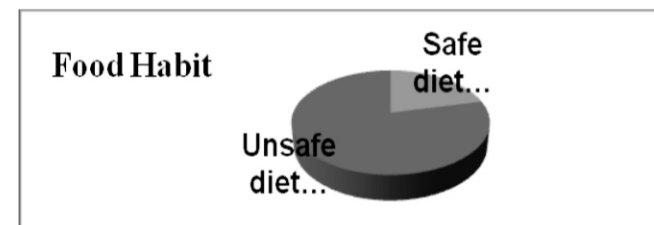

Figure 3 : Awareness amongst studied population regarding food habit.

Figure 4 : Age wise distribution of the entire population unaware about safe diet

3   Awareness of addiction

Table -1 shows out of 45 women breast cancer patients 35 are non addicted. Fig.5 shows 78% of population are aware of bad effects of alcohol and nicotine but 22% of population are not. Fig. 6 shows age wise distribution of non addicted subjects. Where 46-55 age group of patients is predominant and 36-45 age groups are closer to the above.
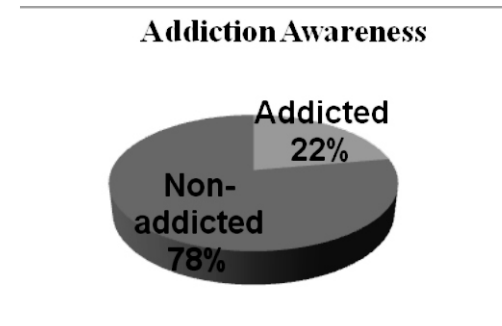

Figure 5 : Percentage chart of addiction vs. non addiction aware population
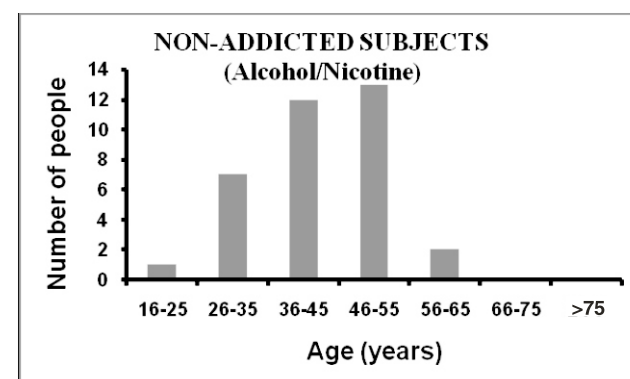

Figure 6 : Agewise distribution of non addicted subjects [35 subjects].

4   Awarness of irregular work schedule

Nightshift duty staff, regular flight attendants, person exposed to radiation may suffer from breast cancer. Results show only 2% populations remains in such category. Nobody was aware about the bad effect of these (Table 2 & Fig. 7). Table 1 shows age wise distribution of subjects having regular work schedule. This indicates 36-45 age group of women are worst sufferer because although they maintain

regular work schedule knowingly or unknowingly they are victim of breast cancer may be due to some other factors. This indicates age is a most important factor responsible for breast cancer in women. Fig 8 shows ranges of age versus no. of patients having regular work Schedule.
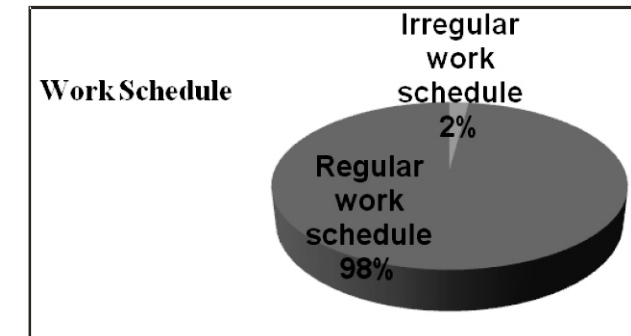

Figure 7 : Chart of % of regular work schedule & irregular work schedule population

Figure 8 : Age wise distribution of the entire population of regular work schedule

5.   Awareness of contradiction for availing contraceptives / HRT

Table 2 shows out of 48 women breast cancer patients 40 availed contraceptives/HRT. Fig.9 through pie chart shows 83 % population availed contraceptives/HRT. Awareness of contraindication (factor responsible for causing breast cancer) of using contraceptives/HRT is lacking in majority of the patients. Table 2 shows age wise distribution of subjects availing contraceptives.Fig.10 shows 36-45 age group of patients are most sufferer and 46-55 age group is closer to it. 16 – 25 of age group are least sufferer patients who availed contraceptives/HRT.

From various population control programs people are now aware of use of contraceptives as an effective tool for birth control. But they are not aware of the difficulties or side effects of such drugs. Awareness of side effects of Hormone

Replacement Therapy [HRT] is also lacking. 17% of the population of the study did not use contraceptives /HRT. For them factor for causing disease might be other.
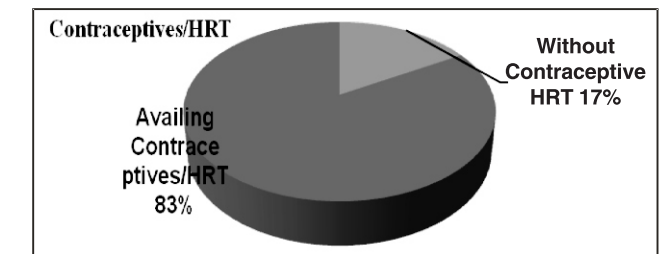

Figure 9 : Chart showing % of population availing & not availing contraceptives or HRT

Figure 10 : Agewise distribution of the entire populations availing contraceptive or HRT.

CONCLUSIONS

This study indicates that awareness level about prevention of breast cancer of the public from the point of view of BSE, food habit, addiction, irregular work schedule, availing contraceptives or HRT is very much lacking.

From the above it may be concluded that, only 4% of the public are aware about proper methods of breast self examination, 79% are unaware of safe diet and 22% are unaware of the demerits of addiction. Also, all of the 2% of population of irregular work schedule are unaware of its harmful effects and 83% of the population are not aware of the contraindications of using contraceptives or HRT which may cause breast cancer. Various government hospitals, NGOs and other organizations are campaigning to spread the awareness level of general public about the different risk factors of breast cancer. More and more these programs are carried out, people will be more aware &   lesser will be the risks of this fatal disease.

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CRITICAL, ETHICAL AND LEGAL DILEMMA WITH COMBINED / TWIN PACK LABELING OF FORMULATIONS

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ABSTRACT

Label of a formulation provides its identification and the product details. A label should provide scientifically accurate and clear instruction to health care practitioners for prescription drugs and to consumers for over-the-counter drugs and supplements. Security of pharmaceutical products is particularly important as it ensures that medications are not tampered with before they reach customers. However, we find that there are many lacunae between the way of labeling and regulatory aspects related to that. Many pharmaceutical manufacturers take the opportunity skillfully to avoid essential information on labels. Labeling of combined/ twin packs is one such critical area to demonstrate. Here some interesting findings related to twin-packs are highlighted with their possible consequences.

INTRODUCTION

Drug labeling refers to all of the printed information that accompanies a drug, including the label, the wrapping and the package insert. The term labeling means all the labels and other written, printed, or graphic matter upon an immediate container of an article or upon, or in, any package [1]. The label must be scientifically accurate and provide clear instruction to health care practitioners for prescription drugs and to consumers for over-the-counter drugs and supplements [2]. Labeling/packaging is one area that has been strongly neglected by Indian pharmaceutical industry for years. Labeling of pharmaceutical products is a great challenge to pharmaceutical industries unlike those encountered in other industries because of the stringent regulations in place to ensure their accuracy. Overall usefulness of information on a formulation label accompanies the drug, namely, the name of the medicine along with any critical warnings, uses of the medicine along with conditions under which the medicine should not be used, directions for contraindications with any related precautions, symptoms of any adverse reactions to the drug, any risk of drug tolerance or dependency while taking the drug, storage instructions, warning of the danger of giving the drug to someone other than the patients, along with the other necessary legal information, etc. [3]. Further, security of pharmaceutical products is of paramount importance to ensure that medications are not tampered with before they reach patients [4]. Indeed there are lacunae between a label and its legal aspects. In many cases, inadequate regulatory aspects extend the hands of pharmaceutical manufacturers to by-pass essential information on label and this may have some serious consequences. Combined/ twin pack is one such area where many pharmaceutical manufacturers are opportunists to by-pass regulatory aspects. Some cases it is done unknowingly too.

In the present study, we have reported here findings related to twin-pack and highlighted some consequences.

Several licensed manufacturers market their products (such as injectable in powder form) in combined/ twin pack, without mentioning important particulars such as name of manufacturer, manufacturing license no. (M.L.No.), batch/ lot no, manufacturing date, expiry date etc) (Fig. 1) of