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Original Research Article

Short term effects on liver and renal functions following chemotherapy treatment for breast cancer patients in oncology clinic, university hospital Kotelawala Defence University in Sri Lanka

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ABSTRACT

Background: Breast cancer tops the global cancer incidence rates, having the highest rate of death among women. The primary objective of this study was to assess the impact of standard chemotherapy treatment dose adjusted for the Sri Lankan population, on hepatic and kidney function of breast cancer patients.
Methods: The study conducted a cross-sectional, retrospective and prospective analysis of 75 breast cancer patients who received doxorubicin, cyclophosphamide, and paclitaxel chemotherapy regimen with normal liver and renal function at baseline at UHKDU oncology clinic. The study population had a mean age and BMI of 54.04±11.33 years and 26.7±3.89, respectively. Prior to starting the 16-cycle chemotherapy treatment, mean serum SGOT, SGPT, Creatinine, and eGFR values were 27.57 U/l, 31.32 U/l, 0.71 mg/dl, and 99.07 ml/minute/1.73 m^2 respectively.
Results: During the treatment, there was a statistically significant increase in the mean values of SGOT and SGPT ($p<0.05$), whereas there was no significant variation in the mean values of creatinine and eGFR ($p>0.05$) compared to the baseline results. The study identified a significant positive correlation in SGOT ($r=0.793$) and SGPT ($r=0.872$) values, while there was a noteworthy negative correlation ($r=-0.757$) between eGFR and chemotherapy cycle. Furthermore, there was a positive significant correlation between serum creatinine levels and chemotherapy cycle ($r=0.579$).
Conclusions: The dosed adjusted chemotherapy regimen had a significant impact on hepatic function but had no statistically significant impact on renal function among the study population. Further research is recommended to evaluate the long-term effects of standard chemotherapy treatment on liver and kidney functions.

Keywords: Breast cancer, Chemotherapy, Liver function, Renal function

INTRODUCTION

Cancer is one of the deadly diseases found in the global community. According to the data of GLOBACAN database 2020, more than 19 million new cancer cases are identified each year. Worldwide cancer mortality in 2020 was more than 9 million.[1] Over the last 25 years, there has been a twofold increase in the overall incidence of cancer in Sri Lanka, accompanied by a corresponding upsurge in cancer-related fatalities.[2] Among them, breast cancer plays a leading role. Breast cancer in females has now become the most commonly diagnosed cancer type, overtaking lung cancer, accounting for 2.3 million (11.7%) new cases and 0.7 million (6.9%) of the total cancer deaths as the fourth highest contributor of cancer mortality across worldwide.[1,3] According to the statistics,

less than 1% of all diagnosed cases of breast cancer pertain to male breast cancer worldwide in 2020.[4]

While the underlying cause of breast cancer is unclear, there exist several risk factors that could impact the development of breast carcinoma.[5] The common risk factors of breast cancer are; female gender, older age, inherited gene changes of breast tissue, family history and personal history of breast cancer, race and ethnicity of women and exposure to radiation. In addition to these there are certain reproductive, hormonal, life style related and controversial risk factors for female breast cancer.[6,7]

Chemotherapy, radiotherapy and hormone therapy are the leading adjuvant treatment methods used for breast cancer.[8] Among them chemotherapy is the predominantly used adjuvant treatment method in Sri Lanka. Side effects of chemotherapy are usually temporary and most can be controlled. These side effects disappear when the treatment is over. But for some patients, these short- term side effects can last for longer or may develop years after the treatment.[9]

Doxorubicin, cyclophosphamide and paclitaxel chemotherapy schedule is the frequently used chemotherapy schedule for breast cancer patients in Sri Lankan context. That chemotherapy treatment consists of 2 treatment methods. First treatment is a combination of doxorubicin and cyclophosphamide doses per 21 days for 4 cycles and the second treatment is paclitaxel doses weekly for 12 cycles.

Doxorubicin is mostly excreted from liver and only a 15% is excreted from kidney. Cyclophosphamide is secreted 50-70% by the kidneys within 48 hours. Urinary tract epithelium, notably the bladder, can sustain damage from the metabolites of cyclophosphamide.[10] Paclitaxel drug strongly bind to the proteins; mainly albumin (>90%) and metabolized in the liver by cytochrome P450 mechanism and eliminated through the biliary system. A small amount also secreted into urine.[11] As depicted above, over the recent years, several studies have been conducted across different countries, regarding the effect of chemotherapy treatment on many organs and body function specially the liver and renal function following the chemotherapy treatment.[12]

Hence, periodic assessment of the normal function of liver and kidneys in breast cancer patients undergoing regular chemotherapy treatment is crucial for the progress of the chemotherapy treatment.[13] Nevertheless, in Sri Lanka, there is a dearth of significant research or evidence to evaluate the near-term effects of standard chemotherapy treatment, with dosages tailored for the Sri Lankan population, on the liver and renal function of breast cancer patients. Thereby, the current study aimed toward analysing the short-term effects on liver and renal function following the selected standard dose adjusted chemotherapy treatment among breast cancer patients in Sri Lanka. The magnitude of the chemotherapy effects on organs between the two chemotherapy treatments were also evaluated.

METHODS

Study design

It was a prospective cross-sectional study involving seventy-five breast cancer patients in the age between 20-65 with confirmed histological results was conducted, who were being treated from the same adjuvant or palliative basis chemotherapy treatment schedule at University Hospital Kotelawala Defence University, Sri Lanka from November 2021 to April 2022. Only the breast cancer patients who had normal baseline liver function test (LFT) and renal function test (RFT) results were recruited for the study. Patients with altered or impaired liver and renal function, pregnant and lactating women were excluded from the study.

Data collection tools

The ethical clearance was obtained from the ethical review committee of faculty of medicine, General Sir John Kotelawala Defence University (KDU), Sri Lanka (RP/S/2021/18- 28.10.2021). Data and blood samples collection were performed after obtaining informed written consent from the participants. Collection of data was performed under three categories; conducting oral interviews, performing laboratory investigations and reviewing medical records.

Oral interviews were used to collect patient related data: 1) Socio-demographic information (including age and gender), 2) Disease related information (breast cancer stage at the diagnosis, presence of comorbidities, the type of comorbidity).

A few laboratory investigations were performed using a blood sample collected from each patient before each respective chemotherapy cycle. The blood samples were collected into heparinized tubes. The collected samples were analyzed for bio chemical parameters SGPT/serum glutamate pyruvate transaminase (NADH method), SGOT/serum glutamic oxaloacetic transaminase (NADH method) and serum creatinine (alkaline picrate (kinetic method) by using Abbott Architect Plus C4000 fully automated bio chemical analyzer (Abbott Diagnostics, Chicago, USA) at the biochemistry laboratory of University Hospital Kotelawala Defence University. Then eGFR values were calculated using patient creatinine levels associating MDRD (modification of diet in renal diseases) equation.

Medical history, results of previous laboratory investigations and physiological measurements (height and weight of the patients before the commencement of 1st course of chemotherapy treatment) were collected using medical records. Then referring those data, the

body mass index (BMI) of each patient was reckoned by using standard calculations.

Data analysis

The data analysis in accordance with the study's objectives was performed using Statistical Package for Social Sciences (SPSS) version 28.0. Socio demographic data (age, gender), disease related information (cancer stage, status of comorbidities distribution), physiological data (height, weight, BMI) and results of laboratory investigations (SGPT, SGOT, creatinine and eGFR values) were descriptively analysed. The comparison between laboratory investigation results before and after each chemotherapy cycle was carried out using paired sample t-test analysis. Cohen's d values also were calculated to determine the magnitude of the effect. Strength of the chemotherapy effect on organs between the two chemotherapy treatments was evaluated using paired sample t-test analysis. Significant trend of the changes in laboratory test values following chemotherapy treatments were determined using line charts. The correlations between continuous variables were then analyzed using bi variant correlations. The associations between breast cancer stage and age category, BMI category, no of comorbidities were then obtained by using cross tabs (chi-square).

RESULTS

Descriptive statistics

In the current study, seventy-five breast cancer patients who underwent the same standard chemotherapy treatment schedule were studied. Out of them 74 (98.7%) were female and only one (1.3%) was male. The mean age of breast cancer patients was 54.04±11.33 years.

According to the analysis of the physiological measurements of the study population, most of the patients (69.3%, n=52) had obese BMI values and only 13.3% (n=10) had normal BMI values at the stage of diagnosis. The mean BMI value of the study population was reported to be 26.7±3.89 kg/m^2 and more than eighty-five percentage were included in overweight+ obese BMI category.

Breast cancer patients were categorized into 4 breast cancer stages as reported by the TNM diagnosis criteria.14 According to the medical history of the study population, majority of the breast cancer patients (49.3%, n=37) were diagnosed at breast cancer stage 2 and least number of patients (8%, n=06) were identified at breast cancer stage 4.

Certain individuals of the study population received concurrent treatments for conditions other than breast cancer. More than 50% of the patients had even one comorbidity at the stage of breast cancer diagnosis. Most prevalent comorbidity among the study population was hypercholesterolemia (19.7%). Hypertension was identified in 13.8% (19 patients) and 13.1% (18 patients) had diabetes mellitus.

Table 1: Descriptive statistics of demographic, physiologic and disease related information of the study population.

Parameters		Mean±SD/ Frequency
Age (years)	Age category	54.04±11.33
	20-29	01 (1.3%)
	30-39	05 (6.7%)
	40-49	20 (26.7%)
	50-59	22 (29.3%)
	60-69	23 (30.7%)
	>70	04 (5.3%)
Gender	Female	74 (98.7%)
	Male	01 (1.3%)
BMI (kg/m^2)	BMI category	26.7±3.89
	<18.5 (underweight)	0 (0 %)
	18.5-22.9 (normal)	10 (13.3%)
	23-24.9 (overweight)	13 (17.3%)
	>25 (obese)	52 (69.3%)
Breast cancer stage	Stage 1	18 (24.%)
	Stage 2	37 (49.3%)
	Stage 3	14 (18.7%)
	Stage 4	06 (8.0%)
Comorbidities status	Presence of comorbidities	41 (54.7%)
	Absence of comorbidities	34 (45.3%)
Comorbidities types	Diabetes mellitus	18 (13.1%)
	Hypertension	19 (13.8%)
	Hypercholesterolemia	27 (19.7%)
	Other (wheeze, hyperthyroidism)	06 (4.4%)

Bio chemical tests were performed before the initiation of chemotherapy treatment and during the chemotherapy treatment (from course 1 to course 16). The levels of enzymes (serum glutamate pyruvate transaminase and serum glutamic oxaloacetic transaminase) were analyzed for proper functioning of liver. Liver function test was used to monitor the short-term side effects of medication used in chemotherapy to the liver (Figure 1).

The mean SGOT value prior to the initiation of chemotherapy treatment was noted to be 27.57 U/l. The mean values of SGOT levels were observed to be within normal reference range (5-34 U/l) from first to third course of chemotherapy. Afterwards, the mean AST values increased out of normal reference range. However, the SGOT levels increased as the course of chemotherapy further proceeds.

The mean value of SGPT was reported to be within normal reference range (0-55 U/l) from chemotherapy

course 1 to 14. After the 15th chemotherapy course, it increased beyond the normal reference range. The mean value of SGPT was noted to be 31.32 U/l in pre-chemotherapy stage. An increasing level of SGPT enzyme was reported throughout the treatment course.

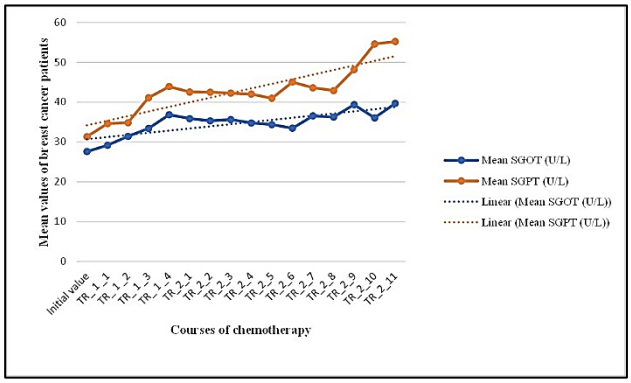

Figure 1: Liver function during the chemotherapy treatment.

Mean creatinine and eGFR values distribution with the chemotherapy cycles are shown below, to estimate the renal function during the chemotherapy treatment (Figure 2).

The mean value of serum creatinine in pre chemotherapy state was 63.19 µmol/l. The mean creatinine level was reported to be within normal reference range (48.95-90.78 µmol/l for women) during all courses of chemotherapy treatment. Although some variations were seen in the mean creatinine value distribution throughout the treatment course, there was no statistically significant variance between values.

Mean eGFR values in pre chemotherapy state was 99.07 ml/minute/1.73 m^2. As showed in the serum creatinine level, eGFR values also found to be within the normal reference range (60-120 ml/minute/1.73 m^2) throughout whole chemotherapy treatment.

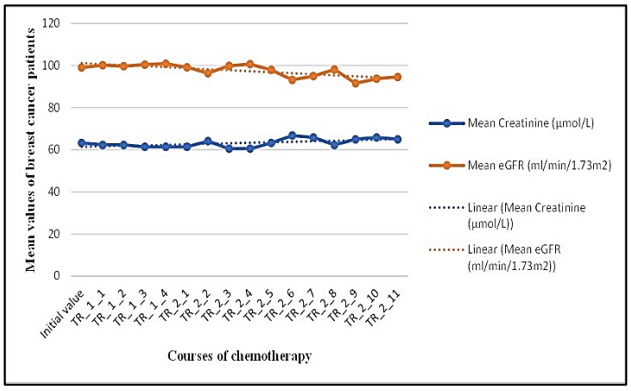

Figure 2: Renal function during the chemotherapy treatment.

The results of laboratory investigations before the initiation of whole chemotherapy treatment were compared with the laboratory investigation values after each chemotherapy treatment cycle to evaluate the effect of chemotherapy treatment on liver and renal function. Most of the serum SGOT and SGPT values had statistically significant variations between the pre-chemotherapy and post-chemotherapy values along with the chemotherapy cycle while majority of serum creatinine and eGFR values had no statistically significant variations between the pre-chemotherapy and post-chemotherapy values.

Table 2: The differences of laboratory test values after each chemotherapy cycle.

Chemotherapy cycle	Treatment course	SGPT	SGOT	Creatinine	eGFR
		P value	P value	P value	P value
1	Treatment 1_1	0.069	0.011*	0.241	0.195
2	Treatment 1_2	0.085	0.008 **	0.416	0.342
3	Treatment 1_3	0.008 **	0.012 *	0.145	0.136
4	Treatment 1_4	0.003 **	0.022 *	0.150	0.135
5	Treatment 2_1	0.007 **	0.002 **	0.060	0.178
6	Treatment 2_2	0.002 **	0.005 **	0.412	0.443
7	Treatment 2_3	0.005 **	0.015 *	0.038 *	0.068
8	Treatment 2_4	0.006 **	0.045 *	0.031 *	0.045 *
9	Treatment 2_5	0.012 *	0.017 *	0.219	0.290
10	Treatment 2_6	0.040 *	0.014 *	0.107	0.093
11	Treatment 2_7	0.018 *	0.106	0.264	0.245
12	Treatment 2_8	0.048 *	0.104	0.472	0.295
13	Treatment 2_9	0.013 *	0.007 **	0.254	0.105
14	Treatment 2_10	0.081	0.044 *	0.187	0.149
15	Treatment 2_11	0.081	0.125	0.268	0.064
16	Treatment 2_12	0.081	0.130	0.295	0.055

P**- p<0.01; P*- p<0.05

Cohen's d effect size was calculated to estimate the magnitude of effect which occurred to the organs as it measures the effect size of the differences between two means. It demonstrated a smaller effect size (d>0.2) for all the chemotherapy cycles which showed a statistical effect (p<0.05) on liver.

Table 3: The differences of laboratory test values before and after chemotherapy for both treatment methods.

Parameter	1st chemotherapy treatment		
	Pre value	**Post value**	**Significance (p)**
SGPT	31.3±20.7	43.9±48.0	0.044*
SGOT	27.6±15.9	36.8±31.0	0.005**
Creatinine	0.71±0.13	0.69±0.13	0.301
eGFR	99.1±14.3	100.8±14.1	0.270
	2nd chemotherapy treatment		
	Pre value	**Post value**	**Significance (p)**
SGPT	43.9±48.0	55.2±48.4	0.692
SGOT	36.8±31.0	39.7±26.3	0.345
Creatinine	0.69±0.13	0.73±0.11	0.446
eGFR	100.8±14.1	94.6±10.7	0.207

In consonance with the SGOT and SGPT values, 1st chemotherapy treatment method (a combination of doxorubicin and cyclophosphamide) demonstrated a remarkable value difference (p<0.05) than the 2nd chemotherapy treatment method indicating an analytical effect on liver function.

Correlations among variables: (confidence interval- 95%)

Correlations were obtained between chemotherapy cycle and mean SGOT, SGPT, creatinine and eGFR values of the study population.

Serum SGOT level was exhibited a positively correlation with the chemotherapy cycle (r=0.793, p<0.001) while serum SGPT level also was displayed positively correlation with the chemotherapy cycle (r=0.872, p<0.001). A positive correlation (r=0.579, p=0.019) was observed between serum creatinine values and the chemotherapy cycle also. eGFR values were negatively corelated with the chemotherapy cycle (r=-0.757, p<0.001).

There was a positive correlation between SGOT values and SGPT values throughout both chemotherapy treatment regimens. The correlation between creatinine and eGFR values represented a remarkable negative correlation throughout both chemotherapy treatment regimens.

Associations among categorical variables: (confidence interval- 95%)

No statistically significant associations were found between breast cancer stage and age category, BMI category, comorbidity status, number of comorbidities.

DISCUSSION

Chemotherapy represents a significant therapeutic modality employed in the management of patients with breast cancer. The biochemistry profile of blood measures the chemical substances which are released or produced during metabolic processes in the body. They provide vital information about the function of different organs. Several studies have proved that there are certain short-term and long-term effects of chemotherapy treatment on the organ function.[9,12] However, there are no intellectual evidences regarding this matter in Sri Lankan population. Therefore, the current study was conducted with the major objective of evaluating the short-term effects of the standard chemotherapy treatment (dose adjusted for Sri Lankan population) on liver and renal function of breast cancer patients. The current study also evaluated the demographic characteristics of the breast cancer patients descriptively.

Based on the findings of the current study, liver functioning test is mainly based on the enzymatic levels of SGOT and SGPT.[15] The mean values of serum SGOT and SGPT were found to be increased throughout the chemotherapy treatment. The mean values of SGOT were observed within normal reference range from 1st to 3rd course of chemotherapy, while the mean values of SGPT were reported to be within normal reference range from 1st to 14th course. Moreover, elevation in serum SGOT and SGPT suggested statistically significant short-term effect on liver function after the selected standard chemotherapy treatment, similar to other studies. However, that effect was not clinically remarkable.[16]

The renal functioning test is mainly based on the levels of eGFR and serum creatinine. Many studies have discovered marked variation in post chemotherapy renal function.[17,18] But, according to the results of the present

study, mean values of both serum creatinine and eGFR were within the normal reference range throughout whole chemotherapy treatment. Although some variations were seen in mean creatinine and eGFR value distribution throughout the treatment course, there were no significant differences between values. Therefore, due to the selected standard chemotherapy treatment (which is dose adjusted for Sri Lankan population) there was no statistically or clinically significant short-term effect on renal function.

The present study was able to find significant correlations between mean SGOT, SGPT, creatinine and eGFR values with the chemotherapy cycle. Thereby, it can be stated that any differences in value, of above-mentioned parameters may depend on chemotherapy cycle of the breast cancer patients. The current study also found a significant positive correlation among mean SGOT and mean SGPT values and significant negative correlation among mean creatinine and mean eGFR values.

It was discovered that majority of the current study population 65.3% (n=49) were >50 years old at the diagnosis stage. Therefore, older age people have a higher vulnerability for having breast cancer than younger population.[6] Furthermore, >50% of the patient population were diagnosed with having any comorbidity. So, the rising incidence of comorbidities and older age at diagnosis in Sri Lanka could potentially impede the administration of appropriate therapy and negatively affect cancer care.[19]

The present study found that 86.6% (n=65) of the breast cancer study population were included in the overweight or obese BMI category (according to the Asian categorization) at the time of breast cancer diagnosis. This finding clearly showed that higher BMI values (overweight or obese) may increase the chance of having breast cancer during their life time and may serve as a significant contributor for the emergence of breast cancer. This observation was also emphasized by the investigations carried out by the studies of Biglia et al, and Chen et al.[20,21]

Furthermore, it was determined that more than 25% of the participants in the study were diagnosed with late-stage breast cancer (stage III and IV). This finding is compatible with a previous study by Wijeratne et al, who conducted a research study using breast cancer patients at National Cancer Institute Sri Lanka during 2016-2020. This indicates the limitations of the country's healthcare system in implementing efficient strategies that target the early detection of breast cancer.

The study of serum bio chemical parameters like SGOT, SGPT, creatinine and eGFR may be a worthful diagnostic tool in different treatment strategies of breast cancer.

There are few limitations. The study was only able to analyse few laboratory test parameters. So, it is researchers' suggestion to perform liver and renal profiles on each patient before chemotherapy treatment cycles respectively. The study included only 75 patients and it will be more significant to consider a larger population in different geographic location across the country to establish national prevalence data and to gain a better understanding of the disease burden, since current data are insufficient.

CONCLUSION

Many studies have proved that there is an effect on liver and renal function following chemotherapy treatment schedule of doxorubicin, cyclophosphamide and paclitaxel. The current study was conducted with the major objective of evaluating the short-term effects of the above-mentioned standard chemotherapy treatment (dose adjusted for Sri Lankan population) on liver and renal function of breast cancer patients.

In accordance with the results of current study, mean SGOT and SGPT values were increased beyond the normal reference range and showed a statistically significant increase throughout the chemotherapy treatment with the initial laboratory test values. Mean creatinine and eGFR values had no significant difference with the initial laboratory test values. Nevertheless, that statistically significant short-term effect on liver function also was not clinically remarkable indicating that there is no chemotherapy related short term effects on liver and renal function for breast cancer patients due to the dose adjusted chemotherapy treatment used in Sri Lanka.

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