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Impact of clinical pharmacist intervention on tamoxifen-related problems among breast cancer women in Babil Province

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ABSTRACT

Patients with breast cancer (BC) are frequently exposed to drug-related problems (DRPs) due to the long-term administration of highly toxic chemotherapeutic agents such as tamoxifen. Clinical pharmacists play a vital role in monitoring these issues and mitigating their frequency and severity. This study has aimed at evaluating the impact of clinical pharmacy interventions on the incidence and intensity of DRPs, including drug interactions, adverse effects, and inappropriate tamoxifen dosing. A pre–post interventional study was conducted at the Babylon Oncology Center, involving 70 women diagnosed with BC who were receiving a monthly tamoxifen treatment. The clinical pharmacist identified a total of 94 DRPs; an average of 1.34 per patient. The most frequent adverse effects attributed to tamoxifen were grade-2 hot flashes (16.9%), grade-2 osteoporosis (13.1%), grade-2 musculoskeletal pain (12.3%), weight gain (10%), and hand / foot swelling (6.9%). Three months following the pharmacist-led interventions, the number of DRPs was reduced to 48. A statistically significant difference was observed between the pre- and post-intervention DRP counts ($p<0.05$). These findings underscore the pivotal role of clinical pharmacists in improving treatment outcomes for BC patients through the effective reduction of DRPs.

1. Introduction

Breast cancer (BC) ranks as the second-leading cause of cancer-related mortality globally, with an estimated prevalence of 2.3 million cases in 2022. Worldwide, BC accounts for approximately 6.9% of all deaths[1].

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Patients with BC are exposed to numerous drug-related problems (DRPs), including adverse drug reactions and drug interactions, largely due to the long-term administration of highly toxic chemotherapeutic agents. Consequently, clinical pharmacists play an essential role in monitoring and mitigating the frequency and severity of DRPs[2].

Tamoxifen's pharmacologic activity is curtailed by its adverse effect profile. Pulmonary embolism, uterine cancer, and stroke are serious complications associated with its use; these have formed the basis for its FDA black box warning issued in 2002. Additional side effects include vaginal discharge, irregular menstruation, oedema, hypertension, hot flashes, nausea, and vomiting[3]. Through the improvement of medication adherence, the management of adverse effects, and the optimization of therapy based on patient age, comorbidities, and polypharmacy, clinical pharmacists contribute significantly to the reduction of DRPs and the enhancement of treatment outcomes for BC patients[4]. This study aimed at assessing the impact of clinical pharmacist interventions on the frequency and severity of DRPs related to tamoxifen, including drug interactions, adverse effects, and inappropriate dosing.

2. Methodology

A pre–post interventional study was conducted at the Babylon Oncology Center of the Merjan Teaching Hospital, in the Babil Province of Iraq, between 18 February 2024 and 1 October 2024. Ethical approval was obtained from the Scientific and Ethical Committee of the Faculty of Medicine of the University of Kufa (ref.: MEC-18; date: 14 February 2024). Written informed consent was obtained from all participants following a detailed explanation of the study's purpose.

The study enrolled 70 women diagnosed with BC who were receiving monthly tamoxifen therapy. Eligibility criteria included an age ≥18 years, a confirmed histopathological diagnosis of BC at any stage or grade, and a signed informed consent. During the observational phase, DRPs were identified in the 70 enrolled patients through face-to-face evaluation by a clinical pharmacist. Documented DRPs included drug to drug interactions involving tamoxifen, adverse effects, and dosing errors. A structured intervention followed, in which the clinical pharmacist provided patient-specific education and therapeutic guidance aimed at preventing or mitigating DRPs.

Outcomes were reassessed 12 weeks post-intervention in order to evaluate changes in the frequency and severity of DRPs. Statistical analysis was performed using SPSS version 24 and Microsoft Excel 2019. The Shapiro–Wilk test was applied in order to assess data normality. Descriptive statistics for categorical variables were reported as frequency and percentage, while numeric variables were presented as mean, standard error of the mean, median, and interquartile range (IQR=Q1-Q3). The Wilcoxon signed-rank test was employed in order to compare DRP frequency before and after the intervention. A p-value below 0.05 was considered as statistically significant.

3. Results and Discussion

Seventy female BC patients (median age: 45 years; IQR: 40–49 years) receiving monthly tamoxifen therapy at the Babylon Oncology Center were included in this study. Each patient underwent a detailed review and interview by a clinical pharmacist, resulting in the identification of 94 DRPs; an average of 1.34 per patient.

Tamoxifen's therapeutic efficacy is largely dependent on its active metabolite, endoxifen, which is generated *via* cytochrome P450 enzymes, particularly CYP2D6. However, this metabolic pathway is subject to inhibition and induction by various co-medications, thereby increasing the risk of DRPs[5].

The incidence of DRPs in this cohort exceeded that reported in a prospective observational study conducted in Thailand[6], likely due to differences in patient population: the Thai study assessed general oncology patients, whereas the present study focused exclusively on BC patients receiving tamoxifen. Among the 94 DRPs identified, adverse effects of tamoxifen represented the most frequent category (68 cases; 73.9%), followed by drug–drug interactions (16 cases; 17.0%) and dosing errors or other issues (8 cases; 8.5%). This profile is modestly higher than that observed in a retrospective cross-sectional study by Degu and Kebede in Ethiopia[7], where adverse drug

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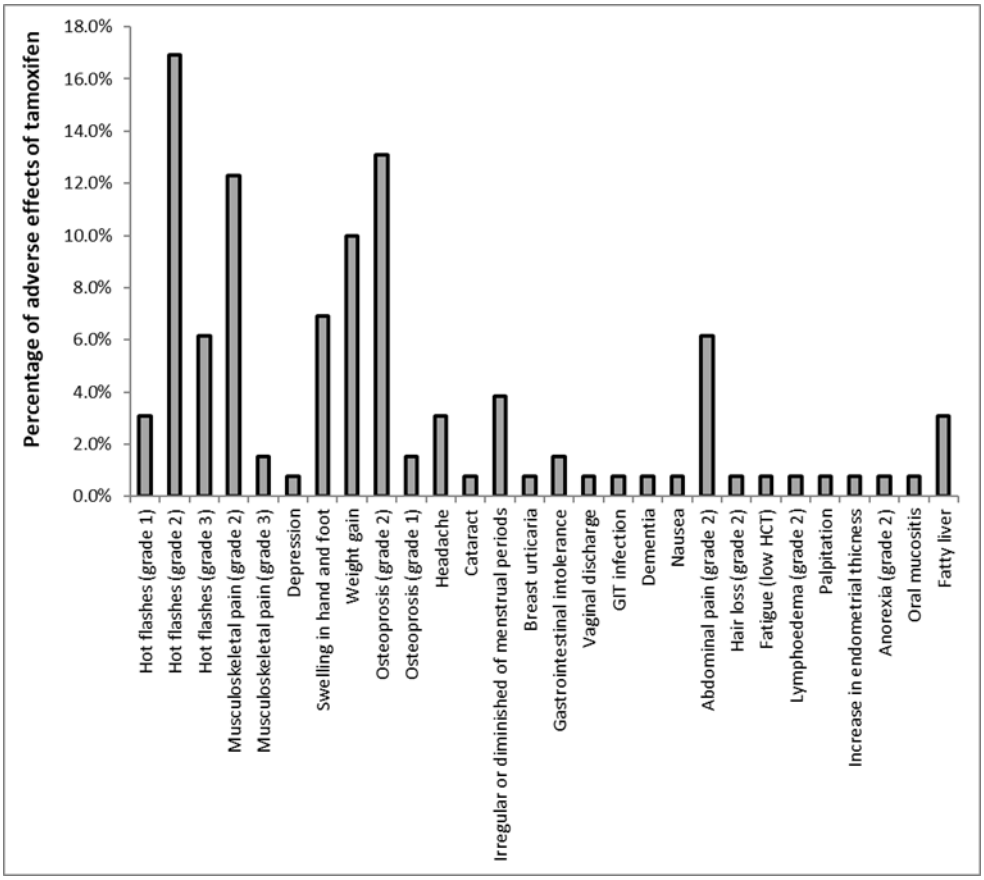

Figure 1. *The frequency of the different types of adverse effects of tamoxifen recorded in this study.*

reactions accounted for 48.6% of the recorded DRPs.

Figure 1 displays the distribution of adverse effects observed. The most common were grade-2 hot flashes (16.9%), grade-2 osteoporosis (13.1%), grade-2 musculoskeletal pain (12.3%), weight gain (10.0%), and hand / foot swelling (6.9%). These findings align with the symptom profile documented by Rosso *et al.*[8] in their assessment of tamoxifen-associated adverse effects.

Following targeted pharmacist-led interventions (including focused review, education, and clinical guidance), the number of DRPs decreased to 48 (mean: 0.69 DRPs per patient). Among these, adverse effects of tamoxifen remained predominant (33 cases; 63.5%), followed by drug–drug interactions (12 cases; 23.1%) and inappropriate dosing (7 cases; 13.5%). The reduction in DRP frequency was found to be statistically significant ($p<0.05$). These findings corroborate prior reports highlighting the critical role of oncology pharmacists in the partial or full resolution of DRPs[9,10].

4. Conclusion

Clinical pharmacists play an indispensable role in oncology settings by improving treatment outcomes for BC patients. Their therapeutic interventions effectively reduce the frequency and severity of DRPs, thereby enhancing patient safety and medication efficacy.

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this study.

Conflicts of interest

None exist.

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