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Master of Pharmacy dissertation by Juhi Maharaj (1627913)

Abstract

Introduction:

Breast cancer is the leading cancer subtype and accounts for the most significant number of cancer-related deaths in females. Cancer patients have an elevated risk of experiencing adverse drug reactions before, after, and while on treatment. Pharmacovigilance prioritises drug and patient safety, however, due to extensive under-reporting, more so in low-to-middle income countries, signal detection and the consequent changes to policy and practice are lacking. Thus, there is a need to analyse the global database of individual case safety reports on anastrozole, fulvestrant and tamoxifen, commonly used hormonal agents for treating breast cancer.

Methods:

A quantitative, secondary approach was taken where descriptive and statistical analysis was conducted on data obtained from the Uppsala Monitoring Centre's global individual case safety report database, VigiBase®. A total of 43 411 anonymised reports were analysed, using Microsoft Excel for data organisation, cleaning, and numerical coding. The seriousness of the reported adverse drug reactions was evaluated and categorised. The statistical analysis program STATA was used. Pearson chi-squared analysis was conducted to determine statistical associations. Further binary logistic regression was conducted, using a p-value of < 0.05 to show statistical significance. Comparisons between the reported adverse drug reactions and those listed on the drug's package inserts were also done.

Results:

The majority of the adverse drug reactions were reported from the "Americas" and "Europe". Most of the reports were from females in the "45 – 64 years" age group. The most frequently reported ADR for anastrozole, fulvestrant, and tamoxifen were "arthralgia", "fatigue", and "death" respectively. The type of adverse drug reactions reported from Africa, albeit few, were not entirely similar to the other continents. The adverse drug reactions that were most frequently found to be statistically significant with the demographic variables were "arthralgia" for anastrozole, "malignant neoplasm progression" and "asthenia" for fulvestrant, and "arthralgia" for tamoxifen. Despite most of the adverse drug reactions listed in the medicines package insert, there were other commonly reported reactions not listed in the leaflet.

Conclusion:

Well-known and frequently reported adverse drug reactions have demonstrated statistically significant associations to several age groups and continents. This research can be used to warrant targeted adverse drug reaction monitoring in specific populations to safeguard and better manage patients at

greater risk of adverse reactions that impact patient quality of life and have considerable cost implications.