National Cancer Institute experience with Generic Anastrozole (Anastrodex, Hikma) in newly diagnosed post-menopausal female Egyptian patients with low burden visceral metastatic breast cancer

Mohamed Maher 1, Mariam M. Elhaddad 2, Abdelhamid M. Fouad 1.

1 Medical Oncology and Hematology Department, National Cancer Institute, Cairo University, Egypt
2 Clinical Pathology Department, National Cancer Institute, Cairo University, Egypt

Abstract

The systemic treatment of metastatic breast cancer (MBC) prolongs survival and enhances quality of life but is not curative. Therefore, treatments associated with minimal toxicity are preferred.

Background

The use of the minimally toxic endocrine therapies is preferred to the use of cytotoxic therapy whenever reasonable.

Most generic drugs carry a lower price than the brand name equivalent. This does not mean lower quality, but consumers should monitor information about the generic form with their physician and medical teams.

Objective

To evaluate the efficacy and safety of Generic Anastrozole (Anastrodex, Hikma) in newly diagnosed post-menopausal female Egyptian patients with low burden visceral MBC and to compare its results with the reported similar studies of the original brand.

Outcomes

Progression-free survival at 12 month

Progression-free survival at 24 month

Anastrozole 70%
Anastrodex 66%
Anastrozole 46%
Anastrodex 40%

Grade 1 and 2 AEs

Anastrozole
Anastrodex

Grade 3 and 4 AEs

Anastrozole
Anastrodex

Responses were defined by RECIST guidelines-EORTC. Adverse events (AEs) were evaluated using CTCAE, Version 5.0

Summary

Thirty patients were assigned to original brand Anastrozole while other 30 received Generic Anastrodex. At 12M, PFS rates were 70% and 66% respectively. PFS at 24M were 46% and 40% respectively. Overall grade 1 and 2 AEs were almost equal in both arms. Grade 3 and 4 AEs occurred in only 1 patient in original brand arm while grade 3 and 4 AEs occurred in 4 patients with Generic Anastrodex. Treatment was discontinued in 10% with original brand due to arthalgia while 30% discontinued treatment with generic form because of AEs mainly GI toxicity and depression.

Albeit of short follow-up, PFS at 12 and 24 month are comparable in both arms. Also, safety profiles were quite similar, with slightly higher rates of grades 3-4 AEs and treatment discontinuation due AEs with generic form. However, more patients and longer follow up are needed to draw a firm conclusion.

Conclusion

Albeit of short follow-up, PFS at 12 and 24 month are comparable in both arms. Also, safety profiles were quite similar, with slightly higher rates of grades 3-4 AEs and treatment discontinuation due AEs with generic form. However, more patients and longer follow up are needed to draw a firm conclusion.