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Opportunities for post-market surveillance of high cost medicines in Australia: Observing trastuzumab-treated women from early through late stage HER2-positive breast cancer (HER2BC)

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Objectives

In 2001 the Australian government circumvented traditional drug subsidy listing processes to create the Herceptin Program (HP) for HER2 metastatic breast cancer (MBC) patients; in 2006 trastuzumab was subsidised for early breast cancer (EBC) on the Pharmaceutical Benefits Scheme (PBS) creating opportunities for data linkage and observing patients across both treatment settings. Clinical trials established the efficacy of trastuzumab for MBC in trastuzumab-naïve patients but little is known about patients initiating trastuzumab in the adjuvant setting and subsequently receiving trastuzumab for MBC. We characterise patterns of treatment and outcomes for these patients in Australia. We estimate time from adjuvant trastuzumab initiation to metastatic trastuzumab initiation and overall survival (OS).

Approach

We identified a cohort of patients with a trastuzumab claim in both PBS and HP records. We calculated duration of EBC treatment as date of first trastuzumab dispensing until 21 days after the last PBS dispensing for trastuzumab or observation of a trastuzumab dispensing record in HP claims, whichever came first. We used Kaplan-Meier methods to estimate time-to-MBC treatment and OS.

Results

Of 11,477 EBC patients treated with trastuzumab between December 2006 and December 2012, 637 were also treated with trastuzumab for MBC. Median age at EBC treatment initiation was 53 (range 17 - 87). 94% of EBC patients received a taxane, anthracycline, cyclophosphamide and/or carboplatin as part of their treatment protocol. 61% of MBC patients received trastuzumab with a taxane, 18% as monotherapy and 7% with

capecitabine. Median duration of trastuzumab therapy in EBC and MBC treatment was 11.3 (95% CI 10.7-11.6) and 9.3 (8.6-10.4) months, respectively. Median time-to-MBC therapy was 27.3 (25.5-28.2) months. Median OS from initiation of EBC and MBC treatment was 58.1 (52.9-65.7) and 23.2 (20.5-25.4) months, respectively.

Conclusion

HER2BC patients initiating trastuzumab for EBC therapy and progressing to MBC treatment are little examined in the clinical trial and observational literature. Australia's unique funding arrangements allowed us to clearly distinguish between treatment for EBC and MBC which is not always possible in dispensing claims alone. We demonstrated: most EBC patients are treated according to guideline recommendations; that this patient cohort receive approximately 20 months of trastuzumab therapy across both settings; and median OS from initiation of MBC treatment is approximately 2 months shorter than in the pivotal clinical trial (25.1 months).

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