



Review

A review of the value of human epidermal growth factor receptor 2 (HER2)-targeted therapies in breast cancer[☆]



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Received 14 September 2017; received in revised form 26 October 2017; accepted 31 October 2017

KEYWORDS

Value;
Cost-effectiveness;
Human epidermal
growth factor
receptor-2 (HER2);
Breast cancer

Abstract The cost of cancer drugs continues to escalate with the rapid development and approval of novel therapies, especially over the course of the last decade. In human epidermal growth factor receptor 2 (HER2)-positive breast cancer, the survival benefits gained by new treatments have been undeniably substantial. It is important to assess the financial value of these therapies for decision making at both the societal and individual level. This information is key for managing resources in resource-limited health care systems, while at the same time supporting patient decision-making and conversations between patient and physicians on cost versus benefit. In this article, we perform a systematic review of cost-effectiveness analyses that have been completed to date on HER2-targeted agents, focussing on those that correlate with standard of care therapy. Our discussion also highlights potential strategies to overcome several limitations associated with measuring value for anticancer drugs.

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[☆] This work was supported by the University of Calgary NAN; CIHR Strategic Training Program in Cancer Research and Technology Transfer (CaRTT) and Academic Development Grant from Western University to MBH.

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1. Introduction

The cost of cancer drugs continues to escalate with the rapid development and approval of novel therapies, especially over the course of the last decade [1]. While being costly, some of these therapies are highly effective with substantial survival benefit. In human epidermal growth factor receptor 2 (HER2)-positive breast cancer, targeted therapies are associated with significant survival benefit in both the adjuvant and metastatic setting. Where previously a poor prognostic marker, the median overall survival of patients with advanced HER2-positive breast cancer has increased substantially since the introduction of HER2-targeted therapies from approximately 20 months, to now approaching 5 years [2,3]. Landmark trials in early and advanced disease are summarised in Tables 1 and 2 respectively, demonstrating the significant survival gains. It is important to know the value of these therapies for appropriate decision-making. In this article, we perform a systematic review of the literature evaluating cost-effectiveness of HER2-targeted therapies. We also explore potential strategies to improve the overall budget impact.

2. Assessment of value for money in healthcare at the social level

Health economists use a variety of methods to assess ‘value for money’ [4]. Cost-effectiveness analyses (CEAs) are commonly used techniques to examine the economic cost of novel medical technologies in the context of their clinical benefit [4]. Results are usually presented in the form of a ratio called the incremental cost-effectiveness ratio (ICER) where a new intervention or treatment is compared with a current one [5]. The ICER provides a measure of average cost per additional life-year (LY) or Quality-adjusted life-year (QALY) gained. CEAs have

become a standard to determine whether new pharmaceutical treatments should be listed in public formularies in many jurisdictions with publicly funded healthcare systems such as the United Kingdom (UK) [6], Australia [7] and Canada [8]. The threshold, however used to determine willingness to pay (WTP) from the perspective of a publicly funded health care system, is not well defined. In Canada, the threshold for most health technologies is \$50,000.00 CAD per QALY. For cancer therapies however, a threshold of \$100,000.00 is commonly used. In the UK, NICE recommends a threshold of £20,000–£30,000 per QALY gained. The intention of setting a WTP threshold is to maximise health benefit within a fixed budget structure. This means that ultimately, the WTP threshold will depend on the overall budget, which is determined independently of economic evaluations, and is variable. In the United States of America (USA), funding bodies have been reluctant to accept constraints on spending on the basis of economic evaluations although there is increasing concern with surging costs of healthcare [9].

3. Assessing value to HER2-targeted therapies in breast cancer

3.1. Methods

We performed a systematic review of CEAs for targeted therapies currently available to treat HER2-positive breast cancer. The terms cost-effectiveness or cost-utility, breast cancer, epidermal growth factor-2 (HER2), and Trastuzumab, Pertuzumab, Lapatinib, or Trastuzumab Emtansine (T-DM1) were searched in MEDLINE and PubMed as well as in the official website of the National Institute for Health and Clinical Excellence (NICE) in UK, Pharmaceutical Benefits Scheme (PBS) in Australia and Common Drug Review

Table 1
Clinical benefit of adjuvant targeted therapies for early stage HER2+ breast cancer.

	Indication	Regimen	OS	DFS
NSABP-B31 and NCCTG N9831 [43]	Adjuvant	AC → T versus AC → TH	OS HR 0.63; 75.2% versus 84.0% at 8.4 years follow up	DFS HR 0.60 P < 0.001; 62.3% versus 73.7% at 8.4 years follow up
Ten year follow up BCIRG 006 [44]	Adjuvant	AC → T versus AC → TH versus TcH	OS HR 0.63 (AC-TH P < 0.0001; 85.9% versus 78.7%) OS HR 0.76 (TCH P = 0.0075; 83.8% versus 78.7%)	DFS HR 0.72 (AC-TH; P < 0.001; 74.6% versus 67.9%) HR 0.77 (TcH; P = 0.0011; 73.0% versus 67.9%)
Ten year follow up HERA	Adjuvant	Standard chemotherapy versus Standard chemotherapy + lyTrastuzumab	OS HR 0.74 P < 0.001 79.4% versus 72.9% at 10 years	DFS HR 0.75 (P < 0.001); 69.3% versus 62.5% at 10 years follow up
NeoSphere [41]	Neoadjuvant	H + T → surgery versus P + H + T → surgery	NA	3 year 79% versus 86%; HR 0.60 (95% CI 0.28–1.27)

T = taxane, H = Trastuzumab P = Pertuzumab, A = Doxorubicin, C = Cyclophosphamide, c = carboplatin, DFS = Disease-Free Survival, OS = Overall Survival.

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