Systematic review of the clinical effectiveness and cost-effectiveness of capecitabine (Xeloda) for locally advanced and/or metastatic breast cancer

Jones L, Hawkins N, Westwood M, Wright K, Richardson G, Riemsma R

CRD summary
This review concluded that capecitabine combination therapy for breast cancer was more effective (and likely to be cost-effective) than single-agent docetaxel, but was associated with higher incidences of adverse effects. More randomised controlled trials (RCTs) on capecitabine monotherapy were needed as no conclusions could be drawn on its therapeutic benefit from available evidence.

Objectives
To examine the clinical effectiveness and cost-effectiveness of oral capecitabine for locally advanced and/or metastatic breast cancer in relation to its licensed indications.

Review methods
Twenty-three databases (including MEDLINE, EMBASE and DARE), trials registers, ongoing research and Internet resources were searched. Bibliographies of retrieved articles and industry submissions were also examined.

Two reviewers independently screened and assessed all titles and/or abstracts including economic evaluations. Eligible for inclusion were randomised controlled trials (RCTs) and observational studies that investigated capecitabine monotherapy in patients pre-treated with an anthracycline-containing regimen or a taxane, or capecitabine in combination with docetaxel in patients pre-treated with an anthracycline-containing regimen.

The economic evaluation was based on data reported in the manufacturer’s submission.

Results of the review
Capecitabine monotherapy (12 low quality non-controlled observational studies): Capecitabine demonstrated anti-tumour activity, but was associated with a particular risk of hand-foot syndrome and diarrhoea. The economic evaluation was hampered by the poor quality of the published studies; compared indirectly with vinorelbine, capecitabine was associated with lower costs and improved patient outcomes.

Capecitabine in combination with docetaxel (one RCT): Combination therapy was superior to single-agent docetaxel for survival, time to disease progression and overall response. Adverse events occurred more frequently with combination therapy. The economic evaluation demonstrated an overall improved score in quality-adjusted life-years (QALYs) for combination therapy with a slight reduction in costs.

Conclusions
No conclusions could be drawn on the therapeutic benefit of capecitabine monotherapy; more RCTs were required. Capecitabine appeared cost-effective compared with vinorelbine, but serious doubts remained; the poor quality of the trials may invalidate this conclusion. Based on limited evidence, combination therapy was more effective than single-agent docetaxel and likely to be cost-effective, but was associated with higher incidences of hand-foot syndrome, nausea, diarrhoea and stomatitis.

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Record Status
This is a high quality systematic review involving CRD that meets the criteria for inclusion on DARE. As CRD reviews are of high quality this structured abstract presents a brief summary of the review methods, the results and conclusions.