Title **Clinical Effectiveness and Cost-effectiveness of Pioglitazone and Rosiglitazone in the Treatment of Type 2 Diabetes: A Systematic Review and Economic Evaluation**

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Aim

To evaluate the clinical and cost effectiveness of pioglitazone and rosiglitazone in treating type 2 diabetes.

Conclusions and results

Of the 1,272 studies identified, 9 met the inclusion criteria. Clinical evidence showed that glitazones reduce glycosylated hemoglobin by approximately 1% and are more effective at higher than at lower doses. Glitazone treatment is associated with weight gain, but data on long-term effects were not available. No prospective RCTs compared pioglitazone to rosiglitazone, but both treatments indicated similar effects. There are no published economic studies on pioglitazone or rosiglitazone. Manufacturers provided economic evaluations for both glitazones. Sensitivity analyses suggest that the cost per quality-adjusted life-year (QALY) of rosiglitazone is most sensitive to dose and treatment effect. In two scenarios comparing rosiglitazone to metformin and sulfonylurea combination therapy, the cost effectiveness of rosiglitazone switches from around £10,000 per QALY to being dominated by the comparator strategy. However, the baseline result should be interpreted with caution.

Recommendations

Clinical evidence showed that glitazones can reduce glycosylated hemoglobin; however, no peer-reviewed data were available on their long-term effects, nor did any prospective RCTs compare pioglitazone with rosiglitazone.

Methods

Electronic databases, reference lists of relevant articles, and 14 research-related resources were consulted via the Internet. A systematic review of the literature aimed at identifying all papers relating to the glitazones. The Jadad method was used to assess the methodological quality of randomized controlled trials (RCTs). A generic proforma for critical appraisal of modeling studies in health economics was used to systematically review the economic assessment studies. This was supplemented by a detailed review of the disease-specific factors within the studies. Where possible, key outcomes were compared. Readers should note that information from the sponsor's submission was submitted in confidence to the National Institute for Clinical Excellence (NICE). Such information was made available to the NICE Appraisals Committee, but has been removed from this version of the report.

Further research/reviews required

Research already undertaken in this area should be published, preferably in peer-reviewed journals. Direct head-to-head comparisons of the glitazones in combination with metformin or sulfonylurea would be helpful. The current license arrangements do not allow for routine use of the glitazones in triple oral combination therapy, or in combination with insulin. Evidence is emerging on use of the glitazones in such combinations; hence, prospective RCTs would be useful. These studies could examine short-term transition strategies and longer term management. The impact of the glitazones in delaying transfer to insulin and the impact on long-term outcomes should also be considered for investigation.

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