Patients and doctors are being misled by published data on medicines

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The drug reboxetine is, overall, an ineffective and potentially harmful antidepressant, according to a comprehensive study of the evidence published in the British Medical Journal today.

The study also shows that nearly three quarters of the data on patients who took part in trials of reboxetine were not published until now, and that the published data on the drug overestimate the benefits and underestimate the harms of treatment - all underlining the urgent need for mandatory publication of all clinical trial results.

Reboxetine has been approved for the treatment of major depressive disorder in many European countries since 1997, but doubts have been raised about its effectiveness on the basis of recent studies and rejection of the application for approval in the United States in 2001. Published trials, however, show a favourable risk-benefit profile for reboxetine.

So a team of researchers at The German Institute for Quality and Efficiency in Health Care (IQWiG) set out to assess the benefits and harms of reboxetine compared with placebo or other antidepressants, known as selective serotonin reuptake inhibitors (SSRIs), for treating adults with major depression.

They also measured the impact of potential publication bias in trials of reboxetine (where positive trial results are more likely to be published than unfavourable results).

They analysed the results of 13 trials, including eight previously unpublished trials from the manufacturer of reboxetine (Pfizer). The overall quality of the trials was good, but the researchers noted that data on 74% of patients were unpublished.

They show that reboxetine is, overall, an ineffective and potentially harmful antidepressant. They found no significant difference in benefit (remission and response rates) versus placebo and inferior benefit versus SSRIs, as well as a higher rate of patients affected by adverse events than with placebo and higher withdrawal rates owing to adverse events than with placebo and the SSRI fluoxetine.

A further comparison of published and unpublished trials shows that published data overestimated the benefit of reboxetine and underestimated harm.

This, say the authors, is a striking example of publication bias, resulting in a distorted public record of a treatment. Publication bias can affect health policy decisions and the content of clinical guidelines, they warn. "Our findings underline the urgent need for mandatory publication of trial data."

In an accompanying analysis, the same authors argue that current regulations on the publication of trial results are insufficient. They believe several measures are required in order to provide patients, clinicians, and health policy makers with unbiased and verified evidence on which to base decisions.

These include mandatory public disclosure of data for all drugs, even for those never approved, public access to trials of older drugs not covered by current law, greater data sharing between regulatory authorities, as well as re-evaluation of a drug if approval is declined elsewhere, and a legal obligation for manufacturers to provide all requested data to

official bodies without restrictions to publication.

In a second analysis, senior researchers Robert Steinbrook and Jerome Kassirer highlight several recent examples that illustrate the problems of trusting drug companies to provide the complete picture about the clinical trials they sponsor. They propose that journals should define full access to all the trial data and require that investigators and journal editors have full access. Editors should also take appropriate action if concerns about data arise after publication. "Trust in the medical literature, not just in industry sponsored trials, is at stake," they conclude.

In an accompanying editorial, BMJ Editors Dr Fiona Godlee and Dr Elizabeth Loder, argue that "the medical evidence base is distorted by missing clinical trial data" and that "urgent action is needed to restore trust in existing evidence."

They believe it is important to re-evaluate the integrity of the existing base of research evidence and, as such, the BMJ will devote a special theme issue to this topic in late 2011.

"Full information about previously conducted clinical trials involving drugs, devices and other treatments is vital to clinical decision-making," they say. "It is time to demonstrate a shared commitment to set the record straight."

Provided by British Medical Journal

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