Why is this important?

Obesity is an epidemic in the United States. There is widespread interest in drug therapy for obesity, but previous drugs have had limited effectiveness and significant harms.

Facts:

- Lorcaserin represents a new class of obesity drug, a selective serotonin 2C antagonist.
- The BLOOM trial was a placebo-controlled randomized trial of lorcaserin; all patients received monthly diet and exercise counseling.
- Patients were obese, predominantly white. Those with diabetes, BP>140/90, and depression were excluded.
- Patients receiving lorcaserin lost an average of 7.9 lbs more than those receiving placebo over 1 year.
- More people receiving lorcaserin reached the goal of losing 5% of body weight. 2 in 10 patients in the placebo group met this goal compared with 5 in 10 patients in the lorcaserin group.
- There was no increase in valvulopathy or other major harms in patients receiving lorcaserin over the 2-year study period.

Concerns:

- Patients who stopped the drug appeared to regain weight.
- The short duration of follow-up limits estimates of long-term safety.
- There was a high level of industry involvement in all aspects of study design and implementation.
- About half of patients in each group dropped out of the study.

**The Bottom Line**

In obese but relatively healthy patients, lorcaserin with diet and exercise leads to an additional 8 pounds of weight loss over one year but weight is regained when the drug is stopped. The clinical importance of this benefit and the harms of taking lorcaserin for greater than one year are uncertain.
Strength of Evidence

(Adapted from Guyatt G BMJ, 26 April 2008, Volume 336)
This refers to the degree to which the findings of this study are likely to be free of bias.

| ++ ++ ++ | High |
| ++ ++ ++ | Moderate |
| ++ ++ | Low |
| ++ | Very low |

Tips for Discussion of Results with Patients

- The magnitude of weight loss was moderate.
- Poor follow-up and patient selection likely led this study to overestimate the benefit.
- The lack of long-term experience limits safety estimate; rare but severe side effects may have been missed.
- The study suggests that to maintain weight loss patients need to continue the drug indefinitely.

References


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The Bottom Line summaries reflect the expertise and opinions of the SGIM EBM Task Force as of the date of release of this summary.