

## Saxagliptin efficacy

### *To the Editor:*

Jadzinsky et al. [1] recently reported their experience on the therapy of treatment naïve patients with diabetes mellitus type 2 with saxagliptin and metformin. Patients were randomly assigned to therapy with saxagliptin 5 mg + metformin (S5M), saxagliptin 10 mg + metformin (S10M), saxagliptin 10 mg only (S10) or metformin only (M). Patients were apparently evaluated weekly from entry into the study until week 6, and then at weeks 8, 12, 16, 20 and 24.

The results published in the report are those obtained at week 24. Unfortunately, the authors did not use an 'intention to treat' analysis. The study design allowed for 'rescue therapy' based on glycemic control criteria. When patients became eligible for 'rescue therapy', they were excluded for the data set: 'Only data collected prior to rescue were used for safety and efficacy analyses'. Many more patients were excluded from analysis in the saxagliptin only group (S10: 19.10%) than in the three other groups (S5M: 6.25%, S10M: 5.88% and M: 9.15%).

The authors note in the discussion that the withdrawal of patient for rescue therapy may lead to an overestimate of the incidence of adverse events. However, they fail to point out that this withdrawal also leads to an overestimation

of the efficacy of the medication regimens, because the data from the rescued patients were essentially erased. This overestimate is particularly important for the saxagliptin only group (S10) because of the particularly high number of patients rescued from that group. It would have been preferable to present an analysis of the efficacy data at the point of withdrawal and to clearly indicate when the withdrawal occurred.

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### References

1. Jadzinsky M, Pflutzner A, Paz-Pacheco E. Saxagliptin given in combination with metformin as initial therapy improves glycaemic control in patients with type 2 diabetes compared with either monotherapy: a randomized controlled trial. *Diabetes Obes Metab* 2009; **11**: 611–22.