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## Diclofenac sodium intramuscularly, or paracetamol intravenously? Question not answered

Sir,

Öncül et al.<sup>1</sup> referred to Precious et al.<sup>2</sup> as stating that a 30% difference in visual analogue scores (VAS) “would be considered as clinically important”, and continues with “so 15 (patients) in each group were needed to ensure a type 1 error of 0.05 and type 2 error of 0.20”. Precious et al.<sup>2</sup> presented no data that allowed a specific sample size of 15 to be inferred when comparing 2 active analgesic drugs. They categorised mean pain scores (on a 10 cm VAS) of <3 cm as comfort days and  $\geq 3$  cm as discomfort days.

“Clinical importance” is based on either observed changes in a population sample or on an external (often subjective) criterion. A 30% reduction in pain has been proposed to indicate clinically important improvement, while  $\geq 70\%$  reduction indicates “much improvement”, and less than 30% reduction is “minimal”. Öncül et al.<sup>1</sup> present no data regarding calculation of a sample size to clarify the power of the trial.

Trials must show that the drug treatment actually reduces pain and is not a consequence of the natural transitory nature of acute postoperative pain. It implies that there is a reduction in pain after treatment compared with before, and that this effect is different from a placebo effect. To estimate the sample size necessary to identify an effect between 2 active analgesics you need to have a valid estimate or population sample of the actual degrees of pain recorded before and after treatment with an active control drug and preferably a placebo control group as well, in addition to the factors that define the term “clinically important”. In the paper by Öncül et al. the test drugs were given during general anaesthesia, which did not allow any comparison between degrees of pain before and after treatment.

Diclofenac sodium given intramuscularly, a comparator drug, was used as the rescue drug on demand after a single dose of the test drug had been given. A survival plot showing the actual times that the rescue medication was given over the whole observation period would add relevant information.

Postoperative facial oedema is one of the longer-lasting postoperative inflammatory symptoms in a large number of

patients. The choice of method used to assess oedema may cause bias. An assessment by an observer is neither accurate nor reliable. Conversely, self-assessment by the patient is a sensitive method that can be correlated with objective extraoral measurement.<sup>3</sup>

Clinicians too often jump to conclusions about the efficacy of drugs based on underpowered trials. Trials must be optimally designed to provide robust data that are useful in making clinical decisions.

## References

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