Authors' response

Sir,

We thank the authors for their comments on our article on effect of clobazam (CLB) in epilepsy patients[1]. The present study was an observational study in which patients were recruited from a consecutive sample of consenting PWE attending the epilepsy clinic in the outpatient department (OPD) of Neurology, All India Institute of Medical Sciences (AIIMS), New Delhi, India. This aim was to study the effect of clobazam as add-on antiepileptic drug in patients with epilepsy during routine practice in an outpatient epilepsy clinic.

The primary objectives of the study were to determine the pattern of CLB prescription, retention rate, proportion of seizure free patients on different doses and reasons for CLB discontinuation in PWE. The secondary objectives were to determine *(i)* median percentage reduction in the number of seizures after CLB treatment and division into four categories: seizure free with no seizure in the last 12 months; ≥50 per cent reduction; <50 per cent reduction and no change in seizure frequency; *(ii)* proportion of patients on different doses of CLB in various seizure outcome groups; *(iii)* most frequently used combination of antiepileptic drugs (AEDs) resulting in seizure freedom; and *(iv)* tolerability of treatment, *i.e.* the frequency and severity of treatment-related adverse effects.

We agree that an observational study with a nested case-control group is appropriate to evaluate the efficacy of drugs. However, our aim was to understand the effect of clobazam as add-on antiepileptic drug in patients with epilepsy and not to compare the effect of clobazam with other antiepileptic drugs. Moreover, this was not a trial which in current clinical trial scenario has several implications with logistics in carrying out a trial. Therefore, this study was solely focused to one group of the patients for whom CLB was the last antiepileptic drug added to the exsisting regimen and we did not consider the control group. Though we agree that the efficacy and safety of a drug are established through rigorous randomized controlled trials, but audits in clinical practice compliment the information derived from these trials[2]. In our study, clobazam being used as an add-on antiepileptic drug was audited for its efficacy and tolerability in different treatment regimens in an Indian tertiary care centre. Various audit studies have been done to evaluate usage pattern, clinical usefulness and side effects of antiepileptic drugs[3,4]. The latter suggestion is appreciated to be taken for further studies on clobazam done as clinical trials; ours was not a clinical trial.

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