use as an off-label drug [3] may pose an ethical dilemma.

4) Neonates have lower plasma clearance and higher volume of distribution; hence, longer half-life of levetiracetam as compared to adults [4]. Most studies in small population groups, have been insufficient to understand the pharmacokinetics and advocate routine use in neonates.This confusion is amplified by various studies where doses as low as 10 mg/kg/day and as high as 80 mg/kg/day have been used. Appropriate neonatal dose needs to be established through phase II trials.

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AUTHOR'S REPLY

We thank the readers for critically evaluating our research study [1]. The queries raised are addressed below:

1. The sample size required was calculated based on difference in proportion of outcomes between the two groups as 31% (levetiracetam 77% and phenobarbitone 36%), and this data was taken from a systematic review on the efficacy of levetiracetam in neonatal seizures [2]. The sample size was calculated based on efficacy and not based on adverse events/safety as efficacy was our primary outcome. We agree that electrographic seizure resolution was not documented and the sample size was inadequate for the outcomes related to various adverse effects; this has already been mentioned as a limitation of the study [1].
2. Hypoxic ischemic encephalopathy (HIE) staging was done and no statistical difference in outcome was noted between HIE stage II *vs*. HIE stage III (11 HIE stage II *vs*. 9 HIE stage III in levetiracetam group and 13 HIE stage II *vs*. 11 HIE stage III in phenobarbitone group).
3. In 2012, FDA approved levetiracetam for use as adjunctive therapy for partial onset seizures in infants and children one month of age and older [3]. In 2013, levetiracetam gained monotherapy indications with new level I, II, and III evidence for use in adult partial onset seizures, adult tonic-clonic seizures and children with benign childhood epilepsy with Centro temporal spikes [4]. Despite lack of studies supporting its use at that time, a 2007 survey demonstrated 47% of pediatric neurologists recommend levetiracetam, off-label for the treatment of neonatal seizures [5].
4. We acknowledge that dose of levetiracetam is not established and we have chosen based on evidence available from off-label use and our experience. In our study, no adverse events were noted with 20 mg/kg. We agree that trials comparing different dose regimens have to be conducted in future.

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