HYOSCINE-B BUTYL BROMIDE IN LABOR: A RANDOMIZED CONTROLLED TRIAL

Sir,

I read with interest the article titled “Role of hyoscine N butyl bromide as labor analgesic” by Aggarwal *et al.* published in the May issue.[1]

I would like to comment on the methodology of the study.

Firstly, it mentions that informed consent was obtained from all the patients before they were recruited. Was it explained to them that this was a research study and not related to their clinical management and they were free to refuse to enter the study and be assured that their clinical care would not be compromised if they refused participation? This is an important issue which needs to be explained to all trial participants before consent is obtained; it makes the consent more valid. There is

no mention of the number of women who refused to give consent to enter the trial, and it therefore can be assumed that all the women were included in the study.

Secondly, although randomization is mentioned, it does not mention by whom and where the randomization was carried out. Successful randomization depends on 2 factors, adequate generation of an unpredictable allocation sequence and concealment of that sequence until assignment.[2] A key issue is whether the schedule is known to, or predictable by, the people involved in allocating the participants to the comparison groups. The treatment allocation should be set up so that the person enrolling the patients into the study does not know in advance which treatment the next person will get, a process called allocation concealment. In this study, allocation concealment did not happen as the principal investigator was assumed to have randomized the patients and knew the sequence and the contents of the syringes, which therefore amounts to compromising the validity of the trial. The study also does not mention who the raters were; therefore, blinding can be questioned. The principal investigator knew the randomization procedure; therefore, it is important to know who the raters were.

According to CONSORT[3] guidelines, there should be a flow chart demonstrating the flow of patients through the trial, which shows the number of people assessed for eligibility, number of people who did not meet inclusion criteria, the number of people who refused to participate, as well as flow of patients after randomization. There was no flow chart in this study. It would also be useful to know whether this trial was prospectively registered before commencement of the trial.

The study could have been improved if these standard recommendations in the conduct of randomization of controlled trials were followed, which could also have improved the internal validity of the trial.

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DOI: 10.4103/0019-5359.55890