Editorial
Ethics in clinical studies, with special reference to obstetric practice

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In the present issue of the Acta Anaesthesiologica Belgica, and following approval from two referees (the Editor’s vote only interferes when there is a controversial advice), the Editorial board has accepted a randomized trial of DOUROUDIAN et al. In this study, the authors evaluated the usefulness of dexamethasone to prevent postdural puncture headache (PDPH). When carefully reading this paper, one will notice that the authors still used the rather outdated 22G Quincke design needles for spinal anesthesia in an orthopedic population. Their study group consisted of 178 orthopedic patients, of which 34 developed PDPH and were divided in two treatment groups. Despite the high incidence of PDPH, not even a surprise in the view of the needle size and design, the study remains underpowered.

It is possible that colleagues in Iran do not have the availability of smaller pencil-point needles. As a consequence, their report may be interesting only for those other countries in the same situation. I can imagine that western anesthesiologists will call into question whether this particular manuscript was worth being accepted. But, even if the incidence of PDPH in our current practice may be far below the incidence reported by DOUROUDIAN et al., the use of a corticosteroid may be considered, merely because epidural blood patches (EBP), probably offered too fast, are not deprived of complications.

It may be hoped that the authors did not select the large Quincke needle on purpose to obtain a sufficient amount of study patients suffering from PDPH. Although they have stated that informed consent and institutional approval was obtained, it is questionable whether patients and ethical board members were really informed about the expected 20% incidence of PDPH. Many other studies may raise similar questions. Some previously published studies have reported a large sample size of patients suffering from PDPH after an accidental tap. These patients received regional anesthesia and were allocated to several treatment options, aiming at avoiding the occurrence of headache (1, 2). To collect 45 or even over 100 accidentally tapped patients, there are several possibilities: the general sample size such as the number of deliveries on a yearly basis was extremely high, the study period covered several years, patients were preferably managed by less experienced residents, or, finally, inappropriate equipment was used.

In addition, obtaining a truly informed consent in such a situation may be difficult. It is ethically questionable to wait for an adverse event such as a dural tap before informing the patient about the problem and asking him or her for an informed consent to participate in a particular study. The value of such an informed consent in a laboring parturient with painful contractions is debatable. Another option is to ask all parturients to sign it before entering in labor and receiving epidural analgesia, in the event of an accidental tap. With an incidence of accidental taps lower than 1% in most centers, this would mean that such consent needs to be obtained in a tremendously high amount of patients.

A few years ago, it was suggested to perform a prospective randomized nationwide study in Belgium in obstetric patients receiving epidural analgesia or anesthesia, aiming at discovering the best strategy for the management of accidental taps. Performing such a multicenter study might allow collecting a larger than ever reported number of patients, hoping to finally clarify the question whether or not, for example, continuous spinal anesthesia (CSA) reduces the occurrence of PDPH, or reduces the need for EBP. With approximately 125000 deliveries per year, a 60% epidural rate for vaginal deliveries (cesarean sections mostly receive a spinal technique), and a 0.6% incidence of accidental taps, it means that almost all patients during one full year should give their consent to end up with three experimental independent groups of at least 150 subjects each. This would lead to a power of 95% at detecting a 50% reduction in the incidence of PDPH in one of those three groups, at an alpha threshold of 0.05. The study has never been done because of the ethical issues raised above.
or the unacceptable amount of energy needed to obtain an informed consent from 75000 patients immediately before receiving their epidural analgesia.

In so far as women in labor were found to remain capable of absorbing information, reasoning, discussing and finally taking an appropriate decision, several authors have claimed that women in labor can give their full informed consent. This remains true, provided they did not receive sedative or analgesic drugs. However, patients in pain may feel forced to give their consent, merely to save time before being relieved. Do patients really understand the principle of up and down sequential allocation studies to determine efficient doses or concentrations? Parpaglioni and colleagues performed such a study in cesarean section patients, during which a visual analogue score (VAS, ranging between 0 to 10) above 3 (!) at incision, delivery or closure was considered to be a failure (3). In addition, do they understand the meaning of a sham or dummy spinal puncture without injecting any drug intrathecally as done in some combined spinal-epidural (CSE) studies (4, 5)?

In conclusion, patients, and particularly parturients, remain highly vulnerable, and the dura mater even more. Correct and timely information is an absolute prerequisite when intending to perform studies. How interesting a study protocol may look like, adequate care of patients should always prevail. The care given to them should be in accordance with up to date standards.

References