Carpenter first described continuous spinal labor analgesia in 1951 after administering an intrathecal infusion of procaine. The resulting analgesia was quite satisfactory but the technique was limited by the inevitable headache associated with the large gauge needle and catheter. In the late 1980s, the development of 28 gauge, or smaller, catheters that can pass through a 22 gauge needle produced a resurgence of interest in continuous spinal analgesia for labor. In 1991, however, four cases of cauda equina syndrome (CES) associated with continuous spinal anesthesia in non-obstetric patients were reported to the Food and Drug Administration (FDA) in the United States [1]. Three of the four cases involved a 28-gauge catheter. After receiving reports of eleven cases, the U.S. FDA required the manufacturers of continuous spinal catheters, 28 gauge or smaller, to withdraw their products from the market [2]. This prompted investigators to try to determine if CES related to the use of a spinal catheter or the drug(s) injected through it. The drug in all eleven reported cases of CES with a 28-gauge catheter was hyperbaric lidocaine 5% in excess of 100 mg. (one other case involved a 20-gauge catheter and hyperbaric tetracaine). Subsequent laboratory animal studies have demonstrated that nerves exposed to hyperbaric lidocaine 5% are permanently damaged [3-6]. It is likely that the small flow rate through the 28 gauge catheter contributed to the pooling of hyperbaric, high concentration drug in the sacral area, resulting in neural injury. Eleven cases of CES have been reported out of an estimated 250,000 procedures, a rate of 0.4/10,000. (Note: actual usage must be estimated as several catheter manufacturers’ products were on the market.) No cases of CES have been associated with the use of intrathecal opioids or with bupivacaine.

As the relationship became clear between hyperbaric, high concentration lidocaine given through a small gauge catheter and CES, investigators concluded that the catheters themselves were not inherently dangerous. The FDA granted approval in 1996 for a multi-center study of the safety and efficacy of continuous spinal analgesia in obstetric patients using a 28-gauge catheter through which only sufentanil and/or bupivacaine was administered.

The study enrolled 425 patients in 6 institutions in the United States. A total of 300 (+25 pilot patients) received spinal catheter drug delivery (CSA), and 100 patients received epidural drug delivery (CEA). The method of drug delivery was predetermined by a computer-generated random list.

The sample size was determined by the following: a review of 32,718 epidural anesthetics (non-obstetrics patients) found a 0.1% incidence of transient neurological deficits and a 0.02% incidence of permanent lesions [7]. As discussed above, eleven cases of cauda equina syndrome in an estimated 250,000 spinal anesthesia procedures gives an estimated incidence of 0.004%. Since for both procedures development of permanent neurological lesions is rare, the number of patients with the event follows a Poisson distribution. The upper limits of the 95% confidence interval are thus 3/N [8]. Therefore, if there are no permanent neurologic sequelae in the 300 patients in the CSA group, then the likelihood of a problem is rare, <1% from the Poisson rule, and post-marketing surveillance will be needed to obtain an estimate of the true incidence.

An epidural group of 100 patients is used to make comparisons of efficacy measures, particularly of equivalence with respect to rate of failed or inadequate blocks and to degree of maternal satisfaction. Epidural blocks fail completely in approximately 4-5% of cases and are patchy or unilateral in approximately 12-15% of cases [7, 9, 10]. In a study of elderly patients undergoing lower extremity surgery, the failure rate of CSA was 1.7% as compared to 9% in the CEA group [11]. We chose to accept differences of 10% in the failure and inadequate block rates for the two techniques to be considered equivalent. With the sample sizes as given and α set at 0.05 for a 2-tailed test, we have 85% or greater power to detect lack of equivalence for both complete failure and unilateral/patchy block.

The drugs for this trial are sufentanil and 0.5% (or a lower concentration) bupivacaine. Although not part of the study, patients who undergo cesarean delivery may receive a single intrathecal injection of preservative free morphine 0.1-0.25 mg through the catheter for postoperative analgesia. This dose range of intrathecal morphine is used routinely to provide postoperative analgesia after cesarean delivery.
Sufentanil has been used successfully for the last 12 years to provide analgesia in obstetrics via both epidural and intrathecal routes. Additionally, an investigation of the potential neurotoxicity of intrathecal sufentanil in a dog model found no morphologic or histologic effects following doses up to 50 µg [12].

Bupivacaine has a long history of safe use in obstetrics. A recent comprehensive review has compared the neurotoxicity of lidocaine with other commonly used local anesthetics [13]. In desheathed amphibian nerves, lidocaine 5% and tetracaine 0.5% produced irreversible conduction block contrasted with bupivacaine 0.75% (without dextrose) which caused 25-50% residual block [3]. 5% lidocaine appears to be as neurotoxic in mammalian A- and C- fibers as in amphibian A-fibers [6]. In 9 dogs exposed to bupivacaine 2% without dextrose there were no histopathological signs of damage, one dog showed meningeal hemorrhage thought to be secondary to the dural puncture [14]. In rats with chronically implanted sacral intrathecal catheters, exposure to lidocaine 5% with dextrose resulted in prolonged tail-flick latency, which persisted throughout the study. Exposure to bupivacaine 0.75% with dextrose, tetracaine 0.5% with dextrose and saline did not result in any permanent change in the tail-flick latency [4].

In the labor analgesia study, the 425 parturients were demographically similar [15]. Patients in the CSA group reported significantly lower pain scores for the first 120 minutes. Not surprisingly, they also reported significantly higher pruritus scores. The initial drug bolus was more likely to provide adequate analgesia in the CSA group. Patients in the CSA group had significantly higher satisfaction scores on the first postpartum day. There were no reported incidences of cauda equina syndrome. There were no permanent neurologic deficits reported either possibly or probably related to either the study catheters or study drugs. There was no difference in the incidence of transient neurologic events between groups. The incidence of postural headache was 8.9% in the spinal group versus 4% in the epidural group (p=0.108). Therapeutic epidural blood patch was administered to 5.2% and 2% of the CSA and the CEA parturients, respectively (p=0.172). There were no differences between the two groups in obstetric or neonatal outcome.

A continuous spinal technique overcomes many of the limitations of a continuous epidural technique. Catheter placement is aided by the reliable endpoint of the appearance of cerebrospinal fluid (CSF), the drug dose requirement is minimal and analgesia or anesthesia can be provided very rapidly. The ability to quickly convert from labor analgesia to anesthesia for cesarean delivery may be highly advantageous for a parturient with a known difficult airway, twin gestation or prior uterine surgery. Data continues to accumulate supporting the safety of the continuous spinal technique for surgery in non-obstetric patients [16]. Development of catheter design is on going and will require additional assessment to understand the advantages and disadvantages of each type of catheter [17].

Future work will focus on the true incidence of complications and their prevention. Surprisingly to this author, a recent retrospective review of serious neurologic complications following spinal (1,260,000 total blocks including single injection and continuous) and epidural (450,000 blocks) anesthesia complications to be more frequent patients who received epidural anesthesia [18]. The incidence of post dural puncture headache in parturients requires further elucidation. Recent data suggests that keeping the intrathecal catheter in place for more than 24 hours may decrease the incidence of post dural puncture headache in obstetric patients [19, 20].

In summary, continuous spinal analgesia and anesthesia can be performed safely and with great efficacy in labor patients. Data suggest that this technique has much to offer both the obstetric and non-obstetric patient populations. Future work will focus on collecting the evidence on which to develop a best practice approach to this technique.
REFERENCES