STYDY PROTOCOL

Title: Study of the use of the ultrasound scan for performing lumbar regional anesthesia.

Date: 10/09/2015

NCT02553746

Principal investigator: Georgios Kotsovolis, Department of Anesthesia, 424 Army General Hospital, Thessaloniki, gskotsos@gmail.com

OBJECTIVE

The main objective of the study is to evaluate if the ultrasound scan of the lumbar spine can facilitate the performance of spinal, epidural or combined spinal-epidural anesthesia, increase the success rate of these techniques and decrease the complication rate.

MATERIAL AND METHODS

Participants

Number: 80

The patients will be allocated to 2 groups. According to data from other similar studies, 40 patients in each group are required to reach statistically significant results with p=0,05 and power 80%.

Origin:

The patients scheduled for surgery under spinal, epidural or combined spinal-epidural anesthesia will participate in the study. Enrollment will begin at 10th September 2015 and will finish when the number of 80 participants is reached.

Inclusion criteria:

- Written consent to participate in the study signed by the patient.
- Surgery under spinal, epidural or combined spinal-epidural anesthesia.
- ASA 1-3.
- Age 18-80 years.

Exclusion criteria:

- Contraindication for regional anesthesia.
- History of lumbar spine surgery.

Materials

- 27G pencil-point spinal needles atraumatic (Pencil Point).
- 18G Tuohy needles and epidural catheters.
- Combined spinal-epidural sets.
- Ultrasound scanner Sonoscape S6.

METHOD

Type of study

Prospective, randomized controlled trial.

Procedure

The 80 patients will be allocated to two groups (40 patients in each group). In the first group (Group U), the needle entry point for the regional anesthesia will be determined by ultrasound scan of the lumbar spine. In the other group (Group L), the traditional landmarks technique will be applied. The two groups will be compared to examine if there is difference in success rate, first-try success rate, number of punctures and time required to compete the technique and complication rate.

Randomization

The randomization will be done by software (www.randomizer.org).

Anesthesia – Perioperative management

500ml Ringer's Lactate will be given intravenously to all patients before the performance of the regional technique and all the usual monitoring devices will be applied. The regional anesthesia will be done with the patients placed in the sitting position via the medial approach. After locating the needle entry point, the skin will be

infiltrated with 3ml of lidocaine. The loss of resistance technique with a saline-filled 18G Tuohy needle will be used for identifying the epidural space.

Interventions

In Group L patients, the traditional landmarks techniques will be applied to determine the puncture point. At the level of the Toiffier line, the spinous process of the L3 or the L4 vertebrae will be identified by palpation. In Group U patients, the needle entry point will be located after ultrasound scan of the lumbar spine according to the technique described by Arzola et all. The ultrasound probe will be placed perpendicular to the vertebral column and will be moved cranially and caudally until the acoustic shadow of the spinous process disappears and the intervertebral space is revealed. Pen marks will be drawn in the middle of the upper and lateral side of the probe and the crossing of the two marks will be the entry point. Before the enrollment of patients in the study, the ultrasound technique will be tested on 20 patients. All the regional anesthetics will be performed by the same anesthesiologist.

Outcomes

The primary outcomes are:

1) Success of the technique (yes/no).
2) First try success (yes/no).
3) Number of punctures required.
4) Frequency of modifications of the trajectory of the needle.
5) Change of puncture level (yes/no).
6) Time required to complete the technique.

Secondary outcomes:

1) Lumbar spine pain (yes/no).
2) Lumbar spine pain score (VAS 0-10).
3) Patient satisfaction.
4) Complications.

In cases of spinal anesthesia, the technique will be considered successful if the patient has any degree of sensory block. In cases of epidural or combined spinal-epidural

anesthesia, the technique will be considered successful if the epidural catheter is confirmed to be in the epidural space. The puncture level will be changed after 4 unsuccessful attempts. The time required to complete the technique will be recorded by the time the patients takes the sitting position until the end of the injection of the local anesthetic (spinal anesthesia) or the confirmation of the placement of the epidural catheter. Lumbar spine pain will be evaluated 12 και 24 hours after the end of the regional anesthetic with 11-degree Numerical Rating Scale (NRS 0-10). Satisfaction from the anesthetic technique will be evaluated by the patient (Yes/Not completely/NO) and he will be asked if he would choose the same anesthetic technique again in the future (YES/NO).

Data recording

Data will be recorded according to the attached case form. Apart from the main parameters, the age, weight and height of each patient and the type of surgery will be recorded.

Statistics

For the comparison of the groups the chi square statistical test will be applied for the following variables:

1) Success of the technique (Yes/No).
2) Success on first attempt (Yes/No).
3) Change of puncture level (Yes/No).
4) Back pain (Yes/No).

For the rest of the variables (attempts required to complete the technique, number of changes of the trajectory of the needle, time required to complete the technique, back pain score, patient satisfaction), the normality of distribution will be tested with the Kolmogorov-Smirnov test. If the data have normal distribution, the student's t-test will be used and if not, the Wilcoxon signed rank test. The SPSS 15.0 software will be used.

Intermediate assessment

6 months after the beginning of the study an intermediate assessment will be performed and the study will be terminated if any serious complications are documented.

Ethics

The study protocol will be eavaluated by the ethics committee of 424 Army General Hospital of Thessaloniki.

Financial issues

No additional financial support is required for the completion of the study.

Benefits

With this study we will investigate if the use of the ultrasound, a device with very low cost of use and no complications, can facilitate the performance of lumbar regional anesthesia.

Timetable

Months / Tasks	09/15	10/15	11/15	12/15	01/16	02/16	03/16	04/16	05/16	06/16	07/16	08/16	09/16	10/16
Study Data collection	→	→	→	→	→	→	→	→	→	→	→	→		
Data summary													→	
Statistics													→	
Results presentation														→