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Spinal versus general anesthesia for transabdominal preperitoneal (TAPP) repair of inguinal hernia: Interim analysis of a controlled randomized trial

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ABSTRACT

Background: General anesthesia has been used as standard for laparoscopic hernia repair by the transabdominal preperitoneal (TAPP) approach. Regional anesthesia has been occasionally applied in high risk patients where general anesthesia is contraindicated. This randomized clinical trial compares spinal anesthesia with general anesthesia for TAPP inguinal hernia repair in non-high risk patients.
Methods: Seventy adult American Society of Anesthesiologists I, II and III patients undergoing elective TAPP inguinal hernia repair were randomized to either general or spinal anesthesia.
Results: Postoperative morphine consumption was significantly less immediately postoperatively ($p < 0.001$) in the spinal anesthesia group. Postoperative pain was also significantly decreased within the first 8 h postoperatively ($p < 0.05$) in the spinal anesthesia group.
Conclusions: Spinal anesthesia offers some advantages in patient analgesia during the early postoperative period after TAPP inguinal hernia repair and can be proposed as an effective alternative method of anesthesia for TAPP repair.

1. Introduction

The advantages of laparoscopic inguinal hernia repair over the traditional open technique, regarding the quality of recovery (less post-operative pain, faster return to work and daily activities and, consequently, a faster recovery of physical activity) have been shown by several studies.[1–5] Traditionally, general anesthesia is routinely used for laparoscopic surgery while regional anesthetic techniques have been occasionally applied in high risk patients, mainly those with cardio-pulmonary comorbidities, where general anesthesia is contraindicated. This is mainly attributed to the fear of possible adverse effects of the CO2 pneumoperitoneum on the awake patient. However, several studies during the last decade have shown the feasibility and safety of performing laparoscopic procedures under spinal anesthesia.[6–10]

Laparoscopic inguinal hernia repair includes two different techniques: the *Trans*-Abdominal Pre-Peritoneal (TAPP) repair and the Total Extra-Peritoneal repair (TEP). The TAPP approach represents a classic laparoscopic procedure where standard CO2 pneumoperitoneum is being used, and as such, the above mentioned skepticism regarding anesthesia is applied to this technique, as well. In contrast, the idea of TEP repair is to avoid pneumoperitoneum, as the area where CO2 is insufflated is the extraperitoneal space. This difference has led several authors to attempt TEP repair under regional anesthesia and report on the feasibility and safety of that option.[11–16] On the other hand, there is a paucity of data regarding the use of regional anesthesia for TAPP inguinal hernia repair; in fact, there is only one pilot study which was carried out by our team. This study demonstrated the feasibility to perform successfully and safely TAPP inguinal hernia repair with low pressure CO2 pneumoperitoneum under spinal anesthesia.[14] Taking into consideration this pilot study and based on our previous experience in regional anesthesia for several laparoscopic procedures,[8,9,14,17] we designed a controlled randomized trial in

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order to compare spinal anesthesia with the gold standard general anesthesia for TAPP inguinal hernia repair in the non-high risk patients. We hypothesized that spinal anesthesia may offer some advantage over general anesthesia in postoperative pain management after TAPP inguinal hernia repair.

2. Methods

The study was approved by the Institution Ethics Committee (UTH5535/12/11) and all participants gave written informed consent. The trial has also been registered in ClinicalTrials.gov (ID: NCT01520857).

Inclusion criteria for the study were: primary, unilateral inguinal hernia, age $\geq$18, American Society Anesthesiologists (ASA) physical status I-III, BMI $\leq$ 35, and normal coagulation profile. Exclusion criteria were: non-reducible/obstructed hernias, bilateral hernias, big scrotal hernias, psychiatric disorders, history of chronic pain or daily intake of analgesics, inability of patients to use PCA pump, previous open surgery in the lower abdomen, contraindication for pneumoperitoneum and contraindication for spinal or general anesthesia.

Patients were randomized to undergo TAPP repair of their inguinal hernia under spinal (SA group) or general anesthesia (GA group). Randomization was done with a computer generated table of random numbers. Identical, opaque, sealed envelopes numbered for each subject with the unique randomization number were used and opened after the arrival of patient to the operating room so both involved teams and patient were unaware of the randomization arm before the operation.

The primary endpoint of the trial was to detect a difference in postoperative opioid consumption administered by PCA pump between the two groups. A sample size of 63 patients per randomization arm was calculated on an expected 25% difference with a power of 80% at detecting this difference at the 5% level. An interim analysis was planned after completion of the first half of patients and the results are presented and discussed herein. Secondary endpoints were defined any differences in postoperative pain, morbidity, patient satisfaction and hospital stay.

During the pre-anesthetic evaluation patients were instructed to use the PCA device. The use of the numeric rate scale for pain at rest (NRS), and at stress (NRS stress) (0 = no pain, 10 = worst imaginable pain) was explained clearly and simply to them. Also, the patients were routinely asked to void just prior to surgery and checked they did so. On patient's arrival in the operating room non-invasive monitoring was established (ECG, SPO_2, NIBP). Patients were monitored continuously during the procedure and monitoring was recorded at 5-min intervals. An intravenous access was established and 500 ml of Ringer solution was given. Before induction of anesthesia oxygen at 5 L/min was given via a face mask. All patients were given 1gr midazolam, 40 mg ondansetron and 50 mg ranitidine hydrochloride intravenously. Anesthetic and surgery technique were always performed by the same teams.

Spinal anesthesia group patients were placed at sitting position and a 25 G pencil point spinal needle was inserted into the subarachnoid space at the L2-L3 intervertebral space under aseptic conditions. Once free flow of cerebrospinal fluid (CSF) was obtained, a total amount of 13–15 mg heavy bupivacaine 0.5% and 20 μg fentanyl was administered itrathecally. Subsequently, patients were placed in a 10^0 Trendeleburg position for 3 min. The accepted sensory level to perform the procedure was T4 dermatome level which was tested using temperature sensation. If the mean blood pressure decreased by more of 20% below the pre-anesthetic level was managed in a standard way (intermittent i.v. infusion of phenylephrine 0,004% solution was started and titrated to effect).

Induction of anesthesia in GA group was performed using propofol at a dose of 2 mg/kg and fentanyl at 2 μg/kg. The total dose of fentanyl which has been administered intraoperatively was 5 μg/kg. *Cis*-atracurium 0.15 mg/kg was administered to facilitate tracheal intubation. Anesthesia was maintained with sevoflurane 2% in a mixture of O2/air. Minute ventilation was individualized for each patient in order to maintain normocapnia. The residual neuromuscular blockade was reversed with neostigmine 0.02 mg/kg and atropine 0.01 mg/kg at the end of the surgery. Intraoperative administration of Paracetamol 1 gr was given intravenously to all patients in both groups at the onset of procedure. Extubation was performed when the patients were able to open their eyes and obey on simple commands. It is worthwhile mentioning that the induction of spinal and general anesthesia didn't took more than 5 min while the reversal of neuromuscular blockade in the case of general anesthesia took 8–10 min.

Laparoscopic TAPP inguinal hernia repair was performed by applying identical technique for both groups. Pneumoperitoneum was established by using the Hasson technique with CO_2 at a maximum intra-abdominal pressure of 10 mmHg and 3 trocars were used in standard positions with no use of local anesthetic at their sites: one 10 mm was inserted at the umbilicus and two 5 mm trocars were placed lateral to the edge of the rectus muscle at the level the umbilicus bilaterally. After pneumoperitoneum was established, the patient was placed in 15^0 Trendeleburg position and turned at an angle of about 15^0 towards the opposite site of hernia. The peritoneum above the hernia defect was incised, reduced and dissected off the spermatic cord structures and the inguinal/femoral space was prepared to accommodate a 10 $\times$ 15 cm titanium-coated polypropylene mesh which was used to cover the hernia defect. The mesh was fixed with 3 tacks (Protack) – one at Cooper's ligament and one at either side of epigastric vessels on the upper part of the prepared space. The peritoneum was closed with another 2–3 tacks as well. No specific effort other than opening the port cannulas was applied at the end of the procedure to evacuate the pneumoperitoneum. The median operative duration from skin incision to the application of the last stitch was 49,53 min for general anesthesia group and 50,62 min for spinal anesthesia group.

After the procedure was completed, patients were transferred to the post-anesthesia care unit (PACU) and they stayed there until they achieved an Aldrete score $\geq$9, (an average of 20 min) and Bromage score I-II for patients receiving spinal anesthesia (an average of 30 min). In the PACU, patients had access to a PCA pump with morphine. Activated dose was 1 mg, with a lockout interval of 10 min and the maximum allowable dose of morphine in 4 h was 20 mg. The PCA pump was used for 24 h. Postoperative management was also standardized for all patients. They were given 1 L of Ringers solution, paracetamol 1gr every 8 h, thromboprophylaxis (low molecular weight heparin) was also administered subcutaneously and omeprazole intravenously for gastric protection. Three to 4 h after the end of surgery patients were allowed to mobilize in bed and to sit out of bed on a chair, and, if they were happy with that, they were allowed gradually to get fully mobilized. This initial period of bed resting was kept in both groups for methodology reasons, as in patients with spinal anesthesia the motor block had to be resolved prior to mobilization, thus avoiding accidents secondary to postural hypotension. They could drink freely and had a light meal, provided there were not nauseated. Patients were discharge 24 h after the procedure, which is the common practice in our hospital, unless any complications had occurred.

Assessment of postoperative pain was done on patients' arrival