

Postoperative Quality of Recovery after General Anesthesia with Local Infiltration or Spinal Anesthesia for Inguinal Hernia Repair: A Prospective, Randomized Clinical Trial

Eduardo T Moro¹, Miller F Lambert^{1*}, Felipe Augusto Horácio Ribeiro¹, Murilo Sunica Targueta¹, Helena Torricelli Pancevski¹, Thiago Patrício de Lima¹ and Joshua Bloomstone²

¹Department of Surgery, School of Medical and Health Sciences, Pontifical Catholic University of São Paulo, PUC-SP, São Paulo, Brazil

²Department of Surgery, University of Arizona College of Medicine-Phoenix, Division of Surgery and Interventional Sciences University College London, London, England

*Corresponding author: Dr Miller Fazoli Lambert, Department of Surgery, School of Medical and Health Sciences, Pontifical Catholic University of São Paulo, PUC-SP, São Paulo, Brazil, Tel: 55-15-996968401; Fax: 55-15-32129900; E-mail: miller_lambert@msn.com

Received date: May 20, 2019; Accepted date: June 06, 2019; Published date: June 13, 2019

Copyright: © 2019 Moro ET, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Abstract

Background: Inguinal hernia repair can be performed using different anesthetic techniques. Although local anesthesia seems to be more cost-effective, spinal and general anesthesia remains very popular as alternatives or even as first-choice techniques. This randomized clinical trial evaluated the quality of recovery among patients submitted to hernioplasty under one of two techniques: general anesthesia using a laryngeal mask and a field block (GA) or spinal anesthesia (SA).

Methods: Seventy patients were randomized to one of two groups: GA or SA. The quality of recovery was assessed using a 40-item scoring system (Quality of Recovery Questionnaire-QoR-40). Early clinical recovery variables, such as the time from the end of surgery to exiting the operating room (OR), the time to fulfillment of the post-anesthesia care unit (PACU) discharge criteria, the occurrence of nausea, vomiting, urinary retention, postoperative pain, and the length of the PACU stay, were also assessed.

Results: No significant differences were observed between groups when comparing the total or individual dimension scores of the QoR-40 questionnaire. The mean time from the end of surgery to exiting the OR was longer in the GA group than in the SA group ($P < 0.01$). The patients in the SA group required a longer time to meet the PACU discharge criteria ($P < 0.01$). The occurrence rates of nausea, vomiting, urinary retention and pain did not differ among the groups.

Conclusions: Quality of Recovery did not differ between patients who underwent inguinal hernia repair under GA or SA as assessed by the QoR-40 questionnaire.

Keywords: Quality of recovery; Questionnaire; Inguinal hernia repair; Postoperative pain; Spinal anesthesia; General anesthesia; Local infiltration; Anesthesia recovery period; Quality indicators

Introduction

Inguinal hernia is one of the most prevalent conditions worldwide. Surgery is the recommended treatment and important advances have been made in the last two decades. Different anesthetic techniques have been proposed for inguinal hernia repair procedures, including local, regional and general anesthesia [1]. Due to its safety considerations, better postoperative pain control, rapid recovery of walking ability and low-cost profile [2], local infiltration has gained increasing acceptance among many surgeons as the first choice of anesthesia for inguinal hernia repair [3]. A recent systematic review including 79 studies evaluated the occurrence of postoperative pain in patients submitted to inguinal hernioplasty using different anesthetic techniques. According to the authors, local anesthesia, with or without general anesthesia, is more effective than spinal anesthesia [4]. Interestingly, according to data from large epidemiological studies on surgeries performed in general hospitals, 60 to 70% of inguinal

hernioplasties are performed under general anesthesia, 10 to 20% are performed under spinal anesthesia and only 5 to 15% are performed under local anesthesia [1]. A possible explanation for the decreased use of local anesthesia may be a lack of knowledge or skills to perform the technique, which would make the use of spinal or general anesthesia more convenient. In addition, the choice may be influenced by other factors such as the surgeon, the patient's opinion or the anesthesiologist's preference [5]. Each technique has advantages and disadvantages. Spinal anesthesia is the first choice in many centers but may be associated with undesirable effects such as urinary retention, lower limb motor blockade and postdural puncture headache [6-9]. In the meantime, general anesthesia is associated with a lower incidence of urinary retention, although the postoperative pain control provided by this technique when applied alone seems to be less effective. In addition, should be considered the possible complications associated with tracheal intubation and the use of neuromuscular blockade [10]. The introduction of the laryngeal mask airway (LMA) associated with propofol based anesthesia has considerably improved the practice of outpatient procedures due to the rapid recovery provided by this technique, whereas muscle paralysis is not required. Seen this, a rational anesthetic approach would be general anesthesia using an

LMA and a field block (including ilioinguinal, iliohypogastric and genitofemoral nerve blocks) to control postoperative pain. Traditionally, studies evaluating perioperative care have focused on outcomes such as the occurrence of nausea, vomiting, pain, or other adverse events. Recently, the quality of recovery from the perspective of the patient has been considered as an alternative outcome in clinical studies to compare the effect of different drugs or anesthetic techniques on patient recovery and satisfaction [11-13]. We hypothesized that general anesthesia using a laryngeal mask and a field block would positively affect the quality of recovery of patients submitted to inguinal hernia repair compared with that of patients who had spinal anesthesia. The primary endpoint was assessed using the 40-item Quality of Recovery Questionnaire (QoR-40) [12,13].

Methods

Study population

This randomized trial was approved by the Research Ethics Committee of the School of Medical and Health Sciences, Pontifical Catholic University of São Paulo (Pontifícia Universidade Católica de São Paulo, PUC-SP), CAAE 45087615.0.0000.5373 (Chairperson Prof. J.A. Costa). The study was registered at ClinicalTrials.gov (NCT02696122) and adhere to CONSORT guidelines. A written consent form was obtained from all participants. Seventy patients aged 18 to 65 years, American Society of Anesthesiologists (ASA) physical status I or II, who were scheduled to undergo local infiltration under general anesthesia *via* LMA or spinal anesthesia for unilateral inguinal hernia repair from August 2016 to November 2017 at Santa Lucinda Hospital were enrolled in this prospective, randomized clinical trial. Patients who (i) refused to participate in the study; (ii) were not able to communicate due to alterations in the level of consciousness or because of neurologic or psychiatric disease; (iii) presented with contraindications to any of the drugs used in the present study; (iv) had history of alcohol or drug dependence; (v) were highly obese as defined by a body mass index (BMI) ≥ 40 ; or (vi) underwent the operation due to recurrent, strangulated, incarcerated or bilateral hernia were excluded from the study.

Study sequence

No premedication was administered. The patients' preoperative data including age, gender, physical status and hernia type according to the Nyhus classification were collected [14]. Thirty-one participants were required for each group considering 90% power to detect a 10-point difference on the QoR-40. This difference represents a 15% improvement on quality of recovery reported in previous studies [12,15]. Taking possible participant losses into consideration, the final sample included one block of 70 subjects who were allocated to two groups according to a random number sequence produced by a web-based generator. Due to the significant differences between the anesthetic techniques, the patients and investigators were not blinded to the group allocation. The anesthetic technique to be used for each individual participant was kept in a consecutively numbered sealed, opaque envelope that was opened at the time of surgery.

Anesthetic and surgical management

Following arrival into the operating room (OR), standard ASA monitoring was conducted. Intravenous (i.v.) midazolam (0.06 to 0.08

mg.kg⁻¹) and 1% lidocaine (30 mg) were administered. Anesthesia was performed according to the following sequences:

GA group: General anesthesia was induced with propofol (2 mg.kg⁻¹) and alfentanil (30 mcg.kg⁻¹). Once an appropriate depth of anesthesia was achieved, the LMA was placed. Anesthesia was maintained by propofol (4 to 5 mg.kg⁻¹.h⁻¹). Ventilation was controlled by adjusting the flow volume and respiratory rate to maintain the end-tidal CO₂ level (PETCO₂) between 30 and 40 mmHg. For local anesthesia, approximately 50 mL of 0.5% ropivacaine was infiltrated along the line of the incision in the subcutaneous plane, followed by a blind peripheral nerve block (e.g. ilioinguinal, iliohypogastric and genitofemoral nerve blocks) and local wound infiltration at the fascia level. Failure of local anesthesia was defined as the presence of movements, sweating, tachycardia or a blood pressure increase >10% of the pre-induction value with the initiation of the surgery. In these cases, further infiltration with an additional 10 mL of 0.5% ropivacaine was provided. At the end of surgery, propofol was discontinued, and the LMA was removed once the patient resumed adequate spontaneous breathing.

SA group: Spinal puncture was performed with the patient in the sitting position using a 26G Quincke needle (B. Braun Melsungen AG) and 15 mg of 0.5% hyperbaric bupivacaine was injected. In cases of complete failure, another puncture was performed, and the same dose of the anesthetic drug was injected. In cases of partial failure, the anesthesia was converted to general anesthesia, and the patient was excluded from the study. All patients were sedated with propofol by continuous infusion at an initial dose of 0.5 mg.kg⁻¹ followed by 2 to 5 mg.kg⁻¹.h⁻¹ as necessary to reach level 5 on the Ramsay Sedation Scale. The Lichtenstein tension-free method was applied in both groups, and all procedures were performed by the same surgical team. Patients who exhibited reductions in systolic arterial pressure (SAP) greater than 30% were given ephedrine (10 mg). Fluid replacement therapy was based on Lactated Ringer's solution infusion at a rate of approximately 500 mL during the first 30 minutes, and then the rate was adjusted to 2 mL.kg⁻¹.h⁻¹. All participants were given i.v. ketoprofen (100 mg) before the end of the procedure. The time to OR discharge was recorded.

Postoperative monitoring

When stable vital signs and respiration were found to be stable, patients were transferred to the PACU. Data related to the occurrence of pain, nausea, vomiting, shivering, and urinary retention and the length of stay were recorded. An 11-point numeric rating scale (NRS), in which zero indicated no pain and 10 indicated the worst pain imaginable, was used to assess postoperative pain every 15 minutes. Morphine was administered at 15-min intervals to maintain the pain score below 4 (1 mg for pain <7 and 2 mg for pain ≥ 7). During the ward stay, all patients received i.v. ketoprofen (100 mg) every 12 hours and dipyrene (30 mg.kg⁻¹, maximum 1 g) every six hours. I.V. tramadol (100 mg) was administered at eight-hour minimum intervals whenever the patients judged their analgesia to be insufficient. Postoperative nausea and vomiting (PONV) was treated with i.v. dimenhydrinate (30 mg). Pain scores, the use of analgesics, and the occurrence of nausea, vomiting, and other complications during the hospital ward stay were recorded.

Questionnaire

Following written informed consent, the QoR-40 questionnaire was completed by patients in the preoperative holding area. Twenty-four

hours after surgery, a blinded investigator then gave each study participant the QoR-40 questionnaire to complete a second time. The QoR-40 assesses five dimensions of postoperative functional recovery: physical comfort, emotional status, physical independence, physiological support, and pain. The total score on the QoR-40 ranges from 40 (very poor quality of recovery) to 200 (excellent quality of recovery) [16,17]. The details of the QoR-40 questionnaire are depicted in the Appendix.

Statistical analysis

Categorical variables are presented as counts (percentages) and were evaluated using Fisher's exact test or the Chi square test. The Shapiro-Wilk test was used to test the hypothesis of a normal distribution. Normally distributed continuous data are presented as the mean ± SD. These data were compared using Student's t test for independent samples. Ordinal data and continuous data that were not normally distributed are presented as medians and ranges and were compared between groups using the Mann-Whitney U test. Statistical significance (P-value) was assessed by a two-tailed test in all instances, and values below 0.05 were considered statistically significant. The statistical analysis was performed using Minitab® version 17.1.

Results

A total of 84 patients were initially assessed for eligibility in this study, but 14 were excluded because they refused to participate or met any of the exclusion criteria. Therefore, 70 participants were randomly allocated to the study groups. Later, one participant in the GA group and 2 in the SA group were excluded due to protocol deviations or changes in the surgical approach. Therefore, the preoperative characteristics, intraoperative parameters, and recovery variables during hospitalization were collected from 34 patients in the GA group and 33 patients in the SA group (Figure 1).

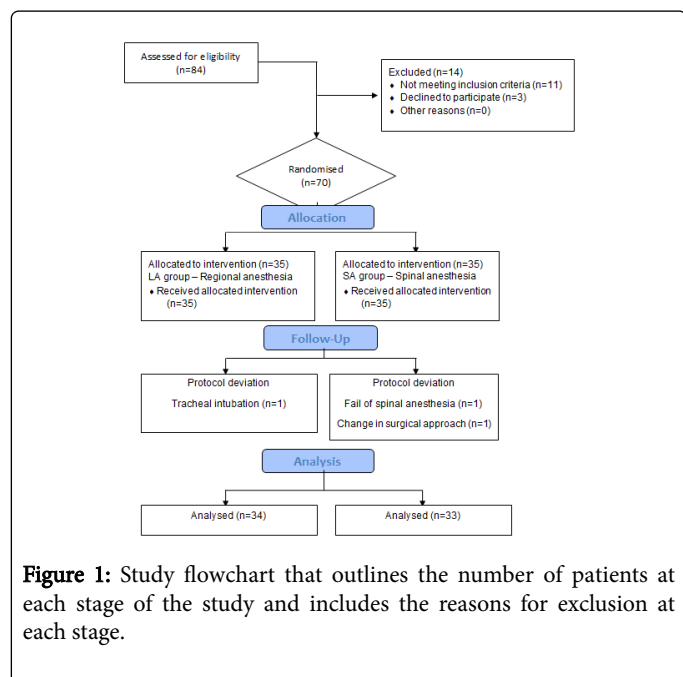


Figure 1: Study flowchart that outlines the number of patients at each stage of the study and includes the reasons for exclusion at each stage.

The studied groups were comparable with respect to age, gender, physical status, surgical duration and hernia classification. The mean time from the end of surgery to exiting the OR was longer in the GA

group than in the SA group. The characteristics of the patients who were included in the study are presented in (Table 1).

	Group LA (n=34)	Group SA (n=33)	p-value
Age (years)	50.0 (40-59)	48 (38-58)	0.85
ASA	-	-	0.54
I	19 (55.9)	16 (48.5)	-
II	15 (44.1)	17 (51.5)	-
Gender			0.61
Female	3 (8.8)	1 (3.0)	-
Male	31 (91.2)	32 (97.0)	-
Nyhus	-	-	0.11
1	4 (11.8)	7 (21.2)	-
2	21 (61.8)	11 (33.3)	-
3A	6 (17.6)	8 (24.2)	-
3B	3 (8.8)	7 (21.1)	-
Surgical duration (min)	76.6 ± 7.9	65.2 ± 6.5	0.03
Time from the end of surgery to OR exit (min)	14.0 ± 1.6	10.5 ± 1.7	<0.01

Data presented as mean ± SD; median (interquartile range) or n (%)

Table 1: Patients' characteristics and operative data.

Primary outcome

All participants completed the questionnaire without difficulties. The preoperative and postoperative QoR-40 scores are presented in Table 2. No differences were observed between groups when comparing the total or individual dimension scores of the QoR-40 questionnaire.

	Group LA (n=34)	Group SA (n=33)	p-value
Preoperative			
Emotional status	44 (42-45)	44 (43-45)	0.59
Physical comfort	59 (58-60)	59 (59-60)	0.42
Psychological support	40 (40-40)	40 (40-40)	0.99
Physical independence	20 (20-20)	20 (20-20)	0.77
Pain	34 (32-34)	34 (33-36)	0.27
Total QoR-40	195 (192-198)	196 (194-198)	0.48
POD1			
Emotional status	44 (41-45)	44 (42-45)	0.97
Physical comfort	59 (56-60)	58 (57-60)	0.89
Psychological support	40 (40-40)	40 (40-40)	0.29
Physical independence	18 (16-20)	18 (16-20)	0.7

Pain	34 (32-35)	34 (33-34)	0.81
Total QoR-40	194 (188-197)	194 (191-197)	0.64
Data are presented as median (interquartile range)			

Table 2: Dimensions of the quality of recovery 40 (QoR – 40) questionnaire by study groups preoperatively and at 24 hours after surgery (POD1).

Secondary outcomes

Recovery characteristics in the PACU are presented in Table 3. No patients presented with PONV or urinary retention during the PACU stay. Patient pain scores in the PACU were assessed by an NRS and were low and similar between the groups. Morphine rescue was not requested by any patient. The time from the end of surgery to exiting the OR was longer for patients in the GA group than for those in the SA group. The patients in the SA group required more time to meet the PACU discharge criteria than the patients in the GA group (Table 3).

	Group LA (n=34)	Group SA (n=33)	p-value
Pain higher score (NRS)	0.5 ± 0.5	0.9 ± 0.8	0.34
Morphine consumption (mg)	0 (0-0)	0 (0-0)	0.4
Urinary retention (%)	0	0	0.99
PONV (%)	0	0	0.99
Urinary retention (%)	5.9	3	0.99
Time required to meet and achieve PACU discharge criteria (min)	30 (24-60)	60 (48-90)	<0.01
Data are presented as No. (%); mean ± SD or median (interquartile range)			

Table 3: Post anesthesia care unit parameters.

During the ward stay, the frequency of nausea or vomiting was similar between the groups. The highest pain score during the ward stay (P=0.67) and tramadol consumption (P=0.26) were comparable between the groups (Table 4). No patients disclosed the routine use of any opioids before the surgery. The previous use of other analgesics was not evaluated (Table 4).

	Group LA (n=34)	Group SA (n=33)	p-value
Pain higher score (NRS)	3.1 ± 0.9	3.4 ± 0.7	0.67
Tramadol consumption (%)	6.1	17.7	0.26
PONV (%)	14.7	9.1	0.71
Urinary retention (%)	5.9	3	0.99
Data presented as mean (± SD) or n (%)			

Table 4: Ward parameters.

Discussion

In this randomized clinical trial, 67 patients were submitted to general anesthesia *via* LMA and a field block or spinal anesthesia. The primary outcome was the quality of recovery at 24 hours after surgery. A patient-centered, simple, easy-to-apply and validated scoring system, the QoR-40 questionnaire, was used to assess pain and other aspects of recovery following anesthesia, including emotional state and physical independence. It is considered the best instrument for the evaluation of the complex and multidimensional process of postoperative recovery in the general surgical population. Many potential advantages are apparent with the use of local anesthesia for inguinal hernia repair compared to general or spinal anesthesia [1]. However, outside of hernia-specialized hospitals, it is far from the most popular technique. Many factors can influence the choice of technique, including the clinical and anatomical aspects of the patients, the surgeon’s skills or cases in which adequate relaxation is required. When local anesthesia is not the first choice, an alternative that provides high-quality anesthesia and a fast recovery must be considered.

To the best of our knowledge, no study has evaluated the quality of recovery in patients undergoing hernia repair using these two approaches (spinal anesthesia versus general anesthesia *via* LMA and a field block) using a validated tool. Currently, the QoR-40 questionnaire is considered the best instrument to evaluate the quality of recovery, as determined by two qualitative reviews and one quantitative systematic review [16,17]. Our results demonstrate no significant difference in the quality of recovery after hernia repair using these two techniques.

A recent review [4] evaluated four studies that compared postoperative pain control in patients submitted to spinal or general anesthesia for hernia repair. Three showed lower pain scores after spinal anesthesia, but this benefit was observed only during the first hours after surgery [18-20]. One study observed no difference between the two techniques in a comparison of the occurrence of a score of 4 or more (based on a 10-point scale) at the time of discharge [21]. In a multicenter randomized controlled trial, the Euro QoL questionnaire was used to evaluate patient satisfaction after hernia repair under local, general or spinal anesthesia. Despite decreased demand for rescue analgesics, pain scores and occurrence of PONV in patients under local anesthesia, the level of patient satisfaction was considered high in all groups [5]. In the present study, the time between the end of surgery and exiting the OR was 4 minutes longer in the GA group. It is not of sufficient magnitude to influence clinical decision-making regarding anesthetic preference. Conversely, during the PACU stay, the time to discharge was 30 minutes longer in the SA group than in the GA group.

Our study has clear limitations. First, the efficiency of ilioinguinal, iliohypogastric and genitofemoral nerve blocks depends on the experience and skills of the person who performs the procedure. Accordingly, the postoperative benefits will be observed only when the correct technique is applied. Second, due to the significant differences between the anesthetic techniques, the anesthesia provider could not be blinded to group identity. However, both the patient and the investigators who distributed the questionnaire the next day were blinded to the group allocation. Third, it would be important to evaluate whether the benefits provided by the anesthesia technique persisted beyond the first postoperative day. The use of analgesics for the first week after inguinal hernia repair was reduced in patients submitted to an ultrasound-guided inguinal field block compared with that of those who received spinal anesthesia [22]. Fourth, although this study was adequately powered to detect differences in the primary

outcome, it may not have had sufficient power to detect differences in the secondary outcomes. Finally, we did not address any aspect of costs. In a similar study, patients submitted to inguinal hernioplasty under spinal or general anesthesia *via* LMA were evaluated, and no difference in cost was observed between the groups [21].

Conclusion

In conclusion, this study evaluated two alternative techniques to local anesthesia for inguinal hernia repair: spinal anesthesia and a field block under general anesthesia with an LMA. We found no differences between the qualities of recovery as assessed by the QoR-40 questionnaire.

Acknowledgements

Graduate medical students were funded by National Counsel of Technological and Scientific Development.

References

1. Kehlet H, White PF (2001) Optimizing anesthesia for inguinal herniorrhaphy: general, regional, or local anesthesia? *Anesth Analg* 93: 1367-1369.
2. Nordin P, Zetterström H, Gunnarsson U, Nilsson E (2003) Local, regional, or general anaesthesia in groin hernia repair: multicentre randomised trial. *Lancet* 362: 853-858.
3. Callesen T, Bech K, Kehlet H (2001) One thousand consecutive inguinal hernia repairs under unmonitored local anesthesia. *Anesth Analg* 93: 1373-1376.
4. Joshi GP, Rawal N, Kehlet H; PROSPECT collaboration, Bonnet F, et al. (2012) Evidence-based management of postoperative pain in adults undergoing open inguinal hernia surgery. *Br J Surg* 99: 168-185.
5. Nordin P, Hernell H, Unosson M, Gunnarsson U, Nilsson E (2004) Type of anaesthesia and patient acceptance in groin hernia repair: a multicentre randomised trial. *Hernia* 8: 220-225.
6. Nordin P, Zetterström H, Carlsson P, Nilsson E (2007) Cost-effectiveness analysis of local, regional, and general anaesthesia for inguinal hernia repair using data from a randomized clinical trial. *Br J Surg* 94: 500-555.
7. Veen RN, Mahabier C, Dawson I, Hop WC, Kok NE, et al. (2008) Spinal or local anesthesia in Lichtenstein hernia repair: a randomized controlled trial. *Ann Surg* 247: 428-433.
8. Bay-Nielsen M, Kehlet H (2008) Anaesthesia and postoperative morbidity after elective groin hernia repair: a nation-wide study. *Acta Anaesthesiol Scand* 52: 169-174.
9. Darrah DM, Griebing TL, Siverstein JH (2009) Postoperative urinary retention. *Anesthesiol Clin* 27: 465-484.
10. Bakota B, Kopljar M, Baranovic S, Miletic M, Marinovic M, et al. (2015) Should we abandon regional anesthesia in open inguinal hernia repair in adults? *Eur J Med Res* 20:76.
11. Hofer CK, Zollinger A, Büchi S, Klaghofer R, Serafino D, et al. (2003) Patient well-being after general anaesthesia: a prospective, randomized, controlled multicentre trial comparing intravenous and inhalation anaesthesia. *Br J Anaesth* 91:631-637.
12. Myles PS, Weitkamp B, Jones K, Melick J, Hensen S (2000) Validity and reliability of a postoperative quality of recovery score: the QoR-40. *Br J Anaesth* 84: 11-15.
13. Gornall BF, Myles PS, Smith CL, Burke JA, Leslie K, et al. (2013) Measurement of quality of recovery using the QoR-40: a quantitative systematic review. *Br J Anaesth* : 2-9.
14. Nyhus LM (1993) Individualization of hernia repair: a new era. *Surgery* 114: 1-2.
15. Castro-Alves LJS, de Azevedo VFL, Braga TFF, Gonçalves AC, de Oliveira GS (2011) The effect of neuroaxial versus general anesthesia techniques on postoperative quality and analgesia after abdominal hysterectomy: a prospective, randomized, controlled trial. *Anesth Analg* 113:1480-1486.
16. Herrera FJ, Wong J, Chung F (2007) A systematic review of postoperative recovery outcomes measurements after ambulatory surgery. *Anesth Analg* 10:63-69.
17. Kluijvers KB, Riphagen I, Vierhout ME, Brölmann HAM, De Vet HCW (2008) Systematic review on recovery specific quality-of-life instruments. *Surgery* 143: 206-215.
18. Tverskoy M, Cozacov C, Ayache M, Bradley EL Jr, Kissin I (1990) Postoperative pain after inguinal herniorrhaphy with different types of anesthesia. *Anesth Analg* 70: 29-35.
19. Özgün H, Kurt MN, Kurt I, Cevikel MH (2002) Comparison of local, spinal, and general anaesthesia for inguinal herniorrhaphy. *Eur J Surg* 168: 455-459.
20. Toivonen J, Permi J, Rosenberg PH (2004) Analgesia and discharge following preincisional ilioinguinal and iliohypogastric nerve block combined with general or spinal anaesthesia for inguinal herniorrhaphy. *Acta Anaesthesiol Scand* 48: 480-485.
21. Burney RE, Prabhu MA, Greenfield ML, Shanks A, O'Reilly M (2004) Comparison of spinal vs. general anesthesia *via* laryngeal mask airway in inguinal hernia repair. *Arch Surg* 139: 183-187.
22. Mokini Z, Vitale G, Aletti G, Sacchi V, Mauri T, et al. (2015) Pain control with ultrasound-guided inguinal field block compared with spinal anesthesia after hernia surgery: a randomized trial. *Surgery* 157: 304-311.