SCIENTIFIC ARTICLE

Iliohypogastric/ilioinguinal nerve block in inguinal hernia repair for postoperative pain management: comparison of the anatomical landmark and ultrasound guided techniques

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Abstract

Objectives: The purpose of this study is to compare the efficacy of iliohypogastric/ilioinguinal nerve blocks performed with the ultrasound guided and the anatomical landmark techniques for postoperative pain management in cases of adult inguinal herniorrhaphy.

Methods: 40 patients, ASA I–II status were randomized into two groups equally: in Group AN (anatomical landmark technique) and in Group ultrasound (ultrasound guided technique), iliohypogastric/ilioinguinal nerve block was performed with 20 ml of 0.5% levobupivacaine prior to surgery with the specified techniques. Pain score in postoperative assessment, first mobilization time, duration of hospital stay, score of postoperative analgesia satisfaction, opioid induced side effects and complications related to block were assessed for 24 h postoperatively.

Results: VAS scores at rest in the recovery room and all the clinical follow-up points were found significantly less in Group ultrasound (p < 0.01 or p < 0.001). VAS scores at movement in the recovery room and all the clinical follow-up points were found significantly less in Group ultrasound (p < 0.001 in all time points). While duration of hospital stay and the first mobilization time were being found significantly shorter, analgesia satisfaction scores were found significantly higher in ultrasound Group (p < 0.05, p < 0.001, p < 0.001 respectively).

Conclusion: According to our study, US guided iliohypogastric/ilioinguinal nerve block in adult inguinal herniorrhaphies provides a more effective analgesia and higher satisfaction of analgesia than iliohypogastric/ilioinguinal nerve block with the anatomical landmark technique. Moreover, it may be suggested that the observation of anatomical structures with the US may increase the success of the block, and minimize the block-related complications.

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Bloqueio dos nervos ílio-hipogástrico/ilioinguinal em correção de hérnia inguinal para tratamento da dor no pós-operatório: comparação entre a técnica de marcos anatômicos e a guiada por ultrassom

Resumo

Objetivo: Comparar a eficácia de bloqueios dos nervos ílio-hipogástrico/ilioinguinal feitos com a técnica guiada por ultrassom e a de marcos anatômicos para o manejo da dor no pós-operatório em casos de herniorrafias inguinais em adultos.

Métodos: Foram randomicamente divididos 40 pacientes, estado físico ASA I-II, em dois grupos iguais: nos grupos AN (técnica de marcos anatômicos) e US (técnica guiada por ultrassom), o bloqueio dos nervos ílio-hipogástrico/ilioinguinal foi feito com 20 mL de levobupivacaina a 0,5% antes da cirurgia com as técnicas especificadas. Escore de dor no avalição pós-operatória, tempo de primeira mobilização, tempo de internação hospitalar, escore de satisfação com a analgesia no pós-operatório, efeitos colaterais induzidos por opiáceos e complicações relacionadas ao bloqueio foram avaliados durante 24 horas de pós-operatório.

Resultados: Escores EVA em repouso na sala de recuperação e todos os valores clínicos durante o acompanhamento foram significativamente menores no grupo ultrassom (p < 0,01 ou p < 0,001). Escores EVA em movimento na sala de recuperação e todos os valores clínicos durante o acompanhamento foram significativamente menores no grupo ultrassom (p < 0,001 em todos os tempos avaliados). Enquanto os tempos de internação e da primeira mobilização foram significativamente maiores no grupo ultrassom (p < 0,05, p < 0,001, p < 0,001, respectivamente).

Conclusão: De acordo com o nosso estudo, o bloqueio dos nervos ílio-hipogástrico/ilioinguinal guiado por US em herniorrafias inguinais em adultos proporciona uma analgesia mais eficaz e maior satisfação com a analgesia do que com a técnica de marcos anatômicos. Além disso, pode-se sugerir que a observação das estruturas anatômicas com a US pode aumentar o sucesso do bloqueio e minimizar as complicações relacionadas ao bloqueio.

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Introduction

Inguinal hernia repair is a common surgical procedure. The incidence is reported as 11/10,000 in persons between 16 and 24 years of age, 200/10,000 in persons more than 75 years of age. Chronic pain occurs in 5–10% after the inguinal hernia repair that creates an important problem. A significant part of pain after hernia surgery is caused by the abdominal wall incision. Postoperative pain management in cases that undergo abdominal surgery is complicated. Despite the effective pain management methods, the frequency of moderate or severe pain is found to be 30–75%.

Various methods and medications are used in postoperative pain management. Peripheral nerve blocks with local anesthetics are a method that may be used in inguinal hernia surgeries for surgery and pain management. Iliohypogastric (IH) and ilioinguinal (II) nerve blocks are used for this purpose.

IH/II nerve block may be performed with the anatomical landmark (conventional, blind technique) or with ultrasound guided techniques. There are studies where the needle entry point is defined in the medial spina iliaca anterior superior in the anatomical landmark technique. However, there are also studies pointing out that lumbar nerve origins and the progresses of IH/II nerves in the anterior abdominal wall may vary. In recent years, the peripheral regional blocks with the ultrasound guided have been found out to be with greater success.

The purpose of this study is to compare the efficacy of IH/II nerve blocks performed with the ultrasound guided and the anatomical landmark techniques for postoperative pain management in cases of adult inguinal herniorrhaphy.

Materials and methods

After approval Medical Researches Ethics Committee 40 cases between 18 and 80 years of ages, ASA (American Society of Anesthesiologist) I–II class, admitted to the General Surgery Clinic for inguinal hernia repair was included into this prospective, randomized and single-blinded study in Uludag University Medical Faculty, Health Practice and Research Center. Ethical approval for this study (Ethical Committee No B.30.2.ULU.0.20.00.02.020/8189) was provided by the Ethical Committee of Uludag University Hospitals, Bursa, Turkey (Chairperson Prof S. Kilitçürgay) on 23 June 2009.

All cases were informed verbally about the purpose and the content of the study before the surgery and signed written informed consent forms were taken from the ones who agreed to participate to the study. Patients with ASA III–IV class, allergy to local anesthetics, hemorrhagic diathesis and clotting disorder and who refused the surgery were excluded from the study.

Patients were randomized by sealed envelope technique into two groups:
- Group AN (n = 20): 20 ml of 0.5% levobupivacaine for the IH/II nerve block with the anatomical landmark technique
- Group US (n = 20): 20 ml of 0.5% levobupivacaine for the IH/II nerve block with the US guided technique.

Cases that were randomly selected for the IH/II nerve block with the anatomical landmark technique were monitored (ECG, pulse oximetry, noninvasive arterial blood pressure) in the procedure room. Patients were sedated with 0.05 mg/kg intravenous midasolam. Entry point was determined in 2 cm medial and 2 cm superior to the spina iliaca anterior superior and skin was disinfect and covered. Following the local anesthesia (LA) infiltration, 22 G 8 cm needle was advanced through the cephhalolateral and inserted to touch the inner surface of the ileum. 10 ml of 0.5% levobupivacaine was administered into the layers of the abdominal wall while the needle was withdrawn. Then, while the needle was advanced with a right angle, loss of resistance was felt during the passage through the external oblique, internal oblique and transversus abdomen muscles respectively and 10 ml of 0.5% levobupivacaine was administered into the muscles while the needle was withdrawn.

Cases that were randomly selected for the IH/II nerve block with the US guided were monitored (ECG, pulse oximetry, noninvasive arterial blood pressure) in the procedure room. Patients were sedated with 0.05 mg/kg intravenous midasolam. The lateral abdominal wall was covered with a sterile sanitary napkin following the skin disinfection and 8–12 MHz linear US probe was placed in the midaxillary line between the iliac wing and the costal margin in the transverse plane. The external oblique, internal oblique and transversus abdomen muscles were monitored with the II and IH nerves. Following LA infiltration, a 80 mm 22 G stimulation needle (Stimuplex® Ultra, Braun, Germany) was advanced around the nerves with US guidance. While 20 ml of 0.5% levobupivacaine was administered at divided doses, LA dispersion around both of the nerves was simultaneously observed.

The sensory block level was assessed in the related nerve innervation area with the “pinprick test” (analgesia test with needle) following the II and IH nerve block with the anatomical landmarks and US guided techniques.

Following the IH/II blocks in the procedure room patients were taken into the operating room and monitored with the ECG, noninvasive arterial blood pressure and pulse oximetry. 0.9% NaCl intravenous infusion was started to administer. After general anesthesia was induced with 3 mg/kg propofol IV, 2 mcg/kg fentanyl IV, laryngeal mask airway was placed to the patients. Anesthesia was maintained with sevoflurane and 40/60% mixture of oxygen/N₂O with additional dose of fentanyl.

At the end of the surgery patients were awakened and taken to the postoperative recovery room. Postoperative pain intensity was assessed by a blind clinician with visual analog scale (VAS, 0: no pain, 10: most severe pain to be estimated), at rest (VAS-R) and at movement (VAS-M), in postoperative at the beginning and 30th minutes in the recovery room; at 2nd, 4th, 8th, 12th, 18th and 24th hours in the surgical clinic and recorded. Dexketoprofen 50 mg IV was administered as a rescue analgesic when VAS-M ≥ 4 was recorded. Meperidin 1 mg/kg IM was planned and administered when VAS-M ≥ 4 was continued to be recorded after the first dose of dexketoprofen. In addition, the first mobilization time, duration of hospital stay and the postoperative analgesia satisfaction score (0: poor, 1: moderate, 2: good, 3: very good, 4: excellent) were evaluated and recorded. Common side effects due to opioids in the postoperative period such as sedation, nausea-vomiting, constipation, allergic reactions; side effects due to the block in the operation area such as infection, bowel perforation, pelvic hematoma, femoral nerve paralysis, and intraperitoneal injection of local anesthetic were evaluated and recorded. Patients were questioned over the phone 1 week after discharge about pain, satisfaction of analgesia and block complications (Infection, hematoma, nerve paralysis, etc.).

Data were statistically analyzed with the SPSS 13.0 analysis software in the application laboratories of the UUFL Department of Biostatistics. In this study, continuous and discrete variates are expressed in median (minimum–maximum) values, and categorical variables are expressed in frequency and percentage values. Mann Whitney U and chi-square test were used for intergroup comparisons. Percentage changes, values in the hemodynamic parameters, and difference score between VAS-R and VAS-M measurements were calculated. While related values were tested between groups with the Mann Whitney-U test, intragroup comparisons were realized with Wilcoxon test. p < 0.05 was considered to be statistically significant.

### Results

None of 40 cases included to the study were excluded. No significant difference was observed between groups in terms of demographic data and surgery durations of cases (Table 1).

There was no statistically significant difference between the groups in the systolic arterial pressure, diastolic arterial pressure and heart rate values in all the assessment points.

| Table 1 Demographic data and surgery durations of cases. |
|---------------------------------|-----------------|-----------------|--------|
| Age (year)                      | Group US        | Group AN        | p-Value|
| 47 (22–74)                      | 58 (25–76)      | 0.265           |
| Body mass index (kg/m²)         | 25 (20–32)      | 24 (20–31)      | 0.925  |
| ASA I/II (n)                    | 16/4            | 11/9            | 0.183  |
| Gender (M/F)                    | 20/0            | 19/1            | 1.000  |
| Surgery duration (minute)       | 57 (35–130)     | 60 (30–90)      | 0.883  |

Group US, IH/II nerve block with the US guided technique; Group AN, IH/II nerve block with the anatomical landmark technique; ASA, American Society of Anaesthesiologists; M/F, male/female. Data are number of cases or the median (min–max) is given.
during the intraoperative and postoperative period. Peripheral oxygen saturation was determined between 98% and 100% in both group for all measurement points.

The length of hospital stay, the first mobilization time and the analgesia satisfaction scores of patients during postoperative clinical follow-up are presented in Table 2. In the US group the duration of hospital stay and first mobilization times were significantly shorter and the analgesia satisfaction scores were found to be significantly higher (p < 0.05, p < 0.001, p < 0.001 respectively) (Table 2).

When VAS at rest (VAS-R) was compared between the two groups, VAS-R scores of the group US in the recovery room and all the clinical follow-up points were found to be less statistically significant than the group AN (p < 0.01 and p < 0.001) (Table 3).

When VAS at movement (VAS-M) was compared between the two groups, VAS-M scores of the group US in the recovery room and all the clinical follow-up points were found to be less statistically significant than the group AN (p < 0.01 in all times) (Table 4).

Dexketoprofen was used in 2 cases (10%) in the US group and in 11 cases (55%) in the AN group; meperidine was used in 1 case in the US group (5%) and in 4 cases in the AN group (20%) as rescue analgesics in the recovery room. The use of dexketoprofen as rescue analgesic in the US groups was found to be less statistically significant than the AN group (p = 0.007).

There were no opioid-related treatment requiring side effects or block related complications in cases during the postoperative follow-up.

### Discussion

Following inguinal hernia surgery, moderate or severe pain may cause increase the duration of hospital stay, unexpected rehospitalization, delay in returning to normal activities and increase in associated costs. Callesen et al. found out moderate or severe pain scores in 60% of cases in the first day of hemorrhaphy and in 33% of cases in the 6th day of surgery. Moreover, it was suggested that insufficient postoperative pain management following hemorrhaphy might be a risk factor for the development of chronic pain. Eklund et al. reported moderate or severe pain 5 years after the operation in the 3.5% of 705 patients who underwent open mesh repair of inguinal hernia. In a review where the frequency of chronic pain after mesh inguinal herniorrhaphy was studied it was reported that 11% of patients had chronic pain and that approximately 1/3 of these patients’ daily activities were affected. Multiple approaches including pharmacology were used in the pain management after hemorrhaphy but an optimal pain management has not been found yet.

### Table 2 Hospital stay, mobilization time, postoperative analgesia satisfaction scores in the postoperative period.

<table>
<thead>
<tr>
<th></th>
<th>Group US</th>
<th>Group AN</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital stay</td>
<td>21 (6–25)</td>
<td>24 (14–26)</td>
<td>0.012</td>
</tr>
<tr>
<td>Mobilization time</td>
<td>75 (30–180)</td>
<td>160 (70–300)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Postoperative analgesia satisfaction score</td>
<td>5 (3–5)</td>
<td>2 (1–4)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
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Postoperative analgesia satisfaction scores: 0: poor, 1: medium, 2: good, 3: very good, 4: excellent. Data are median (min–max).

### Table 3 Visual analog scale scores of pain at rest in the postoperative period.

<table>
<thead>
<tr>
<th></th>
<th>Recovery room</th>
<th>Surgical clinic</th>
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<tbody>
<tr>
<td></td>
<td>0 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Group US</td>
<td>0 (0–5)</td>
<td>0 (0–4)</td>
</tr>
<tr>
<td>Group AN</td>
<td>4 (0–6)</td>
<td>3 (0–4)</td>
</tr>
<tr>
<td>p-Value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
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</table>

VAS: 0: no pain, 10: most severe pain to be estimated. VAS-R: at rest. Data are median (min–max).

### Table 4 Visual analog scale values of pain at movement in the postoperative period.

<table>
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<th></th>
<th>Recovery room</th>
<th>Surgical clinic</th>
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<tbody>
<tr>
<td></td>
<td>0 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Group US</td>
<td>2 (1–6)</td>
<td>2 (0–6)</td>
</tr>
<tr>
<td>Group AN</td>
<td>5 (0–8)</td>
<td>4 (1–6)</td>
</tr>
<tr>
<td>p-Value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

VAS: 0: no pain, 10: most severe pain to be estimated. VAS-M: at movement. Data are median (min–max).
In the adult inguinal hernia treatment guideline that was published by European Hernia Society in 2009, it has been suggested that considering local anesthesia for unilateral inguinal hernia, avoiding spinal anesthesia with high dose long acting agents and the combination of general anesthesia with local infiltration with short acting agents might be an alternative to local anesthesia. Ideal anesthetic technique is identified as acceptable for the patient, suitable for surgery, simple and safe, with low risk of morbidity and low cost.

General anesthesia might have some complications like airway complications, cardiac instability, nausea-vomiting, urinary retention and prolonged hospitalization due to the delay of recovery from anesthesia. In our study, we did not observe any complication related to general anesthesia.

Local anesthesia, blockade with local infiltration technique, specific blockade of IH/II nerves or the combination of these techniques may be used in most of the primary open inguinal herniorrhaphies in adults. In these procedures it has been suggested that intraoperative pain is the most common reason of patient’s dissatisfaction. These techniques may not be applicable in young, anxious, morbid obese cases and the ones with suspected strangulation. It has been told that especially in morbid obesity and scrotal hernias the success of local anesthesia depends on the clinician.

Bhattacharya et al. investigated 25,132 cases retrospectively who underwent unilateral and primary herniorrhaphy with general or locoregional anesthesia techniques between 2005 and 2009. The duration of anesthesia and surgery, admission to the postoperative recovery unit and morbidity rates during 30 postoperative days were studied. Cases with bilateral, femoral, recurrent, obstructed or gangrenous hernias and that would have a simultaneous second surgery were excluded. While high morbidity rate and a little need of postoperative care were being found in the locoregional group, longer duration of anesthesia and surgery were found out in the general anesthesia group. There were no differences in 30 days morbidity rates between two groups. Following the equalization of perioperative risk factors it has been suggested that the locoregional anesthesia was a safe and efficient alternative.

O’Dwyer et al. evaluated 276 cases who underwent inguinal herniorrhaphy under general anesthesia in terms of postoperative pain, recovery of psychomotor and central nervous system and cost. A mixture of lidocaine and bupivacaine was administered in divided doses under the skin, subcutan, subfascial and external oblique aponeurosis in the local anesthesia group. Wound infiltration with bupivacaine was performed in both groups. No difference was found between two groups in term of healing profiles. Researchers suggested that the choice of local or general anesthesia had to be decided by a surgeon and the patient together.

Bell et al. found low postoperative morphine consumption and reduced side effects in cases of cesarean with IH/II nerve block. Gucev et al. performed effective analgesia in cases of cesarean with continuous IH/II nerve block through catheter. Postoperative morphine consumption was found to be reduced 51% in open hysterectomy cases with bilateral IH/II nerve block. Wolfson et al. found that IH/II nerve block in cesarean cases provided lower postoperative recovery pain scores and dose of rescue analgesic. They also found out that preincisional bupivacaine with IH/II nerve block in adult patients who underwent ambulatory open herniorrhaphy under spinal anesthesia reduced the predischarge pain score and dose of rescue analgesic. Also in our study in cases whom IH/II nerve block was performed with US guidance, dose of rescue analgesic and postoperative pain scores was found out to be lower.

IH/II nerve block in pediatric group appears in many studies. Markham et al. compared IH/II nerve block with caudal block in cases of pediatric herniorrhaphy and orchiopepy and found out that both techniques had similar analgesic effect. Lim et al. found out that the blind IH/II nerve block in pediatric inguinal herniorrhaphy cases provided high parent satisfaction with the reduction of postoperative pain.

Anatomical landmark and ultrasound guided techniques for IH/II nerve block are identified in the literature. Traditional anatomical landmark technique is not commonly used because of use of high volumes of local anesthetics and high failure rates.

Weintraub et al. studied the dispersion of the local anesthetic in IH/II nerve block performed with the anatomical landmark technique in pediatric inguinal herniorrhaphy. Blocks with uniform dispersion of local anesthetic around the IH/II nerves with US are considered as effective (14%). Blocks that are dispersed in the adjacent tissues are identified as ineffective (86%) but 24% of these blocks were also clinically ineffective. Clinical success rate of the blocks was found 61% in this study conducted with 62 cases. The success rate was found 72% in a study comparing the IH/II nerve block performed with single and double injection technique in children.

Prevention of nerve damage and management of effective anesthesia in blind block procedures with anatomical landmark is associated with the anatomical locations of the IH/II nerves and the contribution of lumbar nerves to these nerves. Klaassen et al. evaluated the contribution rates of lumbar spinal nerves to IH/II nerves and the distances from the entry points of these two nerves into the abdominal wall to the spina iliaca anterior superior in 200 cadaver dissections. Lumbar spinal nerve contribution rates to the II nerve were 65% L1, 14% T12-L1, 11% L1-L2, and 10% L1-L2; to the IH nerve were 7% T12, 14% T12-L1, 10% L1, 6% T11-T12. It was found that II nerve enters the abdominal wall 2.8 ± 1.1 cm medial and 4 ± 1.2 cm inferior according to the spina iliaca anterior superior; IH nerve 2.8 ± 1.3 cm medial and 1.4 ± 1.2 cm inferior. Complex origins of the IH/II nerves showed that the sensorial components of these nerves may originate from T11 and L1 spinal levels. This finding is compatible with many anatomical studies in the literature. Nyhus' drew attention to the congruence of connections between the II, IH and genitofemoral nerves with the sensorial sensory field and this fact that this situation may be particularly important in regional anesthesia. Welt et al. performed paravertebral block in 30 patients for inguinal herniorrhaphy, but since sufficient sensorial block could not be provided in 6 cases additional anesthetic was administered in spinal levels. High postoperative pain scores and increased use of rescue analgesic in the Group AN in our study, can be explained with the anatomical variations of IH/II nerves supported with literatures.
Iliohypogastric/ilioinguinal nerve block in inguinal hernia repair

Anatomical landmark technique may cause complications even in the experienced hands. Amory et al.41 reported intestinal damage following the IH/II nerve block with the anatomical landmark technique in pediatric herniorrhaphy. Jöhr and Sossai42 drew attention to the preferred needle size in regional blocks reporting colon damage and development of subserosal hematoma. Another complication mentioned in the literature was temporary femoral nerve paralysis.43–46 Ghani et al.47 determined that the incidence of temporary femoral nerve paralysis in adult herniorrhaphy cases was 6%. In our study, there was no block related complication in patients who had IH/II nerve block with the anatomical landmark technique.

According to our knowledge, there was no previous study about efficacy, concentration and dose setting of levobupivacaine in the adult IH/II nerve block. However few studies are available in pediatric patients. Disma et al.48 reported that 0.4 ml/kg dose of levobupivacaine with 0.25% concentration provided postoperative analgesia in children who had inguinal herniorrhaphy. It was found that the optimal levobupivacaine dose might be reduced to 0.075 ml/kg in the IH/II nerve block with the US guidance in children.49

In our study, 20 ml of levobupivacaine with 0.5% concentration was used in both groups with efficacy and safety profile. Signs of local anesthetic toxicity was not observed in any of the cases.

Baarentzen et al.50 evaluated the efficacy of IH/II nerve block with US in 60, ASA I–II class, more than 18 years of age cases who underwent unilateral inguinal herniorrhaphy. After induction of general anesthesia, cases had US guided IH/II nerve block with bupivacaine or saline. Primary measurement was defined as VAS pain score at movement in the postoperative care unit; secondary measurements were defined as VAS pain scores at rest, opioid consumption, postoperative nausea-vomiting, recovery unit and length of stay in the clinic. Analgesic consumption, pain score, perceived health status and capability to daily activities were questioned over the phone at 24–48h after discharge. In the bupivacaine group; time of introduction to postoperative recovery unit, VAS scores at rest and movement at 30th minute, VAS scores at rest at discharge were found significantly lower. VAS score at movement after discharge was found lower in the bupivacaine group but not statistically significant (p = 0.06). No significant difference was found in pain scores between two groups at the postoperative 24th and 48th hours. There was no statistically significant difference between two groups in terms of postoperative opioid consumption in the recovery unit, clinic and after discharge (p = 0.12, p = 0.2, p = 0.15). Perceived health status and capability to perform daily activities were evaluated at home over the phone and showed no difference between two groups. In our study, in cases where IH/II nerve block was performed with US guidance, rescue analgesic doses and postoperative pain scores were found lower at the beginning and 30th minute in the postoperative recovery unit that was compatible with the literature. Pain score at movement at discharge was significantly lower in the US group that was different from the literature. In our study, there was no significant difference in terms of pain, satisfaction of analgesia and complications of the block according to the evaluation made over the phone at home after discharge.

One limitation of our study was not to ask patients whether they would prefer the same technique or not. This would have given more reliable results to us.

In conclusion, in adult inguinal herniorrhaphies, US guided IH/II nerve block provides a more effective and satisfied analgesia compared to IH/II nerve block with the anatomical landmark technique. On the other hand, it may be suggested that the observation of anatomical structures with the US might increase the success of the block, and minimize the block-related complications.

Conflicts of interests

The authors declare no conflicts of interest.

References