Efficacy of Local Anesthetic With Dexamethasone on the Quality of Recovery Following Total Extraperitoneal Bilateral Inguinal Hernia Repair: A Randomized Clinical Trial

Bryan Sakamoto, MD, PhD; Gene Harker, MD, PhD; Andrew C. Eppstein, MD; Kenneth Gwirtz, MD

IMPORTANCE Quality of recovery (directly associated with patient satisfaction) is an important clinical outcome measurement and a surrogate of anesthetic/surgical care quality.

OBJECTIVES To compare the efficacy of a transversus abdominis plane (TAP) block with dexamethasone sodium phosphate and preperitoneal instillation of local anesthetic (PILA) with dexamethasone vs control on postoperative quality of recovery following a bilateral total extraperitoneal inguinal hernia repair (TEP-IHR) (>24 hours). Secondary objectives included efficacy of this technique on postoperative opioid use, nausea and vomiting, and pain scores.

DESIGN, SETTING, AND PARTICIPANTS Conducted from November 2013 to August 2015, this randomized, prospective, single-blinded study compared 2 groups (a TAP block and PILA) with a standard anesthetic technique with no regional technique (control) following bilateral TEP-IHR. This study at the Veterans Affairs Medical Center (Indianapolis, Indiana) included patients ages 18 to 80 years with an American Society of Anesthesiologists physical status of 1 to 3 scheduled for an outpatient bilateral TEP-IHR. Nurses assigning pain scores and administering opioids for pain and staff anesthesiologists administering the Quality of Recovery–40 (QoR-40) questionnaire were blinded.

INTERVENTIONS Patients randomized to receive a TAP block with local anesthetics and dexamethasone, PILA with dexamethasone, or no regional technique (3 groups).

MAIN OUTCOMES AND MEASURES Patient’s response to the QoR-40 questionnaire following a TEP-IHR surgery.

RESULTS The mean (SD) ages in the TAP block (n = 19), PILA (n = 24), and control (n = 23) groups were 58.2 (9.4) years, 62.5 (8.1) years, and 62.9 (7.8) years, respectively. The global QoR-40 scores on postoperative day 1 for the TAP block group (median [interquartile range (IQR)], 178 [173-188]) were comparable with the control group (median [IQR], 174 [150-181]), while the PILA group had better global QoR-40 scores (median [IQR], 184 [175.5-190.75]) (P = .002). The effects of the TAP block and PILA on pain in the postoperative care unit (PACU) (median [IQR], 1 [0-5] and 3.5 [0-6.8], respectively), pain after discharge (median [IQR], 3 [2-5] and 3 [1-5.5], respectively), opioid use after discharge (median [IQR], 6.7 [5-10] and 6.7 [3.3-10], respectively), and incidence of nausea and vomiting in the PACU (4 of 19 [21.1%] and 6 of 24 [25%], respectively) were not significantly different from the control group (median [IQR], 4 [3-6] for pain scores in the PACU; 4 [3-7] for pain scores after discharge; 6.7 [3.3-10] for opioid use after discharge; and 6 of 23 [26.1%] for incidence of nausea/vomiting in the PACU). While there was a significant reduction of opioid use in the PACU in the TAP block group (median [IQR], 0 [0-1.3]) when compared with the control group (median [IQR], 4 [1.3-6.7]) (P = .001), this was not seen in the PILA group (median [IQR], 2 [0-6.4]).

CONCLUSIONS AND RELEVANCE This study demonstrates a better quality of recovery in patients’ receiving PILA with dexamethasone compared with control for a TEP-IHR surgery.

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otal extraperitoneal inguinal hernia repair (TEP-IHR) is a surgical procedure typically performed on an outpatient basis. It is a relatively recent technique that has been reported to have a number of advantages over open hernia repair including less pain, fewer wound complications, excellent recovery, and a high degree of patient satisfaction. Nevertheless, this surgical technique still can result in significant patient discomfort in the immediate postoperative period. Local anesthetics have been reported to improve postoperative analgesia and patient satisfaction when used in a multimodal approach. Although there have been numerous reports on the use of preperitoneal instillation of local anesthetic (PILA) following TEP-IHR, the results are contradictory. Further, a few published studies have reported the analgesic benefits of transversus abdominis plane (TAP) blocks following TEP-IHR, but these benefits appear to be limited.

Evidence from human studies indicates that adding dexamethasone sodium phosphate increases the duration of a variety of regional anesthetic techniques. While increased infection rates or poor wound healing from a single peroperative dose of steroids have been hypothesized, published studies have not supported this hypothesis. To date, the addition of dexamethasone to TAP blocks or PILA for postoperative pain control and quality of recovery following a bilateral TEP-IHR have not been reported.

At the time this study was initiated, 3 techniques for quality of recovery and postoperative analgesia were being used for laparoscopic TEP-IHR surgery at our institution: (1) bilateral TAP blocks with local anesthetics and dexamethasone, (2) PILA with dexamethasone, and (3) a standard general technique with no regional technique. In this quality-control study, the aim was to verify the observation that both bilateral TAP blocks and PILA with the addition of dexamethasone are superior techniques in terms of improved quality of recovery and postoperative pain control when compared with a standard anesthetic technique with no regional technique. To test this hypothesis, the addition of dexamethasone to an ultrasonography-guided bilateral TAP block and PILA was compared with a standard anesthetic technique (control) following a bilateral TEP-IHR in this randomized prospective single-blinded study.

The primary objective of this study was to assess the efficacy of the addition of dexamethasone to the bilateral TAP block and PILA to a standard anesthetic technique on the postoperative quality of recovery using the Quality of Recovery–40 (QoR–40) questionnaire for patients on postoperative day 1 following a bilateral TEP-IHR (>24 hours). Secondary objectives were to compare the efficacy of this technique on postoperative opioid use, nausea and vomiting, and pain scores.

**Methods**

The study was approved by the Indiana University institutional review board (Indianapolis, Indiana) and the Veterans Affairs Medical Center institutional review board (Indianapolis, Indiana); written informed consent was obtained from all patients. This study involved a single institution and 1 staff surgeon who performed all operations with the assistance of a surgical resident. Anesthetic management was performed by 3 staff anesthesiologists and anesthesiology residents or nurse anesthetists under their supervision. All TAP blocks were performed by the staff anesthesiologists (B.S., G.H., and K.G.) who have extensive experience (>7 years) and expertise in the placement of this block. Patients were eligible for participation if they were 18 to 80 years of age, had an American Society of Anesthesiologists (ASA) physical status of 1 to 3, and were scheduled for an outpatient bilateral TEP-IHR. Patients were excluded if they refused to participate, were unable to give consent, had drug allergies to any medications used in this study, were pregnant, or had a bleeding diathesis. Patients who had their surgery converted to an open procedure were removed from the study. Any patient whose anatomy or surgical procedure, in the opinion of the investigator, might preclude the potential successful performance of a TAP block was also removed. Patients were recruited on the day of surgery. Patients were randomized to receive either a standard anesthetic technique with an ultrasonography-guided bilateral TAP block with local anesthetics and dexamethasone, a standard anesthetic technique with PILA and dexamethasone, or a standard anesthetic technique (no regional technique). Group allocation was computer generated and the individual allocations were placed in sealed envelopes prior to the start of the study. Details of the study are shown in the Figure. The full trial protocol can be found in the Supplement.

In the operating room, standard ASA anesthetic monitors were placed. All patients received a standardized general anesthetic consisting of premedication with 1 to 2 mg of intravenous (IV) midazolam and induction with 1 to 2 μg/kg of IV fentanyl and 1 to 2 mg/kg of IV propofol. One to 2 mg/kg of IV succinylcholine was used to facilitate tracheal intubation. The patient’s lungs were ventilated with a 50:50 mixture of oxygen to nitrous oxide or 100% oxygen. Sevoflurane was added for maintenance. To assure suitable operating conditions, neuromuscular blockade was maintained using cisatracurium besylate or IV rocuronium bromide. The patients were given fentanyl citrate in 25- to 50-μg increments (IV bolus) during the case if the anesthesiologist deemed this to be necessary. After the completion of
the surgical procedure and prior to emergence from anesthesia, either an ultrasonography-guided bilateral TAP block with local anesthetic and dexamethasone, PILA with dexamethasone (after the completion of the surgical mesh placement), or no regional technique was performed depending on the patient's group assignment.

**TAP Group**

After completion of the procedure and skin closure, using an aseptic technique, a bilateral TAP block was performed under ultrasound guidance. Twenty-one milliliters of 0.5% bupivacaine (diluted to a total volume of 30 mL with normal saline) and 4 mg of preservative-free dexamethasone were injected into each side of the abdomen wall (total of 30 mL of 0.5% bupivacaine, 30 mL of saline, and 8 mg of preservative-free dexamethasone).

**PILA Group**

Prior to closure of the surgical site, preperitoneal instillation of 15 mL of 0.5% bupivacaine and 4 mg of preservative-free dexamethasone (total of 30 mL of 0.5% bupivacaine and 8 mg of preservative-free dexamethasone) was placed by the surgeon under direct visualization into 2 areas (left and right “triangle of pain”).

Neostigmine methylsulfate (0.05-mg/kg IV) and glycopyrrolate (0.001-mg/kg IV) were used at the conclusion of the surgery to reverse the neuromuscular blockade. Ondansetron, 4-mg IV, was administered for antiemetic prophylaxis prior to emergence from anesthesia.

All surgical procedures were conducted by the same surgeon using a standard technique for bilateral TEP inguinal herniorrhaphy. Initial dissection of the retroperitoneal space was accomplished with a preperitoneal distension balloon (Spacemaker Dissection Balloon; Medtronic/Covidien). A 12-mm Hasson and 2 5-mm low-profile trocars were placed in the midline. Blunt dissection was used to clear the Hesselbach triangle and the ligament of Cooper to reduce any direct or femoral hernias that were present. The lateral preperitoneal space was entered and the peritoneum peeled down laterally to expose the “triangle of pain” (containing the ilioinguinal, lateral femoral cutaneous, and genitofemoral nerves). The cord structures were skeletonized and any indirect hernia sac or cord lipoma was reduced into the preperitoneal space. A nonwoven polypropylene mesh (Surgimesh WN; Aspide/BG Medical) was deployed and anchored to the Cooper ligament with 5-mm absorbable tacks (AbsorbaTack; Medtronic/Covidien). The cord structures were positioned through a slit in the mesh, which was closed with an absorbable tack superolateral to the internal ring and iliopubic tract. Any visible rents in the peritoneum were closed with absorbable endoloops to prevent mesh exposure to the bowel or leakage of preperitoneal anesthetic (if applicable). After desufflation of the preperitoneal space, fascial closure, and, if indicated, standard repair of an umbilical hernia, the incisions were injected with a total of 10 mL of 0.25% plain bupivacaine hydrochloride and closed with absorbable suture and topical skin adhesive.

On arrival in the postanesthesia care unit (PACU), patients were asked to rate their pain at rest using a 0 to 10 numeric rating scale. Nurses in the PACU were blinded to the patients’ group assignment. After the initial rating, pain ratings were repeated at regular intervals during the remainder of the PACU stay. If required, postoperative pain was treated with hydromorphone hydrochloride, 0.2- to 0.4-mg
IV, every 5 minutes to achieve a pain score less than or equal to 3 of 10, or until patients reported they were “comfortable.” Ondansetron, 4-mg IV; droperidol, 0.625-mg IV; or haloperidol, 1-mg IV, were available for episodes of postoperative nausea/vomiting (PONV). Discharge criteria included adequate control of pain, nausea, and bleeding, as well as a patient’s ability to ambulate and void. Patients who could not void had their bladder emptied by catheterization. Pain after discharge was managed with hydrocodone, 5 mg, plus acetaminophen, 325 mg (1-2 tablets by mouth every 4-6 hours, as needed). Patients were contacted by telephone on postoperative day 1 (>24 hours) by an investigator unaware of group assignment. At that time, patients were queried regarding analgesic consumption and pain score. The QoR-40 questionnaire was also administered. Additional data collected included the patient’s age, sex, weight, height, ASA physical status, total amount of hydromorphone used in the PACU, pain scores in the PACU, and PONV in the PACU.

The global QoR-40 score consists of 40 questions that examine 5 domains of patient recovery using a 5-point Likert scale (none of the time, some of the time, usually, most of the time, and all of the time). The 5 domains include physical comfort, pain, physical independence, psychological support, and emotional state. The QoR-40 has been widely validated in patients evaluated before and after surgery. In addition, the QoR-40 has since become the most widely reported measure of patient-assessed quality of recovery after surgery. The QoR-40 is a suitable measure of the quality of recovery after surgery and anesthesia, for both quality assurance and research.

Statistical Analysis
Based on the assumption of an overall SD of 12, it was determined that a sample size of 23 patients per group was required to achieve 80% power in detecting a 10-point difference in the aggregated QoR-40 score between the 2 study groups and control group. A 10-point difference represents a clinically relevant improvement in quality of recovery based on previously reported QoR-40 mean and range values. The QoR-40 questionnaire is also administered. Additional data collected included the patient’s age, sex, weight, height, ASA physical status, total amount of hydromorphone used in the PACU, pain scores in the PACU, and PONV in the PACU.

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The global QoR-40 scores and the dimensions of the QoR-40 questionnaire are reported as medians and interquartile ranges (IQRs). Differences in the QoR-40 scores were analyzed using the Kruskal-Wallis test. Continuous variables are reported as means (SDs) and analyzed using analysis of variance. Categorical data were compared using χ² tests. Pain scores and opioid use (IV morphine equivalents) are reported as medians and IQRs. Differences in pain scores and opioid use were tested using the Kruskal-Wallis test. Statistical inference was evaluated at the 5% level of significance. Post hoc analysis was performed using the Mann-Whitney U test with Bonferroni correction for multiple comparisons (3 groups). Statistical analysis was performed using SPSS version 22 (IBM).

### Table 1. Patient Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>TAP Block (n = 19)</th>
<th>PILA (n = 24)</th>
<th>Control (n = 23)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>58.2 (9.4)</td>
<td>62.5 (8.1)</td>
<td>62.9 (7.8)</td>
<td>.15</td>
</tr>
<tr>
<td>Sex, No.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>19</td>
<td>24</td>
<td>23</td>
<td>NA</td>
</tr>
<tr>
<td>Female</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>ASA status 3/2/1, No.</td>
<td>12/7/0</td>
<td>21/3/0</td>
<td>19/3/1</td>
<td>.15</td>
</tr>
<tr>
<td>Height, mean (SD), cm</td>
<td>179.39 (8.25)</td>
<td>176.11 (5.99)</td>
<td>177.51 (6.18)</td>
<td>.30</td>
</tr>
<tr>
<td>Weight, mean (SD), kg</td>
<td>86.45 (19.74)</td>
<td>87.98 (19.40)</td>
<td>82.48 (12.81)</td>
<td>.55</td>
</tr>
</tbody>
</table>

### Table 2. QoR-40 Scores

<table>
<thead>
<tr>
<th>Domain</th>
<th>Median (IQR)</th>
<th>PILA (n = 24)</th>
<th>Control (n = 23)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical comfort</td>
<td>52 (50-55)</td>
<td>54.5 (51.25-56.75)⁹</td>
<td>49 (45-55)</td>
<td>.03⁸</td>
</tr>
<tr>
<td>Emotional state</td>
<td>40 (37-43)</td>
<td>42 (38-44)</td>
<td>39 (34-43)</td>
<td>.29</td>
</tr>
<tr>
<td>Physical independence</td>
<td>22 (21-23)</td>
<td>24 (21-24)⁹</td>
<td>21 (17-23)</td>
<td>.001⁸</td>
</tr>
<tr>
<td>Psychological support</td>
<td>35 (34-35)</td>
<td>35 (34-35)</td>
<td>34 (33-35)</td>
<td>.02³</td>
</tr>
<tr>
<td>Pain</td>
<td>30 (28-32)</td>
<td>31.5 (27.25-32-75)⁹</td>
<td>27 (25-30)</td>
<td>.02³</td>
</tr>
<tr>
<td>Global</td>
<td>178 (173-188)</td>
<td>184 (175.5-190.75)⁹</td>
<td>174 (150-181)</td>
<td>.005⁸</td>
</tr>
</tbody>
</table>

Abbreviations: IQR, interquartile range; PILA, preperitoneal instillation of local anesthetics; QoR-40, Quality of Recovery–40; TAP, transversus abdominis plane.

⁹ Differences in the QoR-40 scores were analyzed using the Kruskal-Wallis test. Statistical significance when compared with the control group. Post hoc analysis was performed using the Mann-Whitney U test with Bonferroni correction for multiple comparisons.

³ Statistical significance. Reported P values from the Kruskal-Wallis test. All P values are reported as 2-tailed.
Results

From November 2013 through August 2015, 75 patients were enrolled. Of the 75 patients who were enrolled and randomized, 66 completed the study. Details of the study are shown in the Figure. Demographic data and surgical factors were not different among the 3 groups (Table 1). The global QoR-40 scores on postoperative day 1 (>24 hours) after surgery for the TAP block group were comparable with the control group (median [IQR], 178 [173-188] vs 174 [150-181], respectively; Table 2); post hoc analysis showed the TAP block group had significantly improved psychological support subcomponent scores (median [IQR], 35 [34-35] vs 34 [33-35]; P = .008) when compared with the control group. The TAP block group had a significant reduction in the amount of opioids used in the PACU (median [IQR], 0 [0-1.3] vs 0.5 [0-1]), incidence of PONV in the PACU (4 of 19 [21.1%], postoperative pain after discharge (median [IQR], 3 [2-5]), and opioid use after discharge (median [IQR], 2 [0.6-4]), were not significantly different from the control group (median [IQR], 25 [20-25]).

In addition, no infection or poor wound healing in any study patient was noted during the 4-week surgical follow-up. All opioids were converted to IV morphine equivalents prior to statistical analysis and reported in IV morphine equivalents.

Discussion

The primary objective of this study was to compare the efficacy of a bilateral TAP block with local anesthetic and dexamethasone and PILA with dexamethasone vs control on postoperative quality of recovery using the QoR-40 questionnaire the day following a bilateral TEP-IHR (>24 hours). The results suggest that, when compared with a standard anesthetic technique without a regional anesthetic, the PILA with dexamethasone improves global QoR-40 scores (Table 2).

The global QoR-40 score is composed of 5 domains and these domains were compared in a post hoc analysis. All the subgroups of the global QoR-40 scores were improved compared with the control group (Table 2). However, only the psychological support domain was statistically different in the TAP block group (compared with the control group) and physical comfort and physical independence domains were statistically different in the PILA group (compared with the control group). There was no statistically significant difference between the 3 groups in comparing the emotional state and pain domains. Physical comfort, pain, and physical independence are the elements most affected by surgery and anesthesia; thus, in this study, the use of PILA with dexamethasone was associated with improved patient experience and outcome. This result is reflected in the global QoR-40 score seen in the PILA group.

The physical independence domain is composed of 5 questions using a 5-point Likert scale (25 maximum points): have normal speech; able to wash, brush teeth, or shave; able to look after your own appearance; able to write; and able to return to work or usual home activities. An improvement in this domain indicates an improvement in the patient’s ability to per-
form some basic activities of daily living. Although these questions are relatively basic in the activities asked, the PILA group did show a significant improvement when compared with the control group (Table 2). As stated here, the emotional state, psychological support, and pain domains were not statistically different in the PILA with dexamethasone group when compared with a standard anesthetic technique with no regional technique (Table 2). While the significance of this finding is unclear and requires further study, one hypothesis is that the dimension scores for the emotional state and psychological support domains are less prone to change if hospital staff are attentive to the patients’ psychological well-being throughout the perioperative period.22

Patient satisfaction was not specifically measured in this study. Because quality of recovery is directly associated with patient satisfaction,26 we used the global QoR-40 score as a proxy for patient satisfaction. Our results indicate that, when compared with a standard anesthetic technique with no regional technique, patients in this study had a better anesthetic/surgical experience when they received PILA with dexamethasone. From the patient’s perspective, a delayed return to normal activity lowers the patient’s satisfaction for the medical care they received.27 The improvement in the global QoR-40 score in the PILA group suggests better patient satisfaction and thus a quicker return to normal activity when compared with the control group.

While the effects of PILA with dexamethasone on postoperative pain in the PACU, opioid use in the PACU, and postoperative pain after discharge were not significantly different from the control group, the effects did trend in favor of PILA with dexamethasone. As with the PILA group, the postoperative pain in the PACU and postoperative pain after discharge trended in favor of the TAP block group. Because the power analysis was designed to detect a difference in the global QoR-40 scores, and given the trending, a higher-powered study might have detected a difference in these secondary outcome measures. Of note, the TAP block group had a significant reduction in opioid use in the PACU (Table 3). This result appears to support the conclusion of previous studies,11,12 suggesting a limited utility of TAP blocks in this surgical population.

It is unknown whether the effects seen on the first postoperative day with the administration of PILA with dexamethasone have any long-term benefit. This study was developed to determine whether any of the techniques currently used at this facility are efficacious in the acute phase of recovery. However, from the patient’s PACU stay, postoperative day 1 interview, and 4-week surgical clinic follow-up, there were no adverse effects discovered or reported by any of our study patients. Currently, we are investigating the possible long-term benefits of PILA with dexamethasone in our patient population.

Our study had several limitations. The power analysis was designed to detect a 10-point difference in the aggregated QoR-40 score between the 2 study groups and control group. This required a minimum of 23 patients in each group. Because the TAP block group contained only 19 patients, power was lost in this arm of the study. The TAP blocks were placed at the end of the surgery and some patients experienced extensive infiltration of carbon dioxide gas into the tissue planes during the surgical procedure. This infiltration of gas into the tissue planes resulted in mild to extensive tissue attenuation of the ultrasound image, which made identification of the abdominal muscle planes difficult, if not impossible. If patients had extensive tissue attenuation, they were removed from the study; however, if patients had mild to moderate tissue attenuation, a TAP block was performed. This tissue attenuation might have prevented the successful placement of local anesthetic and dexamethasone into the correct tissue plane.

Conclusions

In conclusion, the findings of this study demonstrate a better quality of recovery in patients receiving PILA with dexamethasone compared with a standard anesthetic with no regional technique for outpatient laparoscopic TEP-IHR surgery. The addition of dexamethasone to local anesthetics appears to be a safe, inexpensive, and highly effective method to improve the quality of recovery for patients undergoing outpatient laparoscopic TEP-IHR surgery.

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Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Sakamoto, Eppstein, Gwirtz.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Sakamoto.
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Improved Recovery After Laparoscopic Bilateral Inguinal Hernia Repair

Perception vs Function Improvement?

Robert V. Rege, MD

Sakamoto and colleagues present a randomized, prospective, single-blinded study examining early recovery after bilateral laparoscopic inguinal hernia repair. One treatment group had a transversus abdominis block (TAP) performed by the anesthesiologist, while another group had preperitoneal installation of local anesthetic (PILA) and dexamethasone by the surgeon. A control group had no local intervention. Pain scores blinded to treatment arm, postoperative opioid use, and results of a Quality of Recovery–40 Questionnaire (QoR-40) on the first postoperative day were analyzed. The TAP decreased opioid use in the postanesthesia care unit, but not thereafter, and did not significantly improve global QoR-40 score. Although PILA did not decrease opioid use, global QoR-40 scores were significantly better than for either control or TAP patients.

The results of this study appear straightforward. The PILA treatment is easy to use, requires no special expertise, is quickly performed by the surgeon, and improves the patient’s perception of pain, as measured by the QoR-40. A surgical approach that is easy to perform, provides pain relief, and improves patients’ perception of pain is appealing and may be preferred by both patients and practitioners. However, the global QoR-40 scores did not improve, except for a trend in the PILA group. This suggests that the improved perception of pain was not accompanied by improved function, which is a significant limitation of this study.

It is important to note that the QoR-40 is a subjective measure of quality of recovery, which may not align with objective measures of function. Future studies should include objective measures of function, such as physical activity, to better understand the impact of surgical interventions on patients’ overall recovery. Additionally, the study design could be improved by including a larger sample size and longer follow-up to better assess the long-term effects of TAP and PILA on recovery.