

Randomized Trial

Erector Spinae Plane Block versus Transversus Abdominis Plane Block for Robotic Inguinal Hernia Repair: A Blinded, Active-Controlled, Randomized Trial

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Background: Regional anesthetic nerve blocks are widely used in the treatment of pain after outpatient surgery to reduce opioid consumption. Erector spinae plane (ESP) block is a recently described technique with promising results in different scenarios.

Objectives: To compare ESP block efficacy with the commonly used transversus abdominis plane (TAP) block in patients undergoing robot-assisted inguinal hernia repair.

Study Design: This was a randomized, blinded, active controlled, superiority trial with 2 parallel groups. The study was approved by the local ethics committee. Registration took place on www.clinicaltrials.gov with the identifier NCT04750512.

Setting: Adults undergoing robotic inguinal hernia repair were recruited between January 2021 and April 2022 in a single referral center of southern Switzerland.

Methods: To ensure blinding, the study employed a “double dummy” design, where all patients underwent both TAP and ESP blocks, but only one block was therapeutically active. The therapeutic block contained ropivacaine 0.2%, while the other infiltration contained placebo. The therapeutic intervention varied between groups, with one group receiving the TAP block as the active treatment and the other group receiving the ESP block as the active treatment. Computer generated 1:1 randomization determined allocation, which took place immediately prior to the intervention. As a result, blinding included patients, anesthesia, and surgery providers, outcome assessors and statistical analysts.

The main outcome measure was the highest reported pain score on a Visual Analog Scale (VAS) during the 6 hours following the end of general anesthesia. Secondary outcomes included pain scores at set intervals, analgesic consumption, and complications.

Results: A total of 50 patients (25 per arm) were enrolled and included in the analysis. The study found no significant difference in the mean maximal VAS scores between the 2 groups (TAP block 22.2, ESP block 20, difference 2.2, 95% CI is -12.1 to 16.5). Secondary endpoints, including VAS pain scores at different time points, use of rescue analgesics, time to first walk, duration of stay, and frequency of adverse events, did not show any significant differences between the 2 groups. However, post-hoc analysis suggested a more stable effect over time for the ESP block compared to the TAP block.

Limitations: The main limitation is a higher variance in VAS scores than expected in the power calculations.

Conclusions: ESP block was not superior to TAP block in the treatment of post-operative pain among patients undergoing robotic inguinal hernia repair.

Key words: Inguinal hernia, conduction anesthesia, postoperative pain, robotic surgical procedures, ESP block

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I ncreasing recognition of the risks and complications associated with opioid treatment has sparked a heightened focus on exploring and refining alternative approaches for pain management following routine surgical procedures. Regional anesthesia is associated with a well-established opioid-sparing effect, contributing to a decreased occurrence of postoperative complications, shorter hospital stays, and a reduction in overall hospital costs (1,2).

Regional and local anesthetic techniques after inguinal hernia surgery have been the topic of multiple studies, comparing various infiltrative methods, including wound infiltration, port site infiltration, iliohypogastric and ilioinguinal nerve block, paravertebral block, transversus abdominis plane (TAP) block and epidural analgesia (3). Many trials investigated pain treatment in the setting of open surgery. The continuous evolution towards laparoscopic and robot-assisted techniques changed the etiology and physiology of post-surgical nociceptive acute pain, consequently reshaping the approach to its management. Specifically for inguinal hernia, open approaches cause trauma and somatic pain over a defined area in the inguinal region and can be addressed with local injections and blocks. Conversely, minimally invasive approaches require the placement of multiple trocars across the abdomen and induce lesions of the parietal peritoneum. In this context, infiltrations that effectively target a broader abdominal area and address both somatic and visceral pain become particularly relevant. In the last decade, the TAP block has gained significant popularity as a widely utilized technique. This approach involves the injection of local anesthetic between the fasciae of the internal oblique and transversus abdominis muscles. However, TAP blocks result in an inconsistent but mild opioid-sparing effect (3,4).

The erector spinae plane (ESP) block is a promising technique, recently described and used in the setting of thoracic surgery (5-7). This procedure consists of an injection of a local anesthetic between the deep fascia of the erector spinae muscle and the transverse process. Cadaver studies have shown, though not consistently, that the anesthetic often diffuses anteriorly into the paravertebral space. Previous reports suggest that a component of visceral anesthesia can be expected following the block of the thoracic sympathetic ganglia efferences (8,9).

Several case series and studies in adult and pediatric populations highlight the ESP block as a safe and effective method for preventing postoperative

pain after abdominal surgery (10-13). Direct comparisons with the TAP block also obtained preliminary promising results: a recent prospective study found advantages of the ESP block over the TAP block in terms of postoperative pain and morphine consumption following open hysterectomy (12), and another recent study suggested the same advantages in the setting of bariatric surgery (14). One rather underpowered study found no advantage in combining unilateral ESP block to spinal anesthesia after open surgery for inguinal hernia (15). Meanwhile, another study compared TAP and ESP blocks for laparoscopic hernia repair in children, finding both to be equally superior to placebo in postoperative pain prevention (16). However, to the best of our knowledge, no prospective randomized data has been published in the setting of a minimally invasive hernia repair in an adult population.

OBJECTIVES

We hypothesized that the ESP block would outperform the TAP block in controlling postoperative pain after a minimally invasive abdominal surgery, potentially reducing the need for rescue analgesics.

We therefore compared the efficacy in pain control and safety of ESP block versus TAP block in patients undergoing robot-assisted transabdominal pre-peritoneal patch (TAPP) inguinal hernia repair.

METHODS

The complete study protocol was approved by the local ethical committee. Written consent was obtained from all patients at least one day before randomization. Two separate monitoring visits by an independent clinical trial expert took place to review and approve the quality and completeness of collected data. The trial was registered on ClinicalTrials.gov (www.clinicaltrials.gov) with the identifier NCT04750512.

STUDY DESIGN

This was a single center clinical trial randomizing patients on a 1:1 ratio into 2 parallel groups. To ensure maximal blinding, the study employed a “double dummy” design, where all patients underwent both TAP and ESP blocks, but only one block was therapeutically active, while the other block contained placebo. The therapeutic intervention varied between groups, with one group receiving the TAP block as the active treatment and the other group receiving the ESP block as the active treatment.

We opted to design a superiority trial based on 2 key factors. Firstly, existing research has already indicated potential enhanced benefits of the ESP block in open and laparoscopic surgery settings (12,14). Secondly, the existing advantage of the TAP block over the ESP block in terms of logistics would significantly limit the relevance of a potential result of non-inferiority or equivalence in clinical practice.

Eligibility

Patients were aged 18 or above, undergoing elective robot-assisted TAPP (trans-abdominal pre-peritoneal mesh placement) hernia repair. Enrollment took place in the surgical or anesthesiologic consultation. Exclusion criteria were contraindications to medications and techniques included in the study-protocol, concomitant surgery other than inguinal or umbilical hernia repair, prior complex abdominal wall reconstruction, pre-operative chronic narcotic or opioid usage, known chronic pain syndrome, pregnancy, known or suspected non-compliance, and inability to consent to or follow the procedures of the study. Additionally, patients who were not planned for ambulatory surgery, such as those classified as ASA III-IV [American Society of Anesthesiologists (ASA)] score, or those with bilateral hernias, were also excluded from participation.

SETTING

The study took place at the Ospedale Regionale Bellinzona e Valli (ORBV), a public referral center in southern Switzerland, between January 2021 and July 2022. Anesthesia, perioperative, and postoperative pain management was carried out according to in-hospital standards. Propofol, lidocaine, remifentanyl, and rocuronium were used for induction, and propofol and remifentanyl for maintenance. Perioperative multimodal intravenous analgesia included paracetamol, ketorolac, tramadol, and ketamine according to body weight. Initial postoperative pain management included the sequential administration of metamizole, tramadol, and ketamine when visual analog scale (VAS) score was higher than 50. Rescue analgesia after discharge included 1 g of acetaminophen every 6 hours, 400 mg of ibuprofen every 8 hours, and 50 mg of tramadol every 6 hours. The study intervention was carried out by a selected group of 4 anesthesiologists, who have more than 10 years of experience in ultrasound (US)-guided regional anesthesia.

Randomization and Allocation

A computer generated randomization list was

created using Stata 16.0 (StataCorp) by independent clinical trial unit administrators. The randomization list divided the 2 groups on a 1:1 basis in randomly varied blocks of 2, 4, and 6. Definitive enrollment took place at the time of allocation. Allocation took place through the REDCap platform at the time of intubation, by one of 2 trained anesthesiology nurses (17). The same nurses then prepared a 60 mL ropivacaine solution and another indistinguishable 60 mL saline solution and tagged them as "ESP" and "TAP" according to allocation. A decoding protocol for the allocation sequence was available in case of emergency, but was never needed. Thus, we achieved blinding of patients, all health care providers, data collectors, outcome adjudicators, and data analysts.

Intervention

After induction of general anesthesia, intubated patients were placed in lateral decubitus and US guided ESP infiltration was performed by bilateral injection of 30 mL solution (60 mL total) between the deep fascia of the erector spinae muscle and the transverse process, at the level of the 10th thoracic vertebra. Subsequently, patients were put back in supine decubitus and US-guided TAP infiltration was performed by bilateral injection of 30 mL solution (total 60 mL) in the plane between the internal oblique and transversus abdominis muscles on the midaxillary line, in the triangle of Petit. All patients therefore received one active treatment (60 mL ropivacaine 0.2%) and one placebo infiltration (60 mL saline solution). The robotic surgical procedure was followed according to standard practice and did not differ between groups.

Outcomes

The primary efficacy outcome measure was the score reported on the VAS, which ranges from 0 to 100 mm, with higher scores indicating greater pain intensity. Pain assessments were conducted between the end of general anesthesia and 6 hours after surgery, or until the time of discharge, whichever occurred first. The pain scores were evaluated at rest and during coughing at one and 3 hours after the end of anesthesia, at the time of discharge (approximately 6 hours), and at the time when rescue analgesics were requested. This specific primary outcome measure was selected to minimize bias associated with the use of rescue analgesics.

Secondary outcome measures included pain at 12 and 24 hours (as reported through telephonic follow-up), time to first rescue analgesic, need for rescue

medication, time of first walk after surgery, length of hospital stay, overall complication rate, incidence of vomiting and urinary retention, as well as scores measured on the validated Lansky Play-Performance Scale (LPPS) questionnaire for perioperative patients' satisfaction (18).

Sample Size Calculation

Based on previous research, we assumed that the VAS scores would range between 20 and 50, with a standard deviation of 12 (19,20). The study was designed to have sufficient power to detect a minimal clinically significant difference of 10 points or more on the VAS. A sample size of 46 patients was necessary to provide an 80% chance of detecting, with a significance level of 5%, a decrease of 10 points or more in the primary outcome measure (21). Accounting for a 10% potential dropout rate, we aimed to enroll a total of 50 patients over a period of 18 months. No interim analysis was scheduled as part of the study design.

Statistics

Statistical tests were run using Stata 16.0 to compare the primary and secondary endpoints between the study groups on an intention-to-treat basis. The student's *t* test was run on normally distributed continuous variables, and the chi-square test was run on binary and categorical outcomes. For secondary outcomes, a familywise correction of the significance level was calculated according to the Holm-Bonferroni method (22,23).

RESULTS

One hundred and fifty-three patients were assessed for eligibility as illustrated on the CONSORT flow chart. Recruitment started on January 11th, 2021. The first patient was randomized in January 2021. The 50th patient was randomized in April 2022 and the follow-up ended on May 31st, 2022. No protocol deviation took place during the treatment. No patient was lost to follow-up for the first endpoint, whereas no data on pain at 12 and 24 hours was available for 3 patients who could not be contacted on the day after the operation (one in the TAP block group, 2 in the ESP block group).

On average, the performance of a TAP block took 7.5 minutes, while the ESP block took 10.2 minutes (difference of 2.76 minutes, 95% CI is 1.2 to 4.4 minutes, $P = 0.001$).

Demographic Data

The demographics of the cohorts are described in

Table 1 (24). Data was similar between groups including age, gender, BMI, ASA-score [American Society of Anesthesiologists (ASA) Physical Status Classification System], type and size of hernia, as well as frequency of recurrent hernias. The duration of anesthesia and operating times were also similar between groups. Neither group included patients that underwent a conversion from minimally invasive to open surgical technique. In the TAP group, 2 patients needed surgical drainages due to the dimensions of the hernia sack.

Pain Control

No difference was found in the mean maximal VAS scores for pain during the first 6 hours after the end of the general anesthesia (mean VAS = 20 (SD = 24.1) in the ESP block group vs 22.2 (SD = 26.1) in the TAP block group, $P = 0.758$). Moreover, as shown in Table 2, there was no meaningful difference in pain scores between treatment groups at the set time points of 1, 3, 6, 12 and 24 hours after end of general anesthesia. Risk for use of any rescue analgesics and time to first walk were also the same among cohorts.

Evaluation of patients' satisfaction using the LPPS questionnaire was planned, but was not possible because of poor compliance with compilation ($n = 19$).

Complications and Adverse Events

Table 3 shows that overall complications were few, mild (not higher than Grade I according the Clavien-Dindo classification) and equally distributed. No injection-related complication was observed. A trend of a higher risk of urinary retention requiring catheterization was observed in the ESP block group (2% vs 10%, relative risk of 5, 95% CI 0.63 to 39.8), but with no statistical significance ($P = 0.082$).

Ad Hoc Analysis

Ad hoc analysis showed overall higher pain scores at 12 and 24 hours compared to scores at discharge (Fig. 1), especially in the TAP block group. The mean increase in VAS at rest between 6 and 12 hours was 12.8 in the TAP block group vs. 2.8 in the ESP block group (difference = 10 VAS points, 95% CI is 0.8 to 19.2, $P = 0.034$). The same was true for the mean VAS at rest between 6 and 24 hours, with 11.8 VAS points increase in the TAP block group compared to 0.8 points decrease in the ESP block group (difference = 12.6, 95% CI is 11.6 to 23.6, $P = 0.026$).

DISCUSSION

Each year more than 20 million patients undergo an

inguinal hernia repair, making this operation one of the most common surgical procedures performed worldwide (25). Over the last decades, optimal postoperative pain control and quick return to normal activity have been increasingly regarded as major goals in modern groin hernia management. In this context, minimally invasive surgical techniques as well as combined anesthetic techniques for reducing opioid consumption have gained significant popularity (26). However, there is no international consensus on which anesthesia is most suitable for minimally invasive hernia repair (27). In our general surgical unit, since 2017, patients affected from inguinal hernias have been treated by robot-assisted TAPP under general anesthesia combined with a regional block.

Our present work compares a newly described technique for regional blocks to a well-known, widely used alternative. This randomized, multiple-blinded trial showed no overall difference in the prevention of post-operative pain after elective robotic pre-peritoneal inguinal hernia repair in patients treated with TAP or ESP blocks. Both groups showed satisfactory pain control, with less than half of all patients reporting any pain at rest (before discharge) and only 14% needing rescue analgesics.

The overall frequency of adverse events was the same in the 2 groups, although a trend of higher rates of urinary retention was seen with patients given ESP block. In a post-hoc analysis, frequency and intensity of reported pain was higher at 12 and 24 hours after surgery compared to 6 hours after surgery, possibly as a combined effect of increased mobilization and fading regional anesthesia. This difference was higher in the TAP block group compared to the ESP block group ($P = 0.034$ and 0.026 , respectively), a potentially relevant finding indicating a more constant effect of the ESP block over time.

We believe that our study is reinforced by its robust and consistent methodology, which includes uniform techniques implemented within a single-center. Furthermore, the nearly complete follow-up enhances the strength of the study. To the best of our knowledge, it is the first direct comparison of the 2 techniques in the context of minimally invasive inguinal surgery in the adult population. The measured effects of the tested blocks on pain control are in line with previous results (4).

Limitations

One of the primary limitations of the study is the higher observed variation in reported VAS scores compared to what was predicted based on available literature. This discrepancy may have influenced the sample

Table 1. Baseline characteristics of patients receiving erector spinae plane (ESP) block and transversus abdominis plane (TAP) block for inguinal hernia repair.

	ESP Block n = 25	TAP Block n = 25
Age	60.9 (13.6)	57.7 (13.9)
Gender (man)	22	23
BMI (kg/m ²)	24.7 (4.2)	25.5 (3.5)
ASA 1	4	3
ASA 2	16	19
ASA 3	5	3
Regular Use of NSAIDs	0	1
Direct Hernia	9	9
Indirect Hernia	16	15
Femoral Hernia	0	1
EHS Size 1	1	4
EHS Size 2	19	14
EHS Size 3	5	7
Recurrent Hernia	1	2
Bilateral Hernia	1	2
Duration of Anesthesia	164.4 (31.2)	168.6 (32.2)
Duration of Surgery	93.0 (25.7)	93.1 (24.2)
Intra-OP Complications	0	0
Use of Surgical Drainage	0	2

*Data are means (SD) or numbers.

EHS: The European Hernia Society groin hernia classification (24); NSAIDs: nonsteroidal anti-inflammatory drugs

size calculation, potentially resulting in a smaller number of patients than required.

However, since the mean observed differences in VAS scores consistently remained well below the threshold of 10 mm that is considered clinically relevant, it is unlikely that the study missed a clinically significant difference. A further limitation lies in the fact that blocks could not be tested for efficacy or dermatomal level, introducing the possibility that differences among groups could be attributed not only to different effectiveness of the blocks, but also to different reproducibility. However, this should not impact the interpretation of results from a pragmatic perspective.

With regard to generalizability, it must be noted that we used a robot-assisted TAPP technique, which is still in the early phase of adoption for inguinal hernia repairs worldwide. Nonetheless, we would expect analogous results in the context of other robotic and laparoscopic surgeries of the lower abdomen and abdominal wall.

When compared to the existing literature, the

Table 2. Results of intention-to-treat analysis presented as mean (standard deviation) for continuous variables; absolute numbers for categorical variables.

	ESP Block n = 25	TAP Block n = 25	Difference (95% confidence interval) †	P ‡	p ¹
VAS > 0 at any time before discharge	17	14		0.38‡	1
VAS > 0 at any time resting	13	11		0.57‡	1
VAS > 0 after discharge	22	24		0.3‡	1
VAS > 0 after discharge at rest	17	21		0.24‡	1
Highest VAS between 0 and 6h	20 (24.1)	22.2 (26.1)	2.2 (-12.1 to 16.5)	0.758	1
VAS at 1 h, resting	10.2 (20.7)	9 (16.1)	-1.2 (-11.8 to 9.4)	0.82	1
VAS at 1 h, coughing	12.2 (21.3)	18.6 (25.5)	6.4 (-7 to 19.8)	0.34	1
VAS at 3 h, resting	9 (15.8)	9.2 (13.8)	0.16 (-8.14 to 8.7)	0.97	1
VAS at 3 h, coughing	12.1 (15.1)	11.5 (15.0)	-0.63 (-9.3 to 8.1)	0.885	1
VAS at discharge, resting	7.3 (13.7)	5.4 (10.8)	-1.9 (-9.7 to 5.9)	0.63	1
VAS at discharge, coughing	11.7 (18.7)	6.7 (11.7)	-5 (-14.1 to 4.1)	0.273	1
VAS at 12 h, resting	10.7 (15.7)	18.7 (18.6)	8.1 (-1.9 to 18.1)	0.11	1
VAS at 12 h, walking	18.9 (16.4)	22.9 (18.1)	4.0 (-6.1 to 14.1)	0.431	1
VAS at 24 h, resting	11.3 (14.6)	19.0 (15.2)	7.7 (-1.1 to 16.4)	0.085	1
VAS at 24 h, walking	19.1 (19.3)	26 (18.4)	6.9 (-4.1 to 18.0)	0.215	1
Time to first walk (min.)	173.9 (n = 14)	172 (n = 18)	-1.9 (-53.6 to 49.7)	0.94	1
Discharge on same day	20	22	RR: 0.6 (0.2 to 2.2) ‡	0.6‡	1
Time to discharge, if same day (min)	297 (839)	261.9 (63.2)	35.1 (-16.1 to 86.4)	0.174	1
Use of rescue analgesics within 6 h	3	4	RR: 0.95 (0.76 to 1.19) ‡	0.68‡	1
Time to first rescue analgesics	58 (41.6)	99 (60.6)	41 (64.6 to 146.6)	0.364	1
Use of reserve analgesics in addition to acetaminophen between 6 and 24 h post-op	19	14	RR: 0.74 (0.49 to 1.11) ‡	0.14‡	1

†: Student's t test

‡: χ^2 test

p¹: adjusted p for familywise type I error control according to Holm-Bonferroni (15, 16)

VAS: visual analog scale

h: hours

Table 3. Complications and adverse events.

	ESP Block n = 25	TAP Block n = 25	P‡	p ¹	Risk Ratio (95% CI)
Clavien-Dindo grade I	5	5	1	1	1 (0.33 to 3.03)
Clavien-Dindo > I	0	0	-	-	-
Vomiting	1	0	0.31	0.62	-
Use of antiemetic	2	0	0.15	0.45	-
Urinary retention	5	1	0.08	0.32	5 (0.63 to 39.8)

‡: χ^2 test

p¹: adjusted p for familywise type I error control according to Holm-Bonferroni (15,16)

Adverse events in the TAP block group included one instance each of postoperative seroma, supraventricular tachycardia, and urinary retention and 2x persistent, poorly controlled scrotal or abdominal pain.

present study was not able to confirm the partly highly significant results of various studies that found an advantage of using ESP block over TAP block in other areas of abdominal surgery, despite analogous block technique and similar group sizes (12-14).

The studies display limited differences that could potentially account for the observed discrepancy, including invasiveness of the procedure and anatomical location. One plausible explanation for the inability to detect superiority may be attributed to the overall low pain levels experienced after minimally invasive hernia treatment. In this context, the mean VAS score at 6 hours is approximately 10 mm, which stands in contrast to more invasive interventions like open hysterectomy, where the mean VAS score at 6 hours reaches 25 mm (12).

The previously described superiority of ESP versus TAP block in other minimally invasive abdominal procedures, such as bariatric surgery or cholecystectomy,

suggest the advantage could conversely be attributed to the previously hypothesized impact of the ESP block on visceral pain (8,9).

Both theories mentioned can explain the failure to find an advantage in the context of inguinal hernias in the present as well as in previous studies (15,16).

Another relevant difference lies in the reported level of blinding, which only includes patients and data collectors in the previous studies, whereas in the present study, blinding also included all health care providers and data analysts.

CONCLUSION

In conclusion, when comparing the ESP block to the TAP block in minimally invasive inguinal hernia surgery, no superiority could be found regarding pain control or incidence of adverse events. The choice between the 2 techniques in this setting must weight a slightly more labor- and time-intensive performance of the ESP block against its possible tendency towards a more constant analgesic effect over time. The

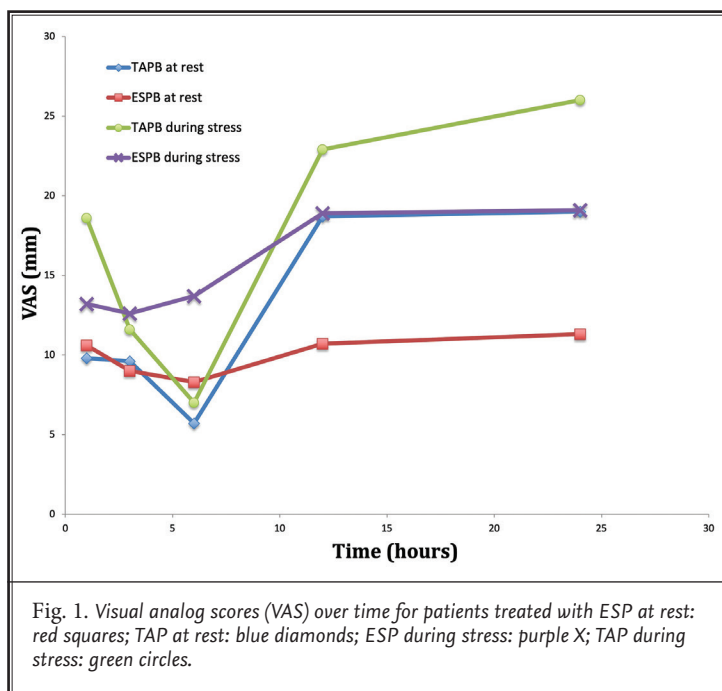


Fig. 1. Visual analog scores (VAS) over time for patients treated with ESP at rest: red squares; TAP at rest: blue diamonds; ESP during stress: purple X; TAP during stress: green circles.

latter, together with the possible higher incidence of urinary retention, could be the focus of further studies.

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