

Received: 2020.02.26

Accepted: 2020.03.06

Available online: 2020.06.10 Published: 2020.08.06

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of Paramedian Approach Subarachnoid Puncture

in Spinal Anesthesia before Hip Fracture Surgery

e-ISSN 1643-3750 © Med Sci Monit. 2020: 26: e923813 DOI: 10.12659/MSM.923813

		in Elderly Patient Study	ts: A Ra	andomized Controlled
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Bac Material//	kground: Methods:	lateral recumbent position, may reduc arachnoid puncture in spinal aesthesia This was a randomized controlled inter of age with hip fracture orthopedics bent position before surgery were enri- tal group, in which a lateral recumber noid puncture. In the control group, su The main outcome was the numbers of	ce the number of a before surger rventional study who were plan colled. The eligit t position with ubarachnoid pu of needle passes	elevated lateral recumbent position, compared to regular of needle passes and attempts required for success sub- y in elderly patients with hip fractures. y in Beijing Jishuitan Hospital. Patients older than 65 years ned to receive subarachnoid block in the lateral recum- ole patients were randomly allocated into the experimen- head and chest elevated 30° was taken during subarach- uncture was performed in the lateral recumbent position. s required for a success puncture. Other outcomes includ- tients reported discomfort score, and complications.
	Results:	sus 3.00, <i>P</i> =0.001) and the number of noid puncture were significantly less i perimental group also had lower disco	attempts (1.00 in the experime omfort scores. T	s in each group. The number of needle passes (2.00 ver- versus 2.00, P<0.001) required for a successful subarach- ental group than in the control group. Patients in the ex- he procedure process, including overall times needed for erences between the 2 groups. Complications were few
Con	clusions:	An elevated lateral recumbent position	-	barachnoid puncture in spinal anesthesia significantly re- ural puncture, and reduced discomfort in elderly patients
MeSH Ke	eywords:	Aged • Anesthesia, Spinal • Spinal I	Puncture	
Full-	text PDF:	https://www.medscimonit.com/abstra	<u> </u>	
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# Background

Hip fracture is a common disease among the elderly, with incidence rapidly increasing especially in Asian countries, resulting in significant economic burden [1]. Spinal anesthesia with subarachnoid puncture is required during surgery for hip joint replacement. However, difficulties in subarachnoid puncture are often encountered owing to lumbar stenosis, narrowing in the spinal canal space, and osteoporosis, which are common in the elder population [2,3]. In addition, hip fracture and pain may affect the body positions that are practical. Positioning for spinal anesthesia is of great importance in exposing a better route for subarachnoid puncture and enhancing the success of the procedure. Complications may also arise as a result of inappropriate position that affect accuracy of puncture process.

In comparison with the midline approach, the paramedian approach is an effective method to lower the difficulties caused by calcification of the interspinous ligament in puncture process. It has been reported to significantly reduce the number of punctures needed for success [2,3]. However, in pediatric patients, there was no reported difference in the success rate of lumbar puncture between the lateral and sitting positions [4]. In elder patients, paramedian lumbar puncture can avoid ligament calcification and interspinous ligament by inserting the needle into the epidural space or subarachnoid space through muscle tissue [2,3]. The paramedian path may considerably reduce the incidence of puncture injury and enhance the success rate of punctures, and may improve the success rate of puncture through the enlarged intervertebral space [5,6]. Few studies have assessed the impact of the lateral position on the success rate of the lumbar puncture [7,8]. Further information regarding the effect of the body position on the puncture success rate is needed.

We hypothesized that by raising the upper body of the patient by 30°, a lateral bending of coronal plane may increase the narrow interspinous and interlaminar spaces in elderly patients, and lower the difficulty of puncture through a paramedian approach resulting in increased success rate. A randomized controlled study was performed to evaluate whether this body position adjustment will increase the success rate of subarachnoid puncture in spinal anesthesia before surgery in elderly patients with hip fractures.

# **Material and Methods**

### Study design and participants

This was a prospective, single-center, randomized controlled study aiming to evaluate whether adjusting the patient position can increase the successful rate of subarachnoid puncture in spinal anesthesia. Elder patients with planned surgery for hip fracture who would undergo subarachnoid block were consecutively enrolled at Beijing Jishuitan Hospital, China, from September 2019 to October 2019. Inclusion criteria were as follows: age 65 years or older, with an American Society of Anesthesiologist (ASA) grade of I to III. Patients were excluded if they: refused participation, had spinal anesthesia contraindications (allergic to local anesthesia, coagulopathy, local infections, or uncertain neurological disorders), had spinal deformities, or had a history of spinal surgery; had a history of intravertebral surgery or scoliosis; were unable to complete the discomfort test due to speech communication disorder; had detected coagulation dysfunction; or switched to epidural anesthesia or general anesthesia before their procedure. Eligible patients were randomly allocated into either the experimental group in which the subarachnoid puncture was performed in a lateral recumbent position with the head and chest elevated 30° (elevated lateral position, ELP) or the control group in which a lateral recumbent position (LRP) was taken during subarachnoid puncture. The number of needle passes and attempts required for success puncture, successful rates, discomfort score, and complications were assessed and compared between the 2 groups.

The study was approved by the Institutional Review Board of the Research Institute of Beijing Jishuitan Hospital ASA Physical Status Classes (No. 201907-05) and registered on August 3, 2019, at the China Clinical Trial Registration Center (*http://www.chictr.org.cn/*) (registration number: chictr-1900024939). All patients signed informed consent before randomization.

#### Randomization

Patients were randomly divided using computer-generated numbers (Research Randomizer, version 4.0). Allocation was concealed by enclosing the codes in a sealed opaque envelope, which were exclusively opened by the attending anesthesiologist immediately before the operation.

#### Spinal anesthesia and surgery treatment

After patients entered the anesthesia preparation room, baseline monitoring (radial artery blood pressure, pulse oximetry, 3-lead electrocardiography) and the intravenous assess for fluid infusion were established. Ultrasound-guided fascia iliaca compartment block was performed with a portable ultrasound device (Wisonic Clover 60vet) equipped with a 5-1 MHz convex array probe, as previously described by Dolan et al. [9]. With an in-plane injection approach, a 22G 50-mm nerve block needle (Stimuplex®; D Plus, B Braun; Melsungen) was used to passing through the fascia iliaca, then 30 mL 0.4% ropivacaine was injected under the inguinal ligament, the junction of the sartorius muscle, and the diaphragm muscle.

**CLINICAL RESEARCH** 

Patients in the control group (LRP) were placed in the standard lateral recumbent position while given the subarachnoid block. Patients in the experimental groups (ELP) were placed in a lateral recumbent position with head and chest raised 30°. Ultrasound scans was performed to determine the position of the sacrum by the median transverse section, then gradually moved to the head end until the predetermined puncture gap was reached [10], then the midline of the lumbar space was marked on the skin. The puncture positioning process followed these steps: first, obtain paramedian sagittal oblique (PSO) images, determine the sacrum, and then move the probe to the side of the head to determine the interlayer gaps from L4/L5, L3/L4, and L2/L3. Second, the anterior complexes (anterior dura, posterior longitudinal ligament, and vertebral body) and posterior complexes (ligamentum flavum, epidural space, and posterior dura) in the spinal canal were identified by parasagittal ultrasound imaging [10]. After obtaining the clearest image, the puncture position was set 1 cm away from the midpoint of the long axis of the ultrasound probe at the tail side. Third, among the 3 lumbar intervertebral spaces, the space with the clearest lateral sagittal ultrasound imaging was selected as the first puncture space. Alternative puncture spaces at other intervertebral levels were also marked on the skin. Fourth, the PSO image quality was classified as good (visible post-complex and pre-complex), medium (a visible post-complex or pre-complex), or poor (neither the pre-complex nor postcomplex was visible) [5,11]. After skin marking and the distance measurement, ultrasonic gel was cleaned from the needle insertion site. A 25-gage Quincke bevel spinal needle (FORNIA Epidural-Spinal Combined anesthesia Kit; ZhuHai, China) was used for the subarachnoid puncture. When the puncture position was on the inner side (5-10°) and the hemispheric side (5-10°), the needle was punctured from the center line to the head side at an angle of 10–15°. After confirming the puncture was successful and the cerebrospinal fluid flowed out, 12 mg of 0.5% ropivacaine was administered. Fifteen minutes after the injection of the anesthetic, we evaluated the effect of anesthesia by observing the plane of the anesthesia block by testing for the loss of cold sensation with a sterile gauze. Surgery was performed as planned after successful subarachnoid block.

Strict aseptic techniques were used during the puncture process. Three anesthesiologists and attending anesthesiologists participated in each operation. All anesthesiologists participated in the study had at least 8 years experiences in spinal anesthesia with more than 100 cases of ultrasound spinal anesthesia scanning. Randomization was also used in allocation of the anesthesiologists to the 2 intervention groups.

#### Outcomes

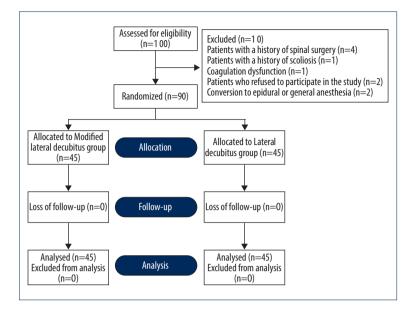
The primary outcome is the number of needle passes required for successful subarachnoid puncture. Success was defined as

clear puncture and backflow of cerebrospinal fluid. A needle pass was defined as each attemptive needle move including the initial insertion or a redirection (any change in the needle insertion trajectory that did not involve complete withdrawal of the needle from the skin). A puncture attempt was defined as the initial insertion move and each following needle insertion attempt preceded by complete withdrawal of the needle from the skin. Secondary outcomes included success rate of the first needle-pass during the first puncture attempt, time for identifying landmarks (time from the first placement of the probe on the skin to the completion of skin marking), time for spinal anesthesia procedure (the time from the first needle insertion to the completion of the intrathecal local anesthetic administration). Other secondary outcomes recorded included incidence of radicular pain, paresthesia, and blood in the spinal needle. The postoperative pain score (NRS) scale (0=no pain, 10=most pain conceivable) was used to measure pain after anesthesia [5]. Patient's satisfaction with the procedure were evaluated using a 1-5 discomfort score system: 1=no discomfort, 2=some discomfort, 3=discomfort, 4=very discomfort, and 5=worst discomfort imaginable [12]. Also included in the evaluation were levels of sensory block tested by the loss of cold sensation, anesthesia block plane, and the PSO image quality.

#### Statistical analysis

According to the results of small sample preliminary study with 15 patients in each group. The success rate of the first attempted puncture in the 2 groups was 80% and 53%. With a setting of the test power of 0.9, and  $\alpha$  of 0.05, a sample size of 45 for each group is needed.

All data analysis was performed using SPSS for Windows (version 22.0; IBM Corp., Armonk, New York, USA). Normality of continuous data were tested using the Kolmogorov-Smirnov test. Normal distributed data were presented as mean±standard deviations (SD), and a *t*-test was used to determine the differences between the 2 groups. Non-normally distributed data were presented as median (P25–P75), and Wilcoxon sum rank test was used to determine the differences between the groups. Categorical data were presented as frequency (percentage), and the chi-square or Fisher's exact test was used to determine the differences interval (CI) of the difference between the success rates of the 2 groups was estimated. The relative risk of binary outcomes was presented with a 95% CI. All tests were 2-tailed, with a *P* value <0.05 considered as statistically significant.



## Results

#### **Baseline characteristics of patients**

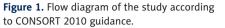
A total of 100 patients were screened with 90 patients eligible and who completed the study (Figure 1). The baseline characteristics of the 2 groups of patients are shown in Table 1. There were no obvious differences in the baseline characteristics between the 2 groups of patients, including demographic characteristics, types of fracture and surgery, and overall health status measured with ASA score.

#### The anesthesia characteristics

Characteristics of anesthesia were compared between the 2 groups, as shown in Table 2. Patients in the 2 groups received the similar doses of intrathecal ropivacaine ( $11.38\pm0.38$  mg versus  $11.36\pm0.36$  mg, P=0.899). The interspace levels and peak sensory dermatome levels used for subarachnoid puncture were with no significant differences between the 2 groups. There was no significant difference between the 2 groups of patients in the anesthesia plane and the spinal canal puncture point after ultrasound identification, indicated by distance from the midline to paramedian needle insertion point ( $1.28\pm0.28$  cm versus  $1.23\pm0.23$  cm, P=0.265), and the depth of the intrathecal space ( $5.51\pm1.51$  cm versus  $5.00\pm1.00$  cm, P=0.125).

# Effect of elevated lateral position on procedure performance

As shown in Table 3, the number of needle passes required for a successful subarachnoid puncture (2.00 versus 3.00, P=0.001) was significantly different between the experimental group and the control group, as well as the numbers of attempts required



(1.00 versus 2.00, P<0.001). The successful rates of subarachnoid puncture at the first pass (48.9% versus 24.4%, P=0.016), at the first attempt (73.3% versus 37.8%, P=0.001), as well as the success rates within 2 passes (80.0% versus 48.9%, P=0.002) and 2 attempts (97.8% versus 82.2%, P=0.030). There were no significant differences in times for identifying landmarks (232.1±45.5 seconds versus 225.4±64.0 seconds, P=0.564), time for spinal anesthesia (271.7+110.5 seconds versus 284.3+126.2 seconds. P=0.617), or total procedure time (503.9±124.3 seconds versus 509.6±141.6 seconds P=0.838). The postoperative pain scores (NRS) were not different between the 2 groups (2.42±1.22 versus 2.62±1.09, P=0.414) between the 2 groups. The satisfactions of patients were estimated with a discomfort score, and the results showed that discomfort levels reported by the patients in the experimental group was significantly lower than that of the control group (2.89±1.05 versus 3.36±0.91, P=0.027).

## Procedure complications and ultrasound development quality

There were no significant differences between the 2 groups in terms of paresthesia, radicular pain, bloody tap, or conversion to the midline approach (Table 4). Furthermore, there was no significant difference in quality of ultrasound views between the 2 groups (Table 5).

# Discussion

For elderly patients with hip fractures, spinal degeneration, and changes in the spinal canal structure may cause difficulty in performing the subarachnoid puncture, which poses a challenge to clinical spinal anesthesia. This was the first randomized controlled study to compare the effects of different

# Table 1. Baseline characteristics of patients.

Characteristics		iental (ELP) I=45		ol (LRP) =45	<b>t/</b> χ²	<i>P</i> -value
Age (years)	80.6±7.3		79.7±7.2		0.570	0.570
Weight (kg)	62.2 <u>+</u> 4.9		62.7±5.4		-0.274	0.785
Height (cm)	164.4±8.1		164.8±8.0		-0.427	0.671
BMI (kg/m²)	23.2±2.6		23.1±2.1		0.054	0.957
Gender						
Male	10	(22.22)	10	(22.22)	0.000	1.000
Female	35	(77.78)	35	(77.78)	0.000	
Type of fracture						
Femoral fracture	31	(68.89)	29	(64.44)	0.200	0.655
Intertrochanteric fractures	14	(31.11)	16	(35.56)	0.200	
Type of surgery						
Intramedullary nail internal fixation	31	(68.89)	29	(64.44)		
Hollow nail internal fixation	6	(13.33)	9	(20.00)		0.627
Total hip replacement	0	(0.00)	1	(2.22)	-	0.627
Half hip replacement	8	(8.89)	6	(13.33)		
ASA						
I	4	(8.89)	2	(4.44)		
ll	26	(57.78)	26	(57.78)	-	0.756
	15	(33.33)	17	(37.78)		

ELP – elevated lateral position with head and chest elevated 30°; LRP – lateral recumbent position; BMI – body mass index; ASA – American Society of Anesthesiologist.

Table 2. The anesthesia characteristics between the 2 groups.

	Experimental (ELP) N=45	Control (LRP) N=45	<b>t/</b> χ²	<i>P</i> -value
Dose of intrathecal ropivacaine (mg)	11.38±0.38	11.36±0.36	0.127	0.899
Distance from midline to paramedian needle insertion point (cm)	1.28±0.28	1.23±0.23	1.122	0.265
Depth of intrathecal space (cm)	5.51±1.51	5.00±1.00	1.550	0.125
Interspace level used for dural puncture, n (%)				
L2/3	7 (15.56)	10 (22.22)		
L3/4	21 (46.67)	19 (42.22)	0.660	0.719
L4~L5	17 (37.78)	16 (26.67)	-	
Peak sensory dermatome level, n (%)				
T8 to T10	14 (31.11)	28 (31.11)	0.000	1.000
T10 to T12	31 (68.89)	62 (68.89)	0.000	1.000

ELP – elevated lateral recumbent position with head and chest elevated 30°; LRP – lateral recumbent position.

Table 3. Comparisons of outcomes between the 2 positions spinal anesthesia.

	Experimental (ELP) N=45	Control (LRP) N=45	<b>Ζ/t/</b> χ²	<i>P</i> -value
Number of passes, Median (P25–P75)	2.00 (1.00~2.00)	3.00 (2.00~3.00)	3.197	0.001
Number of attempts, Median (P25–P75)	1.00 (1.00~2.00)	2.00 (1.00~2.00)	3.597	<0.001
Successful dural puncture at the first pass, n (%)	22 (48.9)	11 (24.4)	5.789	0.016
Successful dural puncture within 2 passes, n (%)	36 (80.0)	22 (48.9)	9.504	0.002
Successful dural puncture at the first attempt, n (%)	33 (73.3)	17 (37.8)	11.520	0.001
Successful dural puncture within 2 attempts, n (%)	44 (97.8)	37 (82.2)	-	0.030
Time for identifying landmarks (s), mean±SD	232.1±45.5	225.4 <u>+</u> 64.0	0.579	0.564
Time for spinal anesthesia (s), mean±SD	271.7±110.5	284.3±126.2	0.501	0.617
Total procedure time (s), mean±SD	503.9±124.3	509.6±141.6	0.205	0.838
Postoperative pain score (NRS), mean±SD	2.42±1.22	2.62±1.09	0.821	0.414
Discomfort score, mean±SD	2.89±1.05	3.36±0.91	2.256	0.027

ELP – elevated lateral recumbent position with head and chest elevated 30°; LRP – lateral recumbent position; SD – standard deviation.

Table 4. Procedure complications.

	Experimental (ELP) N=45	Control (LRP) N=45	Relative risk  (95% CI)	χ²	<i>P</i> -value
Paresthesia, n (%)	6 (13.33)	5 (11.11)	1.114 (0.563~2.205)	0.104	0.748
Radicular pain, n (%)	2 (4.44)	3 (6.67)	0.824 (0.390~1.739)	-	1.000
Bloody tap, n (%)	2 (4.44)	4 (8.89)	0.732 (0.399~1.343)	-	0.677
Conversion to midline approach, n (%)	0 (0.00)	0 (0.00)	-	-	-

ELP – elevated lateral recumbent position with head and chest elevated 30°; LRP – lateral recumbent position; CI – confidence interval.

Table 5. Ultrasound imaging quality.

		Experimental (ELP) N=45		rol (LRP) I=45	<i>P</i> -value	
PSO, n (%)						
Good	36	(80.00)	33	(73.33)		
Intermediate	8	(17.78)	10	(22.22)	0.701	
Poor		(2.22)	2	(4.44)		
TM, n (%)						
Good		(84.44)		(73.33)		
Intermediate		(13.33)	10	(22.22)	0.454	
Poor	1	(2.22)	2	(4.44)	-	

ELP – up-tilted lateral recumbent position with head and chest elevated 30°; LRP – lateral recumbent position; PSO – paramedian sagittal oblique; TM – transverse median view.

This work is licensed under Creative Common Attribution-NonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0) lateral body positions on the success of subarachnoid puncture in spinal aesthesia during surgery of hip fractures. The study found that compared to regular lateral recumbent position, that raising the lateral supine position by having the patient lie on their side with head and chest elevated at a 30° angle with a cushion supporting the affected limb to reduce displacement can effectively improve the success rate of paramedian approach subarachnoid puncture and reduced discomfort.

Since the hip fracture surgeries take 30 to 90 minutes, a single 0.5% ropivacaine subarachnoid anesthesia time was sufficient to meet the needs of completing the operation. Therefore, we used a single spinal needle puncture during the study. In addition, spinal anesthesia could effectively reduce the bleeding caused by the epidural needle puncture and the damage and pain involved in the puncture process.

In a previous study, Rabinowitz et al. compared the effects of the mid-median puncture and median access puncture in elderly patients; they found that the mid-median puncture significantly improved the success rate of the first attempt (85% versus 45%) [13]. The success rates observed were much higher than those in this study. It should be pointed out that a 19-gauge Tuohy needle was used to puncture in the aforementioned previous study. While in our study, a 25-gauge spinal anesthesia needle was used, which has a much smaller diameter that helps to reduce damage during the puncture. However, it was more difficult to change the direction during the puncture process due to the softness of the slimmer needle. Therefore, compared with the results of Rabinowitz et al. research, the success rate of our first attempt was lower. Due to this difficulty to change direction during puncture, it is important to plan the accurate position and angle of puncture before the procedure to reduce potential damage caused by an unsuccessful attempt.

Some studies have shown that an ultrasound pretreatment may increase the success rate of a puncture [14,15] and improve the satisfaction of the overall puncture process [16]. In this study, we used ultrasound to identify the gaps and chose them as the preferred puncture points. Compared with the median approach, the paramedian approach effectively avoided the calcification of the superior spinal ligament and interspinous ligament [13,17]. The slim and soft needle is difficult to track after entering the tissue [18]. Therefore, a beforehand ultrasound-guided positioning was used instead of a real-time guidance approach in this study. After insertion into the tissue, the needle was pushed on the tail along the pre-planned angle.

In this study, the patient's upper body was raised to increase the intervertebral space of on the coronal plane. The increased intervertebral space was positioned by ultrasound, thereby effectively increasing the success rate of the lateral puncture. In addition, since the fracture site of the patient was located on the upper side of the lateral position, by increasing the slope of the lateral lying position, the hip fracture displacement and the pain caused by the fracture displacement may be reduced during the spinal canal anesthesia, and the patient's comfort during the operation could be improved. This allowed patients to better cooperate with changes to the body's position throughout the puncture process. While during the routine puncture with a lateral recumbent position, the patient's head was less likely to rise, resulting in discomfort. Although the NRS evaluation did not show difference in postoperative pain, the comparison of the 2 positions found that patients preferred to raise the angle of the lateral lying position, which were considered more comfortable. It should be pointed out that the baseline pain status may have confounded the postoperative NRS scores. The pain scores before and during the surgery would have provided further information on the differences of anesthesia effects between the 2 groups, however, it was missed in the study design. Nonetheless, as the main purpose of the study was to evaluate the dural puncture process, these missing data may not change the general conclusion of the study.

No significant differences in the times for identifying landmarks, times for overall anesthesia process and total procedure were detected between the 2 groups. These results indicated that different recumbent positions had no significant effect on the overall process time of hip fracture surgery.

There were some limitations of this study. First, this study used ultrasound imaging to determine the puncture gap in patients but did not analyze the length of the anterior complex and posterior complex in different positions. This was done as it is difficult to distinguish the length of the anterior complex and posterior complex in elderly patients, and with varying angles of observation, there may be differences between the data of the anterior complex and posterior complex. In contrast, the adequate visualization of the posterior complex (ligamentum flavum and dura mater) and the anterior complex (posterior longitudinal ligament and vertebral body) can be difficult in obese patients and older patients with narrowed interspinous and interlaminar spaces. Second, we did not use real-time guided punctures in our study since real-time guided punctures would increase the difficulty of the operation [19]. Third, this study excluded patients with ankylosing spondylitis and lumbar spine surgery as it is difficult for these patients to be in the elevated lateral position to increase the widening of the coronary intervertebral space. Fourth, we used ultrasound imaging to measure the acoustic window of the patient. Although it was difficult to obtain evidence that the elevated lateral position widens the patient's ultrasound imaging window, this experiment did prove that elevated lateral position may increase the puncture success rate.

# Conclusions

Elevating the patient's position when conducting a paramedian approach subarachnoid puncture in elderly patients with hip fractures significantly reduced the number of needle passes needed for success and to reduced discomfort. These study results indicate that the correct posture may increase the effectiveness of the puncture and improve the comfort of elderly patients during spinal anesthesia, making this finding worthy of clinical promotion.

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#### **Conflicts of interest**

None.

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