A COMPARISON OF SPINAL ANAESTHESIA WITH LEVOBUPIVACAINE AND HYPERBARIC BUPIVACAINE COMBINED WITH FENTANYL IN CAESAREAN SECTION

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ABSTRACT

BACKGROUND

Recent trends in obstetric anaesthesia show increased popularity of regional anaesthesia among obstetric anaesthetists. General anaesthesia in caesarean section is associated with high morbidity and mortality rate when compared with regional anaesthesia. Regional anaesthesia has its own demerits which are primarily related to excessively high spinal blocks and toxicity of local anaesthetics. Reduction in doses and improvement in technique to avoid high level blocks and increased awareness of toxicity of local anaesthetics have contributed to reduction in complications related to regional anaesthesia. The challenges presented by a parturient requiring anaesthesia or analgesia, or both, make the role of obstetric anaesthesiologist both challenging and rewarding. Spinal anesthesia is a popular technique for caesarean delivery. Hyperbaric Bupivacaine in 8% glucose is often used. Plain or glucose-free, Bupivacaine has been frequently referred to as "Isobaric" in the literature, even after Blomqvist and Nilsson demonstrated its hypobaricity. More recently, several studies have confirmed that plain Bupivacaine is indeed hypobaric in comparison with human CSF. Although hyperbaric local anesthetic solutions have a remarkable record of safety, their use is not totally without risk. To prevent unilateral or saddle blocks, patients should move from the lateral or sitting position rapidly to supine position. Hyperbaric solutions may cause sudden cardiac arrest after spinal anesthesia because of the extension of the sympathetic block. The use of truly isobaric solutions may prove less sensitive to position issues. Hyperbaric solutions may cause hypotension or bradycardia after mobilization. Isobaric solutions are favored with respect to their less sensitivity to postural changes.

MATERIALS AND METHODS

60 full term parturients of ASA Grade 1 and 2 posted for elective caesarean section under spinal anaesthesia were divided in to two groups.

GROUP LF (n = 30) – Received 1.8 ml (9 mg) Levobupivacaine 0.5% + Fentanyl 10 mcg (0.2 ml).
GROUP BF (n = 30) – Received 1.8 ml (9 mg) hyperbaric Bupivacaine 0.5% + Fentanyl 10 mcg (0.2 ml). The parameters measured in the two groups included haemodynamic measurements (Pulse rate, systolic blood pressure, diastolic blood pressure), respiratory parameters (Respiratory rate, oxygen saturation) characteristics of sensory block, characteristics of motor block, intra operative and post-operative complications like nausea, vomiting, shivering, visceral pain, sedation. In the neonate, Apgar score was measured to assess any effects of drugs the neonate.

RESULTS

Hypotension and bradycardia was more in hyperbaric Bupivacaine group (BF). Time for Onset of sensory block and maximum dermatome level reached were similar in both groups. Time for maximum sensory level reached, two segment regression time, T12 regression time and time for first analgesic requirement were early in LF group. Onset of motor block was delayed in LF group. Maximum degree of motor block was same in both groups (Bromage 3). Complete regression of motor block was significantly lower in Levobupivacaine group (LF). Intra operative incidence of nausea and vomiting were comparatively lower in LF group. Complications like respiratory depression, headache, back ache, and pruritus were not seen in both groups. Neonatal Apgar score was similar in all neonates. We recorded APGAR scores of 7 - 10 at 1 and 5 minutes in both groups. No significant postoperative complications were seen both the groups.

CONCLUSIONS

From present study findings and correlating it to the previous studies and literature plain Levobupivacaine 0.5% which is pure s - enantiomer of Bupivacaine is a good alternative for caesarean section in spinal anesthesia as it is less CVS and CNS toxic, early recovery of motor blockade leading to early mobilization of the mother, analgesia almost similar to racemic hyperbaric Bupivacaine. Addition of low dose Fentanyl 10 mcg with Levobupivacaine has dose sparing effect of opioids on local anesthetics, better postoperative analgesia and early recovery from motor block. However if using low dose Levobupivacaine +along with Fentanyl, it is advised to go for combined spinal epidural technique. Action of isobaric Levobupivacaine is independent on gravity in spinal anesthesia.

KEYWORDS

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BACKGROUND

Recent trends in obstetric anaesthesia show increased popularity of regional anaesthesia among obstetric anaesthetists. General anaesthesia in caesarean section is associated with high morbidity and mortality rate when compared with regional anaesthesia. Regional anaesthesia has its own demerits which are primarily related to excessively high spinal blocks and toxicity of local anaesthetics. Reduction in doses and improvement in technique to avoid high level blocks and increased awareness of toxicity of local anaesthetics have contributed to reduction in complications related to regional anaesthesia.

Increased lordosis during pregnancy causes difficulty in opening up lumbar inter-spaces and softening of ligaments facilitates easy introduction of the spinal needle into the subarachnoid space. Engorgement of epidural vessels reduces the epidural space and indirectly the intrathecal space. Inferior vena cava compression by the gravid uterus causes extradural venous engorgement which reduces lumbar cerebrospinal fluid volume. Therefore the drug requirement is reduced for spinal and epidural anaesthesia. Local anesthetic dose is decreased by as much as 30%. Smaller doses of local anesthetic spread to higher segmental levels. Sedative effect of progesterone, increased levels of endogenous opiates and great sensitivity of the nerve fibers to local anesthetics all lead to additional decrease in drug requirement.

AIMS AND OBJECTIVES

The aim of the study is to evaluate following factors when Levobupivacaine 0.5% 9 mg+ 10 mcg Fentanyl and hyperbaric Bupivacaine 0.5% 9 mg + 10 mcg Fentanyl given intrathecally in elective caesarean section.

The objectives are to evaluate the following parameters; Onset and duration of sensory block, Onset and duration of motor block, Intra operative hemodynamic changes, Post-operative analgesia & adverse effects.

MATERIALS AND METHODS

The study group comprised of 60 term parturient women with singleton pregnancy of ASA Grade I between the age groups of 20 – 30 yrs. admitted in King George Government Hospital, Visakhapatnam between May 2012 to April 2013 scheduled to undergo elective caesarean section under spinal anaesthesia for various indications like cephalopelvic disproportion, breech presentation, repeat caesarean section etc. After approval from the hospital ethical committee and taking written, informed consent.

They were randomized to one of the two groups of equal sized prospective, comparative study group using an open protocol design to receive:

Group BF: 1.8 ml of 0.5% hyperbaric Bupivacaine + 10 µgm of Fentanyl intrathecally - 30 cases.

Group LF: 1.8 ml of 0.5% Levobupivacaine + 10 µgm of Fentanyl Intrathecally - 30 cases.

Patients in group BF received 1.8 ml (9 mg) of 0.5% Hyperbaric Bupivacaine and 10 µgm of Fentanyl intrathecally, group LF received 1.8 ml (9 mg) of 0.5% Levobupivacaine and 0.2 ml (10 µg) of Fentanyl intrathecally. Routine pre-anesthetic checkup of all the mothers was done to exclude co-existing medical conditions and complications of pregnancy and to assess airway and spine. Patients with allergic reaction to any of the study drugs and any systemic disease were not included in the study. Routine investigations like hemoglobin%, blood group and typing, urine examination etc., were done and all the mothers within the normal haematological and urological parameters were taken up for the study.

Technique

The parturient was placed in the left lateral position. The skin over the back was thoroughly prepared with Savlon, spirit and draped with sterile towel. A 25G Quincke spinal needle was introduced into the $L_3 – L_4$ intervertebral space gently in the midline until it reached the subarachnoid space. The position of the needle in the subarachnoid space was confirmed by free flow of cerebrospinal fluid through the needle. After aspirating 0.2 ml of cerebrospinal fluid into the syringe, the study drug 1.8 ml of 0.5% Hyperbaric Bupivacaine with 0.2 ml (10 µgm) of Fentanyl to BF group and 1.8 ml of 0.5% Levobupivacaine with 0.2 ml (10 µg) of Fentanyl to LF group was injected into the subarachnoid space slowly at the rate of 0.25 ml/sec. with the bevel cephalad. The needle was withdrawn and the patient turned supine with the left tilt by placing a wedge under the right hip. 100% oxygen via face mask (at the rate of 4 L/min) was administered till the delivery of the baby. Cardiac and respiratory parameters were monitored and assessment of level of sensory and motor blockade was recorded at regular intervals. Injection Mephentermine (3-6 mg) IV was administered when necessary to maintain the systolic blood pressure at or above 90 mmHg. The degree of sedation was recorded as per Ramsey Scale. Blood pressure was monitored at 2 minute intervals and recorded. Pulse rate and oxygen saturation were monitored with pulse oximeter. Other parameters like assessment of sensory blockade and motor blockade were noted. Dermatomal sensory block was recorded every 15 second until maximum dermatome level was reached. The height of the block was recorded again 30 minutes following institution of subarachnoid block. The sensory blockade was identified by the loss of sensation to pinprick, subjectively with 23G IM needle. The onset of sensory block and the height of the block were noted and recorded. Duration of the blockade was noted as follows.

The time from onset of sensory loss at T_6 dermatome level to bilateral regression of sensory block to T 12 segment. Assessment of degree or intensity of sensory block was done using Visual Analogue Scale Score on a 10 cm scale. Motor blockade in the lower limbs was assessed subjectively by asking the patient to move the lower limbs and was noted as follows according to the Modified Bromage scale. Assessment of sedation was done using Ramsay Scale. During surgery incidence of drowsiness, shivering, nausea and vomiting were recorded by direct questioning at regular intervals and symptomatic treatment given. Baby delivery time was noted. After delivery of the shoulder synthetic oxytocin was added to the IV fluids and oxygen was discontinued. Assessment of the new born was done using Apgar score at one and five minutes. The birth weight was noted. The side effects recorded during and after surgery were, Nausea and vomiting, Hypotension, Bradycardia, Drowsiness, Pruritus, Shivering, Respiratory depression, Post dural puncture headache, Urinary retention. The following parameters were compared in two groups and results subjected to appropriate statistical analysis: Hemodynamic changes in mother, Sensory and motor block characteristics, Complications intraoperative and postoperative, fetal assessment by APGAR scores.

Inclusion Criteria

Term gestation, ASA 1 and 2, Age 20 years to 30 years, Single live fetus.

Exclusion criteria

Multiple pregnancy, Pregnancy induced hypertension. Placenta previa, Antenatal patients with acute fetal distress, Patients with previous abdominal surgeries and Body weight >80 kg.

RESULTS

The results and statistical analysis of the study presented below were analyzed using descriptive analysis and student‘s t-test. All the patients were full term parturients who underwent elective caesarean section. The demographic factors of Levobupivacaine group (LF) were, mean age 23.45 yrs. mean height 154.8 cms., mean weight 61.96 kgs. and haemoglobin mean 10.95 gm/dl and hyperbaric Bupivacaine group (BF) were, mean age 25.28 yrs. mean height 154.19 yrs. mean weight 62.35 kgs. and mean hemoglobin 10.23 mg/dl respectively were depicted in Table 1. The data in two groups was almost similar (Table 1).

Data	Group LF	Group BF
AGE (Years)	23.45±2.804	25.28±2.79
Height (cms.)	154.8+23.2	154.19+23.2
Weight (kgs.)	61.96+7.43	62.35+8.03
Haemoglobin% (gm/dl)	10.95+3.58	10.23+0.78

Table 1. Demographic Factors (Mean±SD)

There was significant difference between two groups at 2, 4, 6, 8, 10 minutes ($p<0.05$) where group BF mean pulse rate decreased and it was less than group LF, but from 15 minutes pulse rate stabilized and there was no significant difference (Table 2).

Minutes	Group – LF	Group – BF	P value
0	88.73±10.03	86.90+6.77	0.469
2	91.13±11.25	83.37±7.069	0.002
4	89.37±11.10	80.03±17.69	0.017
6	86.03±13.59	78±16.53	0.045
8	81.40±9.97	75.23+16.4	0.085
10	80±6.67	76.06±4.78	0.003
15	87.07±13.3	85.03±14.95	0.578
30	88.87±7.8	88.33±11.5	0.835
45	89.43±6.46	85.8±8.3	0.064
60	89.37±5.75	85.80±8.31	0.058
120	86.00±3.80	84.80±7.09	0.065
180	91.93±3.96	89.93±6.88	0.067

Table 2. Pulse rate (Mean+SD) and t – test for samples

Preoperatively the mean SBP in the LF group was 117 mmHg which dropped to 98.5 mmHg at 6 minutes after neuraxial block and gradually stabilized and returned to 118 mmHg at 180 minutes, whereas in group BF the preoperative SBP was 114 mmHg which dropped to 97.8 mmHg at 10 min and then reached preoperative levels and remained constant. There was significant difference in both groups ($p<0.05$) at 4, 8, 10 minutes respectively (Table 3).

Minutes	Group LF (n=30)	Group BF (n=30)	P value
Pre-op	117.4±9.35	114±6.25	p = 0.09
2	112.13±8.18	106.5±13.4	p = 0.055
4	107.5±9.5	99.3±16.45	p = 0.022
6	98.50±11.43	100.2±11.36	p = 0.565
8	104.86±11.46	98.70±10.4	p =0.035
10	109.37±9.13	97.8±4.3	p =0.000
15	108.21±9.147	108±8.75	p =0.952
30	109.53+8.076	112±5.83	p =0.180
45	112.33±6.51	113.5±4.57	p > 0.05
60	113.07±5.98	113.5±4.57	p =0.754
120	115.00±5.09	112.00±6.10	p > 0.05
180	118.33±5.92	117.00±4.66	p > 0.05

Table 3. Systolic blood pressure (Mean±SD)

The mean DBP values in two groups LF and BF along with the t–test values for each at given time intervals showed no significant difference in both groups. The mean pre-operative DBP in group was 72.37 which remained almost constant without much fall throughout the period whereas in group BF mean pre-operative DBP was 73.3 mmHg which came down 62.17 at 6 min, then slowly increased to 64.73 at 8 min, 66.43 at 10 min then reached preoperative levels and remained constant (Table 4).

Minutes	Group LF (n=30)	Group BF (n=30)	T test
Pre-op	72.37±8.7	73.33±5.4	P>0.05
2	68.89±8.8	69.00±11.2	p>0.05
4	69.43±9.39	67.47± 15.7	p>0.05
6	68.60±9.02	62.17±9.6	p>0.05
8	66.03±10.12	64.73±12.22	p>0.05
10	70.57±0.0	66.43±9.28	p>0.05
15	69.20 ±8.56	71.17±9.2	p>0.05
30	74.07±6.19	73.57±5.59	p>0.05
45	71.93±7.196	76.33±4.90	p>0.05
60	73.80±7.5	76.3±4.9	p>0.05
120	74.33±5.04	74.67±5.71	p>0.05
180	77.67±5.04	75.33±5.71	p>0.05

Table 4. Diastolic Blood Pressure (Mean ±SD)

The characteristics of sensory blockade in two groups LF and BF and their respective p values were studied. The maximum sensory dermatome level reached was same in both groups T4-6. The onset of sensory block was similar in both groups (p>0.05). The time taken for sensory block to reach maximum level was shorter in group LF 5.85 min than BF (p<0.05). The time to regression by two dermatomes for the sensory block and its regression time to T12 were longer in group BF. Time for first analgesic requirement was 141.5 minutes in LF group and 159.3 minutes in BF group which was statistically significant (p<0.05) (Table 5).

Parameters	Group LF (n=30)	Group BF (n=30)	LF vs. BF (P value)
Height of the Block	T4-T6	T4-T6	P > 0.05
Onset (min)	2+0.5	1.40±0.6	P > 0.05
Time for max level	5.85+0.89	6.78+0.95	0.000*
2 Seg. Regression (min)	80.26±7.30	85.5±9.85	0.023*
T12 Seg. Regression (min)	127.13±8.93	139.96±13.17	0.000*
1st analgesic requirement (min)	141.5±10.38	159.3±14.30	0.000*

Table 5. Characteristics of Sensory Blockade (Mean±S.D) and t-test

The onset of motor block Group LF was 6.32 minutes and Group BF was 4.89 minutes. The difference is statistically significant (p<0.05) among the both groups. The duration of motor block was 96.56 minutes in Group LF and 152.26 minutes in Group BF. The difference is statistically significant (p<0.05) among both groups (Table 6).

Parameters	Group LF (n=30)	Group BF (n=30)	P value
Degree of blockade	Grade 3	Grade 3	>0.05
Onset of motor block (min)	6.32±1.17	4.89±1.29	0.000*
Duration of motor block (min)	96.56±11.66	152.26±15.9	0.000*

Table 6. Characteristics of Motor Block (Mean±S.D)

6 patients in Group LF and 12 patients in Group BF developed hypotension during the surgery which was treated with 3-6 mg mephentermine and intravenous fluids. The incidence of hypotension was statistically significant (p <0.05) among the two groups. Bradycardia was defined as heart rate below 50 per minute 1 patient in group LF and 7 patients of group BF were seen with bradycardia which was treated with single dose of 0.5 mg atropine iv (Table 7).

Parameters	Group LF (n=30)	Group BF (n=30)
Nausea/Vomiting	3 (10%)	7 (23.34%)
Bradycardia	1 (3.37%)	7 (23.4%)
Hypotension	6 (20%)	12 (40%)
Sedation	25 (83%)	26 (86%)
Respiratory depression	-	-

Table 7. Incidence of side effects – Intraoperative (No. & %)

25 patients in Group LF and 26 patients in Group BF experienced sedation of Grad. III (Ramsey Scale).

DISCUSSION

Plain Levobupivacaine has been shown to be truly isobaric to CSF of pregnant women and its use in this setting may therefore offer special advantages because this property may translate to a more predictable spread.[1,2] The spread of isobaric Levobupivacaine in spinal anaesthesia is not dependent on gravity. Fentanyl, a lipophilic opioid in small doses added to local anaesthetics during sub arachnoid block produces a more rapid onset, surgical block of better quality (than local anaesthetics alone) and leads to more rapid recovery of motor function which then allows a quicker discharge post-surgery.[3,4,5,6,7,8] Choi et al reported that the combination of 8 mg Bupivacaine and 10 mcg Fentanyl is as efficient as 12 mg of hyperbaric Bupivacaine.[9] Incidence of bradycardia was comparable with study by Gulen Guler et al (n=30), in their study showed an incidence of bradycardia of 6.67% (2 cases) in LF group and 30% (9 cases) in BF group. [10] A study by Dilek Subasi et al in 2012 demonstrated an incidence of bradycardia that was different and it was 35% in LF group and 16% in BF group, it may be due to the use of hyperbaric levobupivacaine in their study and their criteria for bradycardia.[11] Hypotension is the most common

complication in the spinal anaesthesia.[9] It is known that besides its effects on the mother, it causes acidosis by altering uteroplacental perfusion. Administering hydration using crystalloid or colloid before spinal anaesthesia has proven insufficient.[12,13,14]

A study by Dimarzio G et al 2011 there was higher incidence of hypotension in group B (Bupivacaine). Diastolic blood pressure suffered a great reduction 3 minutes after injection of local anesthetic, in 7 patients of group B there was marked hypotension with placenta hypoperfusion and fetal acidosis without significant impact on 1 minute and 5 minute APGAR score.[15] In present study the incidence of hypotension was 5 cases (16.67%) in LF group and 40% (12 cases) in BF group which was treated with doses of mephentermine 3-6 mg. The less incidence of hypotension in LF group can be attributed to the isobaricity of plain levobupivacaine which causes less sympathetic block level and is less sensitive to postural changes when compared to hyperbaric Bupivacaine group (BF) preventing cephalad spread of drug while positioning the patient leading to higher blockade. The time for maximum sensory block was shorter in LF group (5.85 min) than BF group (6.78 min) which was statistically significant ($p<0.05$) and was similar to the study by Gulen Guler et al 2012.[10] where the time taken for sensory block to reach maximum level was shorter in LF group (11.96 min) than BF group (13.16 min).[10] The time for two segment regression of sensory dermatome was 80.26 minutes in group LF and 85.5 minutes in group BF which was statistically significant which means the 2 segment regression time is longer in BF group. In a study by Dilek Subasi et al 2012 there was no significant difference between two segment regression time in both groups ($p>0.05$) with mean 2 segment regression time being 89.95 minutes in LF group and 82.74 minutes in BF group this may be due to use of hyperbaric Levobupivacaine and hyperbaric Bupivacaine as compared to isobaric Levobupivacaine in our study.[11] In a study by Prabha P et al the time for regression of sensory block to below L1 was 211 minutes in group L (Levobupivacaine) and 183 minutes in group B (Bupivacaine) which is statistically significant indicating prolonged surgical analgesia in group L.[16] A study by Dilek SUBASI et al the time for motor block onset was 2.25 minutes in LF group and 1.45 minutes in BF group without significant statistical difference ($p>0.05$). This may be due to the difference in baricity of Levobupivacaine which was hyperbaric.[11] The Degree of motor block in this study was grade 3 as per modified Bromage scale by the end of10 minutes in both groups in all patients, this was similar to study by Guler et al Gulen where complete motor block was obtained within 20 minutes in every patient in both groups (Bromage 3.[10] In contrast, study by Prabha P et al maximum motor block was Bromage 3 in group BF whereas only 12 of 20 (60%) in group LF had Bromage 3 motor block and 8 (40%) had Bromage 2 which was statistically significant between both groups ($p<0.05$).[16] In present study the mean regression of motor block time was 96.56 minutes in group LF and 152.26 minutes in group BF which was statistically significant, similar results were seen with Gulen Guler et al & Prabha P et al.[10,16] The effects of baricity on block characteristics have been contradictory in literature, while some studies that report the difference in baricity does not affect the block characteristics, on the other hand there are also studies reporting that motor block develops and disappears faster when hypobaric solutions are used.[17,18] Therefore we cannot ascribe the difference of sensory and motor block between the two groups in our study to the difference of baricity only. Intra operative complications encountered in present study were hypotension which was defined as fall in systolic or diastolic blood pressure to more than 25% from baseline, totally in our study there were 5 cases (16.67%) in LF group and 12 cases (40%) in BF group which was statistically significant ($p<0.05$). Titti et al reported that rate of occurrence of hypotension was 62% in elective caesarean operations in which they administered 2.5 ml of 0.5% Bupivacaine, we believe that difference in our results were due to the fact that we decreased the dose of local anaesthetic (9 mg) and added Fentanyl (10 mcg).[19] In a study conducted by Bremerich DH et al 2007 for a dose finding investigation they concluded that 10 mg of Levobupivacaine is recommended for parturients undergoing elective caesarean section under spinal anaesthesia.[20] We took 9 mg and added 10 mcg Fentanyl which reduces the local anaesthetic dose required, hastens the onset of block, provides good analgesia and promotes early motor recovery. Gunusen et al have compared different doses of Levobupivacaine Fentanyl combination in caesarean section and reported that 10 mg Levobupivacaine with 10 mcg Fentanyl combination provides 100% effective anesthesia but incidence of hypotension was high. The higher incidence of hypotension rates reported by them may be related to the difference in the definition of hypotension between studies, while they considered 20% reduction SBP from baseline values as hypotension we accepted the 25% decline as hypotension.[21] Coppejans H C, Vercauteren in their study compared effects of spinal Levobupivacaine with Bupivacaine for caesarean section and found lower incidence of hypotension with the S-enantiomer Levobupivacaine.[22] A Study by Belzarena HD1992 concluded that Combination of Bupivacaine and a low dose of Fentanyl (25 µg) provided excellent surgical anaesthesia with no change in APGAR scores and long lasting postoperative analgesia and very few negative side effects.[23] In the present study there was no postoperative complications like hypotension, headache, PDPH, backache in both groups. NK Girgin et al in 2008 and DilekSUBASI et al in 2012 concluded that the duration of motor block in Levobupivacaine is significantly shorter than racemic Bupivacaine and is advantageous for early mobilisation of the patient they also concluded that Levobupivacaine was less cardiac and neurotoxic than racemic Bupivacaine.[24,11]

CONCLUSION

From present study findings and correlating it to the previous studies and literature plain Levobupivacaine 0.5% which is pure s–enantiomer of Bupivacaine is a good alternative for caesarean section in spinal anesthesia as it is

less CVS and CNS toxic, early recovery of motor blockade leading to early mobilization of the mother, analgesia almost similar to racemic hyperbaric Bupivacaine. Addition of low dose Fentanyl 10 mcg with Levobupivacaine has dose sparing effect of opioids on local anesthetics, better postoperative analgesia and early recovery from motor block. However if using low dose Levobupivacaine along with Fentanyl it is advised to go for combined spinal epidural technique. Action of isobaric Levobupivacaine is independent on gravity in spinal anesthesia.

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