Bupivacaine 0.125% produces motor block and weakness with fentanyl epidural analgesia in children

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Purpose: Epidural infusions of fentanyl ($2 \mu\text{g}\cdot\text{ml}^{-1}$) alone or combined with bupivacaine 0.125% were compared for perioperative analgesia, motor block and other side-effects in children who underwent urological surgery.

Methods: In a prospective, double-blind study, 42 children, ASA I - II, 1-16 yr, were randomly allocated to receive either epidural F (fentanyl bolus $2 \mu\text{g}\cdot\text{kg}^{-1}$ in $0.5 \text{ ml}\cdot\text{kg}^{-1}$ saline followed by $2 \mu\text{g}\cdot\text{ml}^{-1}$ fentanyl infusion) or epidural F-B (fentanyl bolus $2 \mu\text{g}\cdot\text{kg}^{-1}$ in $0.5 \text{ ml}\cdot\text{kg}^{-1}$ bupivacaine 0.25% followed by $2 \mu\text{g}\cdot\text{ml}^{-1}$ fentanyl infusion in bupivacaine 0.125%) after induction of general anaesthesia. Adequacy of analgesia, lower limb motor block and side-effects were assessed four hourly postoperatively.

Results: Both infusion regimens provided excellent analgesia (median objective pain scores = 0). Epidural infusion rates were similar in the F ($0.29 \pm 0.07 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$) and F-B ($0.26 \pm 0.05 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$) groups. Three children in the F group and all children in the F-B group developed lower limb weakness. ($P < 0.05$) Bromage scores were different in the F group (median 0, range 0-0.66) compared with the F-B group (median 0.33, range 0-1) ($P < 0.001$). Other side-effects did not differ.

Conclusion: Postoperative epidural fentanyl infusion provides equipotent analgesia to administration of a solution including both fentanyl and bupivacaine 0.125% and causes less lower limb weakness. No reduction in the fentanyl requirement resulted from the addition of bupivacaine 0.125%.

Objectif : Des perfusions péridurales de fentanyl ($2 \mu\text{g}\cdot\text{ml}^{-1}$) employées seules ou combinées à de la bupivacaine 0,125% ont été comparées pour la qualité de l'analgésie périopératoire, le blocage moteur et les effets secondaires chez des enfants devant subir une chirurgie urologique.

Méthode : Dans une étude prospective et en double aveugle, 42 enfants, ASA I - II, âgés de 1 à 16 ans, ont été répartis au hasard et ont reçu soit une injection péridurale F (bolus de fentanyl de $2 \mu\text{g}\cdot\text{kg}^{-1}$ dans une solution salée de $0,5 \text{ ml}\cdot\text{kg}^{-1}$ suivi d'une perfusion de fentanyl de $2 \mu\text{g}\cdot\text{ml}^{-1}$) ou une péridurale F-B (un bolus de fentanyl de $2 \mu\text{g}\cdot\text{kg}^{-1}$ dans $0,5 \text{ ml}\cdot\text{kg}^{-1}$ de bupivacaine 0,25 % suivi d'une perfusion de fentanyl de $2 \mu\text{g}\cdot\text{ml}^{-1}$ dans de la bupivacaine 0,125 %) après l'induction de l'anesthésie générale. La qualité de l'analgésie, le blocage moteur des membres inférieurs et les effets secondaires ont été évalués aux 4 heures, après l'intervention.

Résultats : Les deux régimes de perfusion ont fourni une excellente analgésie (score objectif de la douleur moyen = 0). Les vitesses de perfusion ont été similaires dans les deux groupes : groupe F ($0,29 \pm 0,07 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$) et groupe F-B ($0,26 \pm 0,05 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$). Trois enfants du groupe F et tous les enfants du groupe F-B ont manifesté une faiblesse des membres inférieurs ($P < 0,05$). Les scores de Bromage ont été différents d'un groupe à l'autre : F (moyen 0, intervalle de 0-0,66), F-B (moyen 0,33, intervalle 0-1) ($P < 0,001$). Les autres effets secondaires étaient semblables.

Conclusion : La perfusion postopératoire péridurale de fentanyl fournit une analgésie équivalente à l'administration d'une solution incluant du fentanyl et de la bupivacaine 0,125 % et cause moins de faiblesse des membres inférieurs. Les besoins de fentanyl n'ont pas été réduits par l'addition de bupivacaine 0,125 %.

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CONTINUOUS lumbar epidural infusions of fentanyl¹ and fentanyl- bupivacaine mixtures² provide excellent postoperative analgesia in adults. Several studies report the successful use of lumbar epidural analgesia for postoperative pain relief in children, either by intermittent boluses^{3,4} or by continuous infusion.⁵⁻⁷ Some of the children receiving epidural infusions containing local anaesthetic postoperatively develop motor block and weakness of their lower limbs. This can be frightening and upsetting to children, especially those who are young, who do not understand why they cannot move their legs.

Children are encouraged to mobilise as soon as possible after surgery. The presence of motor block may delay mobilisation until the epidural has been discontinued. Moreover, early removal of the epidural catheter may be requested to allow mobilisation which may deny the child full benefit of the epidural analgesia.

Epidural fentanyl infusions are effective for postoperative analgesia in children⁶ and do not produce motor block of the lower limbs. Although epidural fentanyl has been compared with epidural morphine for postoperative analgesia in children,⁸ it has not been compared with an epidural infusion containing local anaesthetic.

To date, no clinical study has evaluated the quality of postoperative analgesia and degree of motor block produced with the use of continuous epidural infusions in children. Furthermore, it is not known if the addition of bupivacaine to fentanyl in epidural infusions confers any advantage in children. Therefore we compared equipotent epidural infusions of fentanyl alone and with bupivacaine 0.125% for perioperative analgesia, incidence of motor block and other side-effects.

This study was designed to compare the analgesic potency, motor block of the lower limbs and side-effects experienced by children receiving epidural infusions of either 2 $\mu\text{g}\cdot\text{kg}^{-1}$ fentanyl (F) or 2 $\mu\text{g}\cdot\text{kg}^{-1}$ fentanyl with bupivacaine 0.125% plain (F-B) who underwent urological surgery.

Methods

After human ethics committee approval, 42 children (ASA I and II, aged 1- 16 yr) who were scheduled for ureteral reimplantation, pyeloplasty, hypospadias repair and nephrectomy were studied. Epidural analgesia had been requested by the parents in all cases for postoperative analgesia. Written-informed parental consent was obtained and also a verbal assent from all children over seven years old. The study was prospective, randomised and double-blind. Children with coagulopathy, neurological deficit, neuromuscular dis-

ease, a systemic infection or allergy to fentanyl or bupivacaine were excluded.

On arrival in the operating theatre, an electrocardiograph, an automated blood pressure cuff and a pulse oximeter were applied to the child. Anaesthesia was induced with 5 $\text{mg}\cdot\text{kg}^{-1}$ thiopentone *iv* or by inhalation of nitrous oxide, oxygen and halothane and tracheal intubation was facilitated with 0.1 $\text{mg}\cdot\text{kg}^{-1}$ pancuronium. Those children in whom anaesthesia was induced intravenously breathed nitrous oxide 70% in oxygen by face mask during intravenous cannulation. Anaesthesia was maintained with halothane in nitrous oxide 70% and oxygen. Supplemental muscle relaxation with pancuronium was administered as indicated by a nerve stimulator.

Following induction of anaesthesia, the child was placed in the left lateral position and using the loss-of-resistance to saline technique, the epidural space was detected at the L₃₋₄ or L₄₋₅ interspace. A 22-gauge epidural catheter was introduced aseptically into the epidural space via a 19-gauge Tuohy needle. An epidural test dose of bupivacaine 0.25% with epinephrine 1 in 200,000, was given to confirm correct placement: 1 ml for a child $\leq$ 8 yr, 2 ml for a child $>$ 8 yr. This is the standard test dose used in our institution. Epidural drugs were prepared by a physician who did not take part in the evaluation. Children received either epidural F (a bolus of 2 $\mu\text{g}\cdot\text{kg}^{-1}$ fentanyl in 0.5 $\text{ml}\cdot\text{kg}^{-1}$ saline followed by an infusion of 2 $\mu\text{g}\cdot\text{kg}^{-1}$ fentanyl) or epidural F-B (bolus of 2 $\mu\text{g}\cdot\text{kg}^{-1}$ fentanyl in 0.5 $\text{ml}\cdot\text{kg}^{-1}$ bupivacaine 0.25% plain followed by an infusion of 2 $\mu\text{g}\cdot\text{kg}^{-1}$ fentanyl in bupivacaine 0.125%). The bolus was a maximum volume of 25 ml. The epidural infusion rate was commenced at 0.25 $\text{ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$.

Adequacy of intraoperative analgesia was assessed by monitoring the minimum end-tidal halothane concentration (min_{ET} Halo) required to maintain heart rate and blood pressure within 10% of preoperative baseline, in the absence of any other factors which may have influenced cardiovascular stability. The infusion rate was increased to a maximum of 0.4 $\text{ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$ to provide adequate analgesia. The block was deemed a failure if an end-tidal halothane concentration of 1% was required to maintain cardiovascular stability. If this occurred, the child was withdrawn from the study and analgesia provided by intravenous morphine. At the end of surgery, the inhalational agent was discontinued and neuromuscular blockade was reversed with 50 $\mu\text{g}\cdot\text{kg}^{-1}$ neostigmine and 20 $\mu\text{g}\cdot\text{kg}^{-1}$ atropine. The trachea was extubated when protective pharyngeal reflexes had returned.

The epidural infusion was continued postoperatively for up to 48 hr. Epidural drugs were prepared by nurses who did not take part in evaluating the children. Adequacy of analgesia was assessed when the child

TABLE I Patient demographic data

	<i>Fentanyl group</i> (<i>n</i> = 20)	<i>Fentanyl - Bupivacaine group</i> (<i>n</i> = 20)	<i>P</i>
Age (yr)*	5.2 ± 2.8	5.0 ± 4.3	NS
Sex (F/M)	8/12	9/11	NS
Weight (kg)*	19.1 ± 5.8	19.4 ± 13.0	NS

* Data are expressed as mean ± standard deviation

TABLE II Types of surgery

	<i>Fentanyl group</i> (<i>n</i> = 20)	<i>Fentanyl- Bupivacaine group</i> (<i>n</i> = 20)
Ureteral reimplantation	11	10
Nephrectomy	3	1
Pyeloplasty	3	2
Hypospadias repair	3	7

Data are expressed as number of cases

TABLE III Epidural data

	<i>Epidural infusion</i>		<i>P</i>
	<i>F</i>	<i>F-B</i>	
min _{ET} halo (%)*	0.7 ± 0.16	0.6 ± 0.20	NS
infusion rate* (ml·kg ⁻¹ ·hr ⁻¹)	0.29 ± 0.07	0.26 ± 0.05	NS
infusion* (hr)	40.4 ± 7.8	35.4 ± 13.4	NS
OPS†	0(0-7)	0(0-9)	NS

* Data are means ± standard deviation

† Data are median (range)

Abbreviations: F = fentanyl group; F-B= fentanyl-bupivacaine group; min_{ET} halo = minimum end tidal halothane concentration; NS = not significant; OPS = objective pain score

reached the recovery room and every four hours by the objective pain score (OPS).⁹ Visual analogue scores¹⁰ were requested from children over six years old when they were awake. A bolus of epidural infusion was given in the recovery area in the presence of an OPS > 4 or if the child complained of pain. In addition, the epidural infusion rate was increased as necessary up to 0.4 ml·kg⁻¹·hr⁻¹ to maintain the OPS ≤ 2. If the OPS remained > 4, intravenous morphine was prescribed and the epidural infusion discontinued. If the child was pain-free between two consecutive assessments the epidural infusion rate was reduced by 10%. Belladonna and opium suppositories were administered for bladder spasms. Acetaminophen *po* was administered every four hours as needed for pyrexia.

The volume of epidural infusion per hour and the total volume of epidural infusion administered were

TABLE IV Bromage score

<i>Bromage score (%)</i>	<i>Intensity of motor block</i>
0	None - full flexion of knees and feet
33	Partial - just able to move knees
66	Almost Complete - able to move feet only
100	Complete - unable to move feet or knees

TABLE V Side-effects

	<i>Epidural infusion</i>		<i>P</i>
	<i>F</i>	<i>F-B</i>	
Lower limb weakness*	3 (15)	20 (100)	< 0.05
Bromage score†	0 (0-0.66)	0.33 (0-1)	< 0.0001
Resp. depression*	0	0	NS
Vomiting incidence*	16 (80)	13 (65)	NS
number of episodes			
- in first 24 hr†	3 (0-5)	2 (0-6)	NS
- after 24 hr†	0 (0-2)	0 (0-2)	NS
incidence of dimenhydrinate use*	13 (65)	12 (60)	NS
Pruritus- incidence*	3 (15)	5 (25)	NS

* Data are number of children (%)

† Data are median (range)

Abbreviations: F= fentanyl group; F-B= fentanyl-bupivacaine group; NS = not significant

recorded. The times of commencing and discontinuing the epidural infusion were documented. The mean epidural infusion rate and the mean infusion rate of epidural fentanyl used in each group were calculated.

Movement of the lower limbs was assessed in the recovery room and four hourly afterwards: any weakness of either of the lower limbs was documented and a Bromage Score (BS)¹¹ performed. The Bromage score recorded was the mean score for both lower limbs and was measured as a percent. All children were observed for spontaneous leg movement. When no spontaneous movement of the lower limbs was observed, older children were asked to bend their knees and flex their ankles. Small children, who had not moved their legs spontaneously, had the soles of their feet stroked to elicit movement. Children with normal power in their lower limbs were encouraged to mobilise with the epidural infusion in place. The number of children who mobilised was recorded and for those children who did not mobilise, the reasons for failure were documented.

After discharge from the recovery room and on admission to the ward, baseline heart rate, respiratory rate, and sedation score were recorded and reassessed every hour thereafter. Blood pressure and sensory level were recorded every four hours. Side-effects such

as respiratory depression, nausea, vomiting and pruritus and their treatment were recorded by the ward nurses. All medication given during the study period was recorded.

The sample size was determined using a power analysis for proportions based on expecting motor block in about 50% of patients receiving the epidural fentanyl-bupivacaine combination and, at the most, in 5% of patients receiving epidural fentanyl, given the pharmacological properties of the drug. With an $\alpha = 0.05$ and $\beta = 0.2$, the sample size is 20 patients per group for a power of 80%. Demographic and parametric data were expressed as mean $\pm$ standard deviation. Parametric data were analysed using the unpaired Student *t* test. Non-parametric data were analysed using MannWhitney U test and nominal data with Fisher's exact test. $P < 0.05$ was accepted as statistically significant.

Results

Forty two children (aged 1 - 16 yr) scheduled for elective urological surgery were studied. Twenty one children received epidural F and 21 lumbar epidural F-B. No intravenous opioids were given. Two children were withdrawn from the study. One child in the F group was withdrawn because the epidural was inserted in the thoracic region. One child in the F-B group whose epidural catheter fell out shortly after returning to the ward was also withdrawn. Data were analysed for the remaining 40 children.

Demographic data did not differ between groups (Table I). The type of surgery performed on children in the study is listed in Table II. The duration of surgery was similar in the F group (125 ± 35 min) and in the F-B group (131 ± 70 min).

Both infusion regimens provided excellent intraoperative analgesia. There was no difference in mean end-tidal halothane concentrations (%) required to maintain cardiovascular stability between groups: 0.7 ± 0.16 in the fentanyl group compared with 0.6 ± 0.20 in the fentanyl- bupivacaine group (Table III). Haemodynamic stability during anaesthesia occurred in 17 children in the F group and in 18 children in the F-B group. The remaining children experienced minor fluctuations in heart rate and blood pressure. One child in each group required a bolus of epidural solution intraoperatively and the infusion rate increased to achieve stable cardiovascular parameters.

Both infusion regimens provided excellent postoperative analgesia. The OPS measured every four hours had median scores of 0 in both groups throughout the study period (Table III). Figure 1 shows the distribution of the OPS recorded throughout the 24 hr period for F and F-B groups. Unfortunately visual

FIGURE 1 The Objective Pain Score was used to determine the adequacy of analgesia postoperatively.

FIGURE 2 The incidence of lower leg weakness is shown for both groups.

FIGURE 3 The Bromage Score was used to determine the incidence of motor block postoperatively.

analogue scores were uninterpretable. One child in the F-B group was distressed six hours after the operation. A bolus of epidural infusion did not relieve distress and the epidural was removed. Belladonna and opium suppositories were administered in 6/16 children in the F group and 3/16 children in the F-B group. Seven children in the F group and six children in the F-B group received acetaminophen.

Epidural infusion rates were similar in the F group ($0.29 \pm 0.07 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$) and in the F-B group ($0.26 \pm 0.05 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$) (Table III). Epidural fentanyl infusion rates did not differ between the two groups: $0.59 \pm 0.13 \text{ }\mu\text{g}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$ and $0.52 \pm 0.10 \text{ }\mu\text{g}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$ for the F and F-B groups respectively. The durations of the epidural infusions were similar: $40.4 \pm 7.8 \text{ hr}$ for epidural F and $35.4 \pm 13.4 \text{ hr}$ for epidural F-B (Table III).

A summary of the Bromage Score is shown in Table IV. The incidences of side-effects of the epidural infusions are shown in Table V. All children in the F-B group and three children in the F group had weakness of the lower limbs ($P < 0.05$). Two of the three children in the fentanyl group, recorded as not moving their legs in the postanesthetic care unit, were recovering from anaesthesia when the initial assessments were made and had no motor block on the ward subsequently. The third child in the F group did not move his legs for assessments on the ward but moved them intermittently between assessments. Figure 2 illustrates the leg weakness observed in F and F-B groups. Figure 3 illustrates the distribution of Bromage scores recorded in F and F-B groups during the entire study period. Bromage scores were different in the F group (median 0, range 0-0.66) than in the F-B group (median 0.33, range 0-1). ($P < 0.001$). Three children in the F group and none in the F-B group mobilised while the epidural infusion was running.

Respiratory depression did not occur. Sixteen children in the F group and 13 in the F-B group vomited in the first 24 hr postoperatively (Table V). Thirteen children in the F group and 12 in the F-B group received intravenous dimenhydrinate postoperatively. Only two children in the F group and 4 in the F-B group continued to vomit after 24 hr postoperatively. Pruritus occurred in three children in the F group and in 5 in the F-B group. Two children in the F group received intravenous diphenhydramine for pruritus. Urinary retention did not occur since the children had urinary catheters.

Discussion

An epidural fentanyl infusion ($2 \text{ }\mu\text{g}\cdot\text{ml}^{-1}$) provided comparable intraoperative and postoperative analgesia to an epidural fentanyl ($2 \text{ }\mu\text{g}\cdot\text{ml}^{-1}$)-bupivacaine 0.125% infusion in children undergoing urological surgery. Furthermore, fentanyl alone provided significantly less

lower limb weakness. The addition of bupivacaine 0.125% to the epidural fentanyl infusion did not result in reduced epidural infusion rates and the incidence of side-effects attributable to opioid use was unaffected.

Intraoperative epidural analgesia in this institution is usually provided by solutions containing local anaesthetic. A previous publication of the efficacy of epidural opioids for analgesia in children undergoing urological surgery also reported the use of an initial epidural bolus containing local anaesthetic prior to surgical incision.¹² In this study, fentanyl alone provided comparable intraoperative haemodynamic stability to fentanyl-bupivacaine. The doses of fentanyl infused epidurally are similar to those reported in a previous study in children.⁶ In the present study however, no additional epidural boluses of fentanyl were required.

Addition of bupivacaine to the fentanyl epidural did not cause a reduction in the rate of fentanyl infused. This has been reported in an adult study where bupivacaine 0.1% did not reduce the requirement for epidural fentanyl infusion after major abdominal surgery.¹⁵ The benefit of reducing the opioid requirement in a fentanyl-containing epidural would be a reduction in the side-effects associated to the presence of the fentanyl component, namely respiratory depression, vomiting, pruritus and urinary retention. Addition of bupivacaine 0.125% in our study did not lead either to a reduction in these side-effects.

Motor weakness occurred in all children who received bupivacaine 0.125%. Motor weakness is undesirable postoperatively since it prevents children from mobilising after surgery and may distress small children. Anaesthetists may also be alarmed at the possibility of the local anaesthetic masking a developing neurological cause of weakness. In labouring women, epidural infusions of $2.5 \text{ }\mu\text{g}\cdot\text{ml}^{-1}$ fentanyl alone or $1.7 \text{ }\mu\text{g}\cdot\text{ml}^{-1}$ fentanyl, bupivacaine 0.04% and $1.7 \text{ }\mu\text{g}\cdot\text{ml}^{-1}$ epinephrine allowed approximately 70% of them to ambulate.¹³ One reason for the differing effects of epidural bupivacaine on lower limb motor block in children and adults may be the differing concentrations used. Bupivacaine is usually used in concentrations $>0.1\%$ in epidural infusions for children.^{5,14} Furthermore, epidural infusions in children are usually commenced at $0.25 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$, equivalent to a rate of $17.5 \text{ ml}\cdot\text{hr}^{-1}$ in a 70 kg adult, which is higher than is used in epidural infusions in adults. The maximum infusion rate in this study in both epidural groups, $0.4 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{hr}^{-1}$ was chosen as recommended in guidelines to avoid toxic levels of bupivacaine.⁷ Motor weakness experienced in children receiving epidural infusions of bupivacaine may be reduced by using weaker concentrations than in our study or by reducing the dose infused.

In this study, only three children, all in the F group, ambulated with the epidural infusion running. This

small number was disappointing and resulted from a general reluctance from the ward staff to mobilise children with epidural infusions since previously this had not been nursing policy. There were also concerns that the epidural could be displaced if the child got out of bed. The three children who mobilised were very comfortable and the epidurals were not displaced. Further experience of children mobilising with epidurals in situ will undoubtedly lead to greater acceptance.

Objective pain scores were recorded in all patients according to protocol. Unfortunately, visual analogue scores recorded were uninterpretable for several reasons. First, many readings were missed when the children were sleeping. Second, there was unfamiliarity of the nurses with the chosen scoring system and third, failure to understand the task by some of the children.

Children in both epidural groups experienced marked nausea and vomiting for the first 24 hr after surgery. This may be attributable to the fentanyl component in both epidural infusions. In a previous report, the incidence of nausea or vomiting was only 20% in the first 24 hr postoperatively in children receiving epidural fentanyl infusions after various operations.⁸ Other possible causes are the long anaesthetic, the nature of the surgery, the absence of prophylactic antiemetics and regular intravenous antibiotics postoperatively. Use of a prophylactic antiemetic may ameliorate the problem. Fortunately, the incidence of vomiting was markedly reduced after the first 24 hr. An audit of postoperative vomiting in children after urological surgery would give us better insight into the effects of different analgesic regimens including a comparison with intravenous morphine.

In summary, the use of an epidural fentanyl ($2 \mu\text{g}\cdot\text{ml}^{-1}$) infusion provides equipotent analgesia to an epidural fentanyl ($2 \mu\text{g}\cdot\text{ml}^{-1}$)-bupivacaine 0.125% infusion in children undergoing urological surgery, using the Objective Pain Score for assessment of analgesia. An epidural fentanyl ($2 \mu\text{g}\cdot\text{ml}^{-1}$) infusion alone produces a considerably lower incidence of motor block and weakness of the lower limbs. Both regimens were associated with a high incidence of postoperative vomiting in the first 24 hr, where prophylactic antiemetics were not used. Furthermore, the use of epidural opioids was not reduced by the addition of bupivacaine 0.125%. The incidence of side-effects attributable to the administration of epidural opioids was unaffected.

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