Original Article

Comparison between dexmedetomidine and ketofol in the prevention of postoperative emergence delirium in pediatric patients undergoing orofacial cleft surgery: A randomized controlled trial

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Abstract

Background and Aims: Emergence delirium (ED) is a common postoperative complication in pediatric patients. To avoid postoperative ED, sedative medications have been utilized in addition to general anesthesia. In this study, the primary objective was to assess the incidence of postoperative emergence of delirium at 0-, 10-, 20-, 30-, and 60-min intervals. Secondary objective was to assess postoperative analgesia (0, 10, 20, 30, and 60 min) and hemodynamic parameters (mean arterial pressure, pulse, oxygen saturation).

Material and Methods: In this randomized controlled study, 105 American Society of Anesthesiologists I and II patients, aged between 3 months and 2 years, scheduled for orofacial cleft surgery were enrolled. Patients of group I received dexmedetomidine (0.3 μg/kg), group II received ketofol (a mixture of ketamine 0.25 mg/kg and propofol 1.0 mg/kg), and group III received normal saline 10 min before extubation. The incidence of postoperative ED using the Watcha scale and the postoperative pain using the Face, Legs, Activity, Cry, Consolability (FLACC) scale were recorded.

Results: The Watcha scale at the immediate postoperative period and at 10-, 20-, 30-, and 60-min intervals was 0 (1), 1 (1.75), 1 (1), 2 (2), and 3 (2) in group I, 1 (1), 2 (1), 2 (2), 2 (3), and 3 (2) in group II, and 2 (1), 3 (1), 3 (1.25), 4 (1), and 4.5 (1.5) in group III, respectively, at the above time points. On comparing group I with groups II and III, the difference was significant ($P < 0.01$). The FLACC score at the immediate postoperative period and at 10-, 20-, 30-, and 60-min intervals was 1 (1), 1 (1), 1 (1), 2 (2), and 3 (2) in group I, 2 (2), 2 (1), 2 (2), 2(3), and 3 (2) in group II, and 4 (1), 3 (1), 3 (1.25), 4 (1), and 4.5 (1.5) in group III, respectively, at the above time points. The FLACC score was also lower in group I in comparison to groups II and III. The difference among the groups was significant ($P < 0.01$). The incidence of postoperative delirium was lower in group I at 20% (7/35) than in group II at 29% (10/35) and in group III at 49% (17/35), and difference among the groups was significant (<0.01).

Conclusions: We conclude that both dexmedetomidine and ketofol are effective in reducing postoperative ED. Dexmedetomidine is more effective than ketofol in preventing postoperative ED in the pediatric population.

Keywords: Cleft lip, cleft palate, dexmedetomidine, emergence delirium, ketamine, propofol

Introduction

Emergence delirium (ED) after orofacial surgery in the pediatric population is a common complication and is difficult to manage. ED is defined as a state of acute confusion during recovery from anesthesia, presenting with disorientation, hallucinations, restlessness, and purposeless behaviour. The

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incidence of ED in children is much higher than in adults.[1] The reported incidence of postoperative ED ranges from 2% to 80% in pediatric patients.[2,3] Among the surgical factors, head and neck surgeries, including corrective surgery for orofacial clefts, are the independent risk factors for ED.[4,5] The incidence of postoperative ED in cleft lip was 62.82%, while in cleft palate it was 74.11%.[5]

Various methods used to reduce postoperative ED in pediatric patients undergoing orofacial cleft surgeries include regional block, inhalational anesthestic agent desflurane (24%),[6] premedication, α2-agonists like clonidine and dexmedetomidine (17%),[7] propofol (58.6%),[8] and μ-opioid agonists. In this study, we used dexmedetomidine and ketofol for the prevention of ED. Our primary objective was to assess the incidence of postoperative ED at 0-, 10-, 20-, 30-, and 60-min intervals. Secondary objective was assessment of postoperative analgesia (0, 10, 20, 30, and 60 min) and hemodynamic parameters (mean arterial pressure, pulse, oxygen saturation). The aim of this study was to compare the effectiveness of dexmedetomidine and ketofol in reducing the incidence of postoperative ED in pediatric patients undergoing orofacial cleft surgery. We hypothesized that dexmedetomidine would be more effective than ketofol in preventing postoperative ED in the pediatric population.

Material and Methods

This is a single-center, double-blinded, randomized controlled trial that was conducted in our tertiary care center over a period of 17 months, from July 2021 to November 2022. This study was commenced after obtaining clearance from the institutional ethical committee, and it was registered in the Clinical Trial Registry of India (CTRI 2021/06/034077). One hundred and five American Society of Anesthesiologists (ASA) Physical Status I and II patients of both sexes (female and male), in the age group between 3 months and 2 years, scheduled for orofacial cleft surgery were included in our study. ASA III or more patients with cardiovascular disease, difficult intubation (more than three attempts, endotracheal intubation time >10 min), and patients on anticonvulsant medication were excluded from the study. Patients scheduled for orofacial cleft corrective surgery who met all the inclusion criteria were enrolled in the study. A patient information sheet with the details of the study was provided to all the parents, and written informed consent was obtained before enrolling them in the study. Patients were randomized into three groups (with 35 patients in each) using computer-generated random numbers. This was performed by the principal researcher until a group was assigned, and the patients were examined on the day before surgery. According to ASA guidelines, fasting was advised. Premedication was not recommended. Simple randomization was done using Statistical Package for the Social Sciences 22, and the patients were allocated to any of the three groups using computer-generated random numbers: group I received dexmedetomidine (0.3 μg/kg diluted in normal saline to a volume of 10 ml) 10 min before completion of the operation; group II received ketofol (ketamine 0.25 mg/kg and propofol 1.0 mg/kg were combined and diluted to a total amount of 10 ml by adding normal saline) 10 min before completion of the operation; and group III received 10 ml of normal saline 10 min before the end of surgery. Random allocation sequences were enclosed in sealed, opaque envelopes. Allocation concealment was done on the day of surgery by another anesthesiologist, who opened the topmost envelope and administered the drug according to the group assigned. Postoperative monitoring and data collection were done by another anesthesiologist blinded to the group assigned. Standard anesthesia monitoring using an electrocardiogram, a pulse oximeter, and a noninvasive blood pressure monitor was performed in the operating room. Sevoflurane 8% in 100% O_2 was used to induce the patient, and this treatment was continued until the patient lost consciousness. Fentanyl (2 μg/kg) and atracurium (0.5 mg/kg) were administered for endotracheal intubation once an appropriate depth of anesthesia had been reached. After a laryngoscopy, an endotracheal tube (Ring, Adair and Elwyn) of proper size was used for intubation. Anesthesia was maintained by sevoflurane and oxygen–air mixture (50:50) to target a minimum alveolar concentration of 1. Local anesthesia, bupivacaine 0.125% (maximum dose limit of 2 mg/kg), was injected at the surgical site. Fentanyl 1 μg/kg was administered as an incremental dose when the heart rate and the mean arterial pressure increased by more than 20% from baseline. The last dose of fentanyl was given 30 min before the end of the procedure. The study drug was administered by an infusion pump 10 min before the completion of surgery. Children in group I were administered dexmedetomidine; those in group II were administered ketofol; and those in group III were administered normal saline. After the completion of surgery, reversal of neuromuscular blockade was done with neostigmine 0.05 mg/kg and atropine 0.02 mg/kg IV on the attainment of signs of reversal. Once the patient's gag reflex had returned and regular spontaneous breathing had resumed, the trachea was extubated. Both the length of the procedure and the time spent being exposed to sevoflurane (from the start of mask induction to the end of anesthetic inhalation) were noted. IV paracetamol 15 mg/kg was given every sixth hourly in the postoperative period. Patients were transferred to the post-anesthesia care unit (PACU). Our primary outcome was the incidence of postoperative ED at 0-, 10-, 20-, 30-, and 60-min intervals. Secondary outcomes were postoperative analgesia (0, 10, 20, 30, and 60 min) and hemodynamic

parameters (mean arterial pressure, pulse, oxygen saturation). In PACU, the incidence of ED was assessed using watcha scale, graded as follows: 0: asleep; 1: calm; 2: crying but can be consoled; 3: crying but cannot be consoled; 4: agitated and thrashing. Patient with a score of >2 was considered to have ED.[9] The occurrence and severity of ED were observed immediately after awakening, that is, when the child had the first response to a command or opened the eye on command (T0), and then every 10 min for the next 30 and then 60 min (T10, T20, T30, and T60). In the PACU, encouraging parental contact was the first line of defence against delirium; if did not work, midazolam (0.05–0.1 mg/kg) was given IV. Postoperative pain was measured at the time of awakening, or when the child's eyes opened for the first time on command (T0), and again after 10, 20, 30, and 60 min. We also noted when the first analgesic was needed. The Face, Legs, Activity, Cry, Consolability scale, or the FLACC scale, was used to measure postoperative pain. Each category receives a score between 0 and 2, for a total of 10 (0: comfortable and relaxed; 1–3: mildly uncomfortable; 4–6: moderately painful; and 7–10: severely uncomfortable or painful).[10] We calculated the sample size based on a study conducted by Ali *et al.*[11] in which they reported the incidence of ED to be 80%. Assuming a 40% decrease in the incidence of ED on treatment with dexmedetomidine and setting an alpha error at 5% and power at 80%, the sample size came out to be 34 in each group. Thirty-five patients were included in each group for the study. Statistical analysis was performed using Statistical Package for the Social Sciences 22 software. The Watcha scale and the FLACC score were expressed as the median (interquartile range). Kruskal-Wallis test, was used for the assessment of Watcha scale and the FLACC score. Continuous quantitative variables were expressed as mean ± standard deviation and qualitative variables as percentage. The Chi-square test was used to assess categorical variables. The analysis of variance test was used for continuous quantitative variables. The differences among variables were statistically significant at $P < 0.05$.

Results

We assessed 120 patients for the eligibility posted for orofacial cleft surgery, of which eight patients did not give consent and seven patients did not fulfill the inclusion criteria. Figure 1 depicts the consort flow diagram of patient progress through the study. After being randomly assigned to one of three groups (group I: 35, group II: 35, and group III: 35), all the recruited patients completed the trial, and their data were examined. The demographic baseline data for each of the three groups is shown in Table 1. There were no significant differences ($P > 0.05$) in the parameters between any of the three groups. Out of the 105 orofacial cleft surgery patients, group I had 15 cleft lip cases and 20 cleft palate cases, group II had 14 cleft lip cases and 21 cleft palate cases, and group III had 16 cleft lip cases and 19 cleft palate cases. Table 1 shows the demographic data of the three groups of patients, which were comparable, and there was no clinically significant difference among the research groups. Our primary outcome was the Watcha scale at the immediate postoperative period and at 10-, 20-, 30-, and 60-min intervals, which was 0 (1), 1 (1.75), 1 (1), 2 (2), and 3 (2) in group I, 1 (1), 2 (1), 2 (2), 2 (3), and 3 (2) in group II, and 2 (1), 3 (1), 3 (1.25), 4 (1), and 4.5 (1.5) in group III, respectively, at the above time points. On comparing group I with groups II and III, the difference was significant ($P < 0.01$). The FLACC score at the immediate postoperative period and at 10-, 20-, 30-, and 60-min intervals was 1 (1), 1 (1), 1 (1), 2 (2), and 3 (2) in group I, 2 (2), 2 (1), 2 (2), 2 (3), and 3 (2) in group II, and 4 (1), 3 (1), 3 (1.25), 4 (1), and 4.5 (1.5) in group III, respectively, at the above time points. The FLACC score was also lower in group I in comparison to groups II and III. The difference among the groups was significant ($P < 0.01$). The incidence of postoperative delirium was lower in group I at 20% (7/35) than in group II at 29% (10/35) and in group III at 49% (17/35) and the difference among the groups was significant (<0.01) [Figure 2]. There was no statistically significant difference in heart rate, mean arterial pressure, or oxygen saturation among these groups. We did not find any study drug-related adverse effects like sedation, bradycardia, tachycardia, hypotension, or nystagmus among the groups.

Discussion

Our study shows that both dexmedetomidine and ketofol are effective in reducing postoperative ED in comparison to the control group. However, dexmedetomidine is more effective than ketofol in reducing the incidence of postoperative ED in pediatric patients who have undergone cleft lip and cleft palate surgery. The patients who received dexmedeto midine had a lower Watcha scale and FLACC score than the ones who received ketofol in cleft lip and cleft palate surgery [Tables 2 and 3]. Numerous studies have shown the role of dexmedetomidine in reducing the incidence of post-anesthetic agitation in children with cleft lip and palate.[8,12-14] In a study conducted by Huang *et al.*[8] on cleft palate surgery, they compared dexmedetomidine infusion (0.5 μg/kg/h) with propofol (2 mg/kg/h). They found that the incidence of ED was 20.1% in the dexmedetomidine group, whereas in the propofol and control groups, the incidence of ED was 58.6% and 85.7%, respectively. In our study, the incidence of ED was 20% in the dexmedetomidine group, 29% in the ketofol group, and 49% in the saline group. Peng and Zhang[12] studied the effect of continuous IV infusion of dexmedetomidine on the

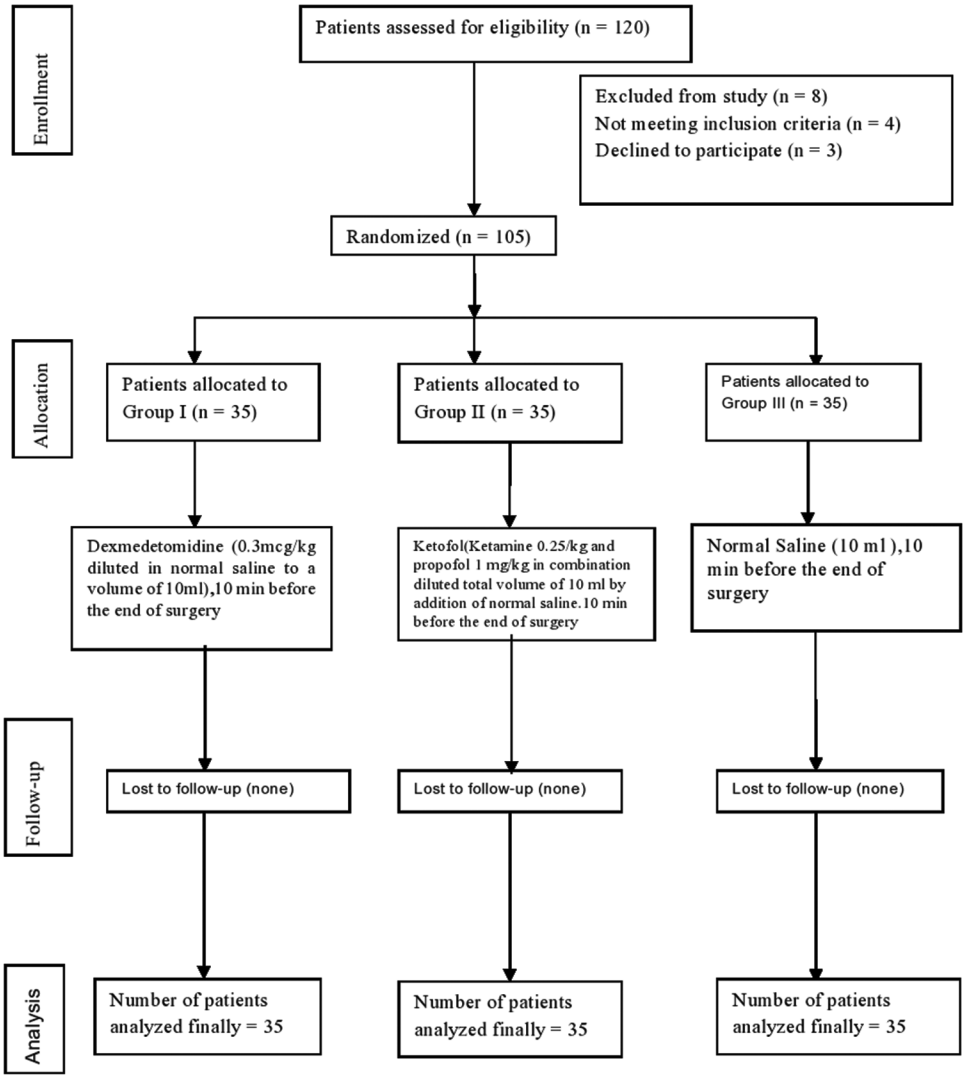

Figure 1: Consort flow chart

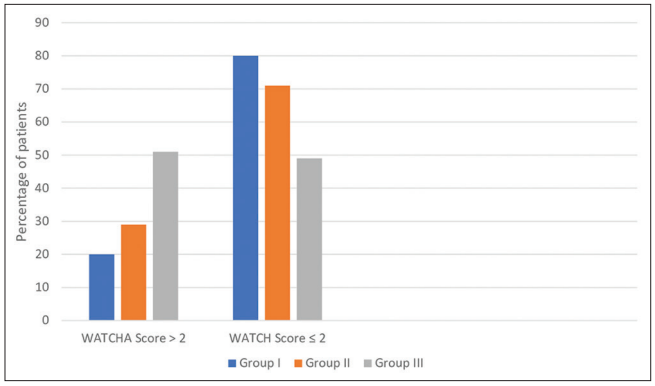

Figure 2: Incidence of emergence delirium (Watcha scale >2 and ≤2)

incidence of EA after general anesthesia in infants undergoing cleft palate repair surgery. They found that the incidence of EA was 15% with dexmedetomidine infusion. Xu *et al.*[13] explored the effect of different doses of continuous infusion of dexmedetomidine (0.25, 0.5, 0.75, and 1.0 μg/kg/h) in cleft lip and palate surgery. They found that 0.75 μg/kg/h dexmedetomidine showed excellent effects in the recovery period, and the FLACC score decreased with fewer side effects. In our study, dexmedetomidine 0.3 μg/kg reduced the FLACC score. Liu *et al.*,[14] in their meta-analysis, also showed the efficaciousness of dexmedetomidine in children undergoing cleft lip and palate repair. They found that dexmedetomidine reduced the need for postoperative rescue analgesics and the incidence of emergence agitation in children. Dexmedetomidine provides analgesia via multiple mechanisms. It inhibits nociceptive C- and Aα-fibers in a dose-dependent manner. It also acts on α2 receptors in the locus ceruleus area, leading to inhibition of nociceptive signal transmission through the posterior spinal horn. Furthermore, it inhibits norepinephrine release from the presynaptic neurons, leading to its hyperpolarization and decreasing pain transmission to the brain.[15] Ali *et al.*[11] found that ketofol at a dose of ketamine 0.25 mg/kg in combination with propofol 1 mg/kg

Table 1: Demographic data and type of procedure

Variant		Group I	Group II	Group III	*P*
Age (months)[a]		13.26±6.44	13.90±7.03	11.57±4.78	0.28
Weight (kg)[a]		7.74±2.28	7.47±2.98	7.27±2.33	0.06
Duration of surgery (min)[a]		90±29.78	80±26.91	90±25.66	0.98
Fentanyl requirement[a] (μg)		15±10.53	20±9.88	15±10.59	0.77
Male/female[b]		19/16	21/14	18/17	0.76
Type of procedure	Cleft lip/cleft palate[b]	15/20	14/21	16/19	0.88

[a]ANOVA test, data expressed as mean and SD. [b]Chi-square test, data expressed as frequency. ANOVA=analysis of variance, SD=standard deviation

Table 2: Watcha score at different time intervals

Variables	Type of surgery	Group I Median (IQR)	Group II Median (IQR)	Group III Median (IQR)	*P*
Immediate postoperative (T0)	Cleft lip	1 (1)	1.5 (1)	2 (0.75)	0.01
	Cleft palate	1 (1)	1 (1)	2 (1)	0.02
	Total	0 (1)	1 (1)	2 (1)	0.01
10 min (T10)	Cleft lip	1 (0)	1 (1)	1 (1)	0.02
	Cleft palate	1 (1.75)	2 (1)	3 (1)	0.01
	Total	1 (1)	2 (1)	3 (1)	0.01
20 min (T20)	Cleft lip	1 (1)	1 (0)	2 (0)	0.01
	Cleft palate	1 (2)	2 (1.5)	2 (1)	0.01
	Total	1 (1)	2 (2)	3 (1.25)	0.01
30 min (T30)	Cleft lip	1 (1)	0.5 (1.25)	3 (1)	0.01
	Cleft palate	2 (1.75)	1 (2)	3 (1)	0.01
	Total	2 (2)	2 (3)	4 (1)	0.01
60 min (T60)	Cleft lip	2 (0)	2 (1.25)	2.5 (1)	0.04
	Cleft palate	2 (0)	2 (1)	3 (1)	0.10
	Total	3 (2)	3 (2)	4.5 (1.5)	0.02

Kruskal–Wallis test, data expressed as median and IQR. IQR=interquartile range

Table 3: FLACC score at different time intervals

Variables	Type of surgery	Group I Median (IQR)	Group II Median (IQR)	Group III Median (IQR)	*P*
Immediate postoperative (T0)	Cleft lip	2 (1)	2 (1)	4 (1)	0.03
	Cleft palate	2 (2)	3 (1)	4 (2)	0.01
	Total	1 (1)	2 (2)	4 (1)	0.01
10 min (T10)	Cleft lip	2 (1.25)	2 (1)	4 (2)	0.02
	Cleft palate	2 (2)	3 (1)	4 (1.25)	0.01
	Total	1 (1)	2 (1)	3 (1)	0.01
20 min (T20)	Cleft lip	2 (1)	3 (2)	3 (1)	0.02
	Cleft palate	2 (1.5)	2 (2.25)	4 (1)	0.04
	Total	1 (1)	2 (2)	3 (1.25)	0.01
30 min (T30)	Cleft lip	2 (2)	2 (3)	3 (1)	0.01
	Cleft palate	2 (2)	3 (1)	4 (1)	0.01
	Total	2 (2)	2 (3)	4 (1)	0.01
60 min (T60)	Cleft lip	3 (1)	2 (1.25)	3.5 (1)	0.04
	Cleft palate	3 (2.25)	3 (2.25)	4.5 (2.25)	0.01
	Total	3 (2)	3 (2)	4.5 (1.5)	0.01

Kruskal–Wallis test, data expressed as median and IQR. FLACC=Face, Legs, Activity, Cry, Consolability, IQR=interquartile range

was as effective as dexmedetomidine at a dose of 0.3 μg/kg for the prevention of ED in children undergoing orthopedic surgery. In our study, we also found that dexmedetomidine 0.3 μg/kg and ketofol 0.25 mg/kg reduces ED. Ketofol reduces the ED because ketamine is an *N*-methyl-D-aspartate receptor antagonist, when used in a small dose, it has both opioid-sparing and effective analgesic properties.[16] Propofol produces sedation in low doses. It is an ultrashort-acting drug, and depending on the time of administration, it reduces the emergence of agitation.[17] The combination of ketamine and

propofol (ketofol) utilizes these two properties to decrease the incidence and severity of emergence agitation, which is the rationale for administering this drug in this study. A meta-analysis showed the effect of dexmedetomidine on ED. When compared to placebo, midazolam, and opioids, the authors of the meta-analysis found that dexmedetomidine significantly decreased the incidence of post-anesthesia ED in pediatric patients. However, dexmedetomidine did not exhibit this superiority when compared to propofol and ketamine.[18] Amer and Abdallah[19] compared dexmedetomidine (0.2 μg/kg) and propofol (1 mg/kg), and they observed that dexmedetomidine was superior to propofol in the prevention of ED and also reduced the FLACC score in pediatric patients undergoing cataract surgery. According to Prasad *et al.*,[20] dexmedetomidine and ketofol caused a significant reduction in the incidence and severity of emergence agitation when compared to the control group. Both drugs were equally helpful in preventing emergence agitation. Children given dexmedetomidine were calmer and met the discharge requirements earlier than those given ketofol. In our study, we compared dexmedetomidine to ketofol, and we found improved results in terms of early ED control and lower FLACC scores in the dexmedetomidine group than the ketofol group.

Limitations

A constraint of the research is its small sample size. The effect of pain on children's behaviour presented a potential source of confounding the outcome. Future studies and treatments can benefit greatly from including a control group and making sure that this group is given proper analgesia because pain may act as a confounding factor in the prevalence of developing delirium.

Conclusions

We conclude that both dexmedetomidine and ketofol are effective in reducing postoperative ED in comparison to the control group. However, between the two drugs, dexmedetomidine is more effective than ketofol in preventing postoperative ED in the pediatric population.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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