Effectiveness of bilateral erector spinae plane block on intraoperative requirement of fentanyl in patients undergoing cardiac surgery: a randomized controlled interventional study

Parbeen Bano[a], Anjum Saiyed[a], Adhokshaj Joshi[a], Gouda M. Sunil[a], Nikhilesh Ladha[b], Reema Meena[a], Arish Husain[c], Mohammad Hashim[a]

[a]Department of Anaesthesiology, Sawai Man Singh Medical College, Affiliated to Rajasthan University of Health Science, Jaipur, Rajasthan, [b]Department of Community Medicine & SPH, PGIMER Chandigarh, Affiliated to PGIMER Chandigarh, India, [c]Department of Anaesthesiology (intern), Rajasthan university of health science college of Medical science, Jaipur, Affiliated to Rajasthan University of Health Science, Jaipur, Rajasthan, India.

Correspondence to Anjum Saiyed, MD, Department of Anaesthesiology, Sawai Man Singh Medical College, Jaipur, Affiliated to Rajasthan University of Health Science, Jaipur, J-180, Rajeev Gandhi Marg, Adarsh Nagar, Jaipur 302007, Rajasthan, India.
E-mail: dranjumsaiyed@gmail.com

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Background and objectives
Erector spinae plane block (ESPB) is a newly defined and effective interfacial plane block. Cardiac surgeries are performed mainly via a median sternotomy leads to significant postoperative pain. Multiple studies have confirmed that ESPB is effective in cardiothoracic and abdominal surgeries. This study aimed to compare the efficacy of ESPB in two groups (group A and group B) for the intraoperative requirement of fentanyl (entropy index guided), hemodynamic variables, need of first rescue analgesia in the postoperative period, and side effects.
Settings and design
The study was designed as a prospective, randomized, control, hospital-based interventional study.
Patients and methods
A total of 60 patients, 18–65 years old of either sex who underwent cardiothoracic surgery by midline sternotomy under general anesthesia, were divided into either group A (n=30), which received ultrasound-guided bilateral ESPB by 25 ml 0.5% ropivacaine with dexmedetomidine 0.5 μg/kg with general anesthesia), or group B (n=30), which received general anesthesia without block.
Statistical analysis used
To observe the difference in quantitative variables between both groups Student's t test/analysis of variance test was performed. The Fisher's exact or χ^2 test was used to establish the association between qualitative variables.
Results
The median requirement of fentanyl (μg/kg/h) in group A and group B was 1.97 (1.43–2.83) and 2.55 (1.55–3.19). This difference was statistically nonsignificant (P=0.348). The mean time of first rescue analgesia in group A and group B was 10.9 ±8.6 and 7.1±4.4 h, respectively ($P<0.05$). Demographically both groups were comparable.
Conclusions
ESPB produced safe and effective analgesia in the postoperative period following cardiac surgery.

Keywords:
cardiopulmonary bypass, dexmedetomidine, erector spinae plane block, fentanyl

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Introduction

The majority of cardiac surgery is done through a median sternotomy, which causes moderate to severe perioperative pain and a nonnegligible risk of chronic pain. Macaire and colleagues found that 'Cardiac surgery through median sternotomy may be associated with the development of chronic sternal pain, with a reported incidence of 11% to 56% at one year after surgery. Persistent postoperative acute pain, opioid use, and high BMI are among risk factors for the development of post-sternotomy chronic pain' [1].

Patient satisfaction and clinical outcome improve when the pain is well managed. There is no clearly superior technique thus the optimal approach for treating perioperative pain, maximizing analgesia, limiting adverse hemodynamic, and pulmonary complications is regarded to be a combination multimodal analgesic regimen (using multiple techniques).

Regional anesthesia techniques for cardiac surgeries could be thoracic epidural analgesia (TEA), thoracic

paravertebral block, erector spinae plane block (ESPB), and a few other fascial blocks [2].

Forero *et al.* [3] defined the ESPB as one of the most recent approaches for the treatment of persistent thoracic neuropathic pain and postoperative pain in thoracic surgery.

As the erector spinae fascia extends from the nuchal fascia cranially to the sacrum caudally, local anesthetic (LA) agents extend through numerous levels, and the block can be more effective over a large area, the main thoracic nerves that supply the sternum range from T2 to T6. In this ultrasound-guided technique, a LA is applied between the erector spinae muscle and the transverse process of the thoracic vertebra leading to the spread of LA cephalic, caudally, and through the paravertebral space.

ESPB is easy to perform and a comparatively safe method in which the transverse process acts as an anatomic barrier and avoids needle insertion to the pleura, decreasing the risk of pneumothorax as well as direct spinal cord injury, epidural hematoma, and central infection; moreover, the safety margin could make it possible to perform in a ward or in an outpatient clinic setting [4–6]. To increase the duration of analgesia with single-shot peripheral nerve blocks we add dexmedetomidine as an adjuvant with ropivacaine. Effective use of thoracic ESPB for decreasing the need for intraoperative opioid requirement and postoperative analgesia has been reported in breast surgery and thoracic surgery [7,8].

This study was performed to compare the effectiveness of bilateral ESPB on the intraoperative requirement of fentanyl in patients undergoing cardiac surgery via median sternotomy, intraoperative hemodynamic parameters, postoperative need for first rescue analgesia, and the side effects were also compared.

Patients and methods

The present study was designed as a prospective randomized, single-blinded, controlled, interventional study. The study was conducted in the cardiothoracic surgery operation theater, Department of Anesthesiology, in a tertiary level institution after obtaining due permission from the institutional ethics committee. This clinical trial was prospectively registered in Clinical Trials Registry India. We enrolled 60 eligible patients aged between 18 and 65 years of either sex scheduled for cardiac surgery via a sternotomy, had an American Society of Anesthesiologists status (ASA) of II and III, weight between 40 and 65 kg. We excluded patients who were not willing to participate in the study, with a history of allergic reactions to LAs, patients on anticoagulant therapy and history of coagulation disorders, and local infection at the proposed site of puncture for ESPB. Eligible patients were randomized to one of the two groups using computer-generated random numbers and a 1 : 1 allocation ratio. Allocation concealment was fulfilled by an assistant not involved in the study, and randomization was achieved in sequentially numbered, sealed, opaque envelopes. The patients were randomly allocated into two groups using the sealed envelope technique: group A included 30 patients who received single-shot bilateral ESPB with 25 ml 0.5% ropivacaine (a LA agent) with injection dexmedetomidine 0.5 μg/kg and standard general anesthesia. Group B included 30 patients who received standard general anesthesia without block. Informed consent was obtained from every patient after explaining the process and the visual analog score (VAS) scale in their language.

Outcome measures

The primary outcome measure was to assess and compare the difference in intraoperative median fentanyl consumption (entropy index guided) in both the study groups. The secondary outcome was to assess and measure hemodynamics variables (hemodynamics variables heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), Mean arterial blood pressure (MAP), oxygen saturation) every 15 min intraoperatively, and after every 2 h in the postoperative period, to measure the time of requirement of first rescue analgesia and side effects in both the study groups.

Sample size calculation

A sample of 30 cases in each group is required at 95% confidence and 80% power to verify the expected difference of 540.67±133.98 μg in mean consumption of fentanyl in both groups (as per the article) [9].

Ultrasonography-guided erector spinae plane block technique

ESPB was performed in a sitting position under sterile conditions before the start of the surgical procedure. A high-frequency 12 MHz linear ultrasound probe with a sterile sheath was placed longitudinally after injecting 3 ml of 2% lignocaine on each side. Thoracic bilateral ESPB was performed in patients of group A at T4–T5 levels, with a 20 G Tuohy needle. ESPB was performed in plane, cephalocaudal direction, targeted to the

middle of the transverse process of thoracic vertebrae, fourth–fifth vertebrae. The drug was injected and the spread was seen in the ESP plane craniocaudally in real time (Fig. 1).

General anesthesia details

All patients satisfying the selection criteria were evaluated in preanesthesia checkup. After confirming nil by mouth status and written informed consent, routine monitors were attached. Internal jugular vein and femoral arterial cannulation were done under LA. Entropy electrodes were attached. Patients were premedicated and induced with midazolam intravenous (0.05 mg/kg), fentanyl intravenous (2 μg/kg), etomidate intravenous (0.3 mg/kg), and rocuronium intravenous (0.9 mg/kg) were given as a muscle relaxant to facilitate endotracheal intubation. Patients were ventilated with 100% oxygen; under direct laryngoscopy patients were intubated with an appropriately sized endotracheal tube. Bilateral air entry was checked and endotracheal tube was secured. The surgery was allowed to start and anesthesia was maintained with 100% oxygen, 0.6% sevoflurane, and intermittent vecuronium intravenous (0.01 mg/kg/ in every half an hour), midazolam 0.01 mg/kg hourly. In the intraoperative period invasive blood pressure (IBP), ECG, oxygen saturation, end-tidal sevoflurane, and end-tidal carbon dioxide were monitored. The entropy-monitoring measures the depth of anesthesia and facilitates anesthetic titration. Entropy index was maintained in a range between 40 and 60 during surgery if the score exceeded more than 60, injection of fentanyl 1 μg/kg intravenous bolus dose was repeated. Total consumptions of fentanyl were noted; median consumption of fentanyl in micrograms per kilogram per hour was calculated and the duration of surgery was noted. Injection Paracetamol 1 g intravenous was administered after completing the surgery. Patients were shifted to the ICU, according to our institutional protocol 1 g of paracetamol intravenous was given every 8 h, hemodynamic variables (HR, SBP, DBP, MAP, oxygen saturation) were noted, when patients fulfilled the criteria for extubation, the patient was extubated and extubation time was noted. Postoperative pain at rest and while coughing was measured using the VAS (0, no pain and 10, worst pain imaginable). If the VAS score was greater than 3 in both groups, injection diclofenac 75 mg was administered as rescue analgesia.

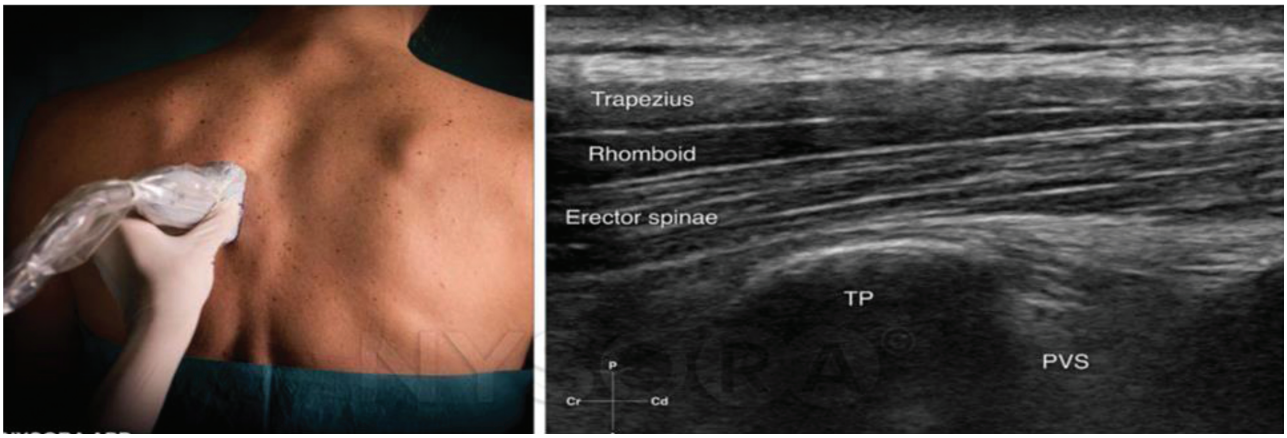
Statistical analysis

Statistical analyses were processed using SPSS, Statistics for Windows, version XX (IBM Corp., Armonk, N.Y., USA) version 21.0 software. Continuous variables were presented as mean with SD and categorical data were presented as numbers and percentages or median (interquartile range), depending on whether the data were distributed normally or not. To observe the difference in quantitative variables between both groups Student's *t* test/analysis of variance test was performed. The Fisher exact or χ^2 test was used to establish the association between qualitative variables. *P* value less than 0.05 was considered to be statistically significant.

Results

The study was carried out among 63 adult patients who have undergone surgeries via median sternotomy. As there were three mortalities due to surgical causes, ultimately our sample size was 60 cases who were divided into two groups of 30 each. Thus, 60 study

Figure 1



Probe position and ultrasound image of an erector spinae block at the level of T5.

participants were included for the analysis, which was equal to the estimated sample size.

The demographic data was comparable in terms of age, sex, weight, BMI, and ASA physical status (Table 1).

In this study, there was a statistically significant difference trend shown in heart rate after the block and before the bypass among both groups ($P<0.05$) (Fig. 2).

A statistically significant difference in MAP was visible only after coming off from cardiopulmonary bypass (Fig. 3).

The median requirement of fentanyl (μg/kg/h) in group A and group B was 1.97 (1.43–2.83) and 2.55 (1.55–3.19), respectively. The results showing requirement of fentanyl was less in group A but this difference was statistically nonsignificant ($P=0.348$) (Table 2).

Table 1 Demographic data

Variables	Group A	Group B	*P* value
Age (year)	42.7±15.1	49.7±15.3	0.331
Sex (male/female)	15/15	21/9	0.114
BMI (kg/m^2)	20.62±2.76	20±5.33	0.993
ASA (%)			
II	44.2	64.7	0.252
III	55.8	35.3	0.252

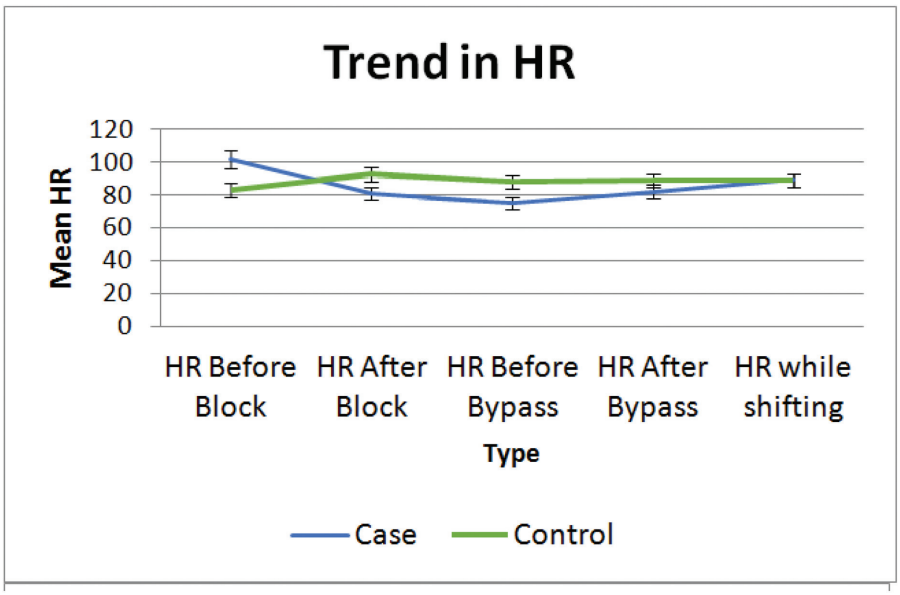
ASA, American Society of Anesthesiologist.

The mean value of time of first rescue analgesia after extubation in group A and group B is 10.9±8.6 and 7.1 ±4.4 h, respectively. This difference was statistically significant ($P=0.037$) (Table 2).

Discussion

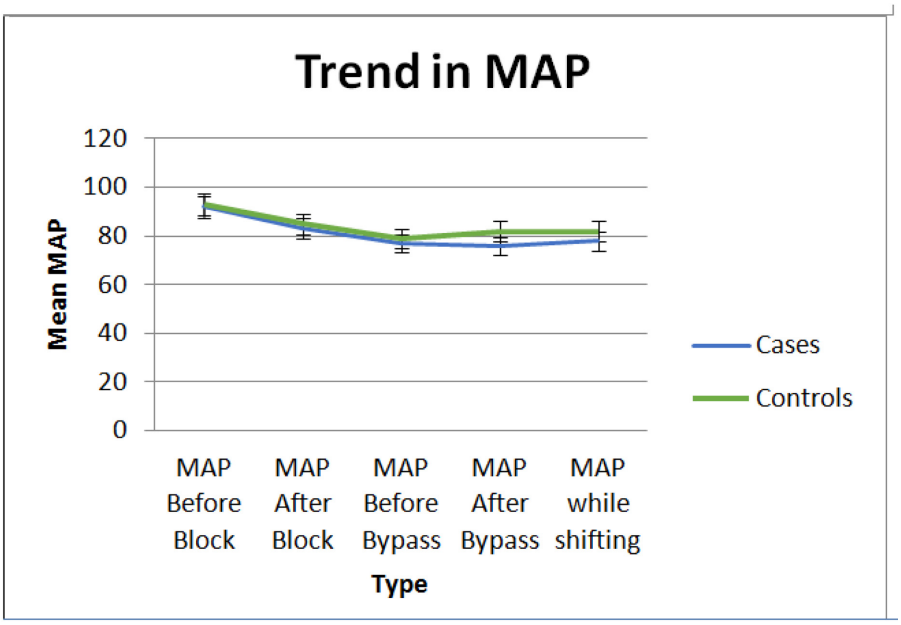
In this study, we planned for a single-shot ultrasound-guided bilateral ESPB with an adjuvant injection of dexmedetomidine 0.5 μg/kg on each side. The idea for giving a single-shot ESPB is explained as LA spreads in a craniocaudal manner; the erector spinae fascia extends from the nuchal fascia cranially to the sacrum caudally, explaining the ability of single-shot ESPB to cover multiple dermatomal levels. There was still a need for methods to extend the analgesic effect of the single-shot nerve block postoperatively, so we added an adjuvant with ropivacaine. Dexmedetomidine was associated with improved quality and duration of analgesia with no serious side effects. Dexmedetomidine as an adjuvant is considered exceedingly safe and successful for ASA II and III patients. Previous research has shown plausible mechanisms for dexmedetomidine's impact in improving blockade efficacy. In a study done by Gao and colleagues 'dexmedetomidine vs. dexamethasone as an adjuvant in ESPB,' they found that dexmedetomidine with ropivacaine, increased sensory block duration, provided effective acute pain control after surgery, and reduced the requirement for rescue analgesia. It also shortened postoperative hospital stay for patients undergoing video-assisted thoracoscopic

Figure 2



Mean heart rate in different time interval {Case (Group A) Control (Group B)}.

Figure 3



Mean arterial pressure in different time interval {Case (Group A) Control (Group B)}.

Table 2 Comparison of intraoperative fentanyl consumption, duration of surgery, extubation time, and need for first rescue analgesia

Variables	Group A	Group B	*P* value
Intraoperative fentanyl (μg/kg/h)	1.97 (1.43–2.83)	2.55 (1.55–3.19)	0.348
Duration of surgery (h)	3.18±1.02	3.39±1.43	0.522
Time of extubation (h)	14.2±3.8	13.5±3.6	0.48
First rescue analgesia postextubation (h)	10.9±8.6	7.1±4.4	0.037

lobectomy surgery. Dexmedetomidine works as vasoconstriction around the site of injection. It delays the absorption of the LA and prolongs the effect of the LAs; dexmedetomidine has analgesic effects and analgesic-sparing properties [10].

Ultrasound-guided ESPB is a relatively easy and safe block to learn. As the endpoint of the injection needle is away from the pleura, there is less risk of pneumothorax after ultrasound-guided ESPB.

The demographic data were comparable in terms of age, sex, weight, and ASA physical status (Table 1).

In the present study, there was a significant difference in heart rate after block in group A and this difference was probably due to dexmedetomidine that we added as an adjuvant. In this study, baseline MAP in both groups was comparable. There was no statistically significant difference in MAP at different time intervals except when patients were taken off the cardiopulmonary bypass in both groups. The present study was similar to the study conducted by Adhikay and colleagues. They found that MAP remained unchanged in both pre-ESPB and post-ESPB from baseline, and we found no differences in MAP in either group, except that MAP was statistically significantly higher in group B [11].

The median intraoperative requirement of fentanyl was less in the ESPB group as compared with group B, but this difference was statistically not significant (P=0.348).

Singh and colleagues reported a case study on ESPB as an alternative to continuous TEA for perioperative pain management in a patient undergoing cardiac surgery. They concluded that the ESPB is easy to perform and can serve as an alternative to TEA in optimum perioperative pain management in cardiac surgery [12].

Our study was similar to the study conducted by Kaushal *et al.* [13]. They also found less intraoperative fentanyl consumption in group B (ESPB) 10.45±3.23 μg than group C (no block) 11.46±2.06 μg; this result was statistically not significant.

The result of our study was comparable with a study by Nair and colleagues, who reported that the mean intraoperative fentanyl requirement in ESP was 118.70±28.88 μg and in the control group was 145.20±28.66 μg, which was statistically significant (P=0.000 unpaired t test) [14].

A study conducted by Wasfy *et al.* [15] was in accordance with the present study. Intraoperative fentanyl consumption in micrograms was significantly less in study group B (403.75±44.63 vs. 685±99.47) in control group A, after ultrasound-guided ESPB in coronary bypass surgery.

In this study, it was observed that there was no statistically significant difference in group A and group B in the mean duration of extubation (P>0.124). The study was performed by Kaushal and colleagues which were in accordance with our study and found that the mean duration of extubation time among both the groups was statistically not significant In the ESPB block group the mean duration of extubation was 45.36±5.48 min and in the control group it was 47.23±5.80 min (P>0.05) [13]. In a study conducted by Macaire *et al.* [16], they concluded that the mean duration of extubation time in the study group was 14.5 h (4.5–22 h) and 17 h (5–20 h) in the control group (P>0.05).

In a study by Shim and colleagues at the median interquartile range of the postoperative rescue pethidine consumption was significantly less [25 mg (25 mg)] in the ESP group than that in the control group [50 mg (56.2 mg); P=0.006] in thoracoscopic surgery. Based on the findings of this prospective trial, it is clear that the ultarsound-guided ESPB group requires a longer duration of rescue analgesia [17].

Gürkan amd colleagues conducted ESPB in breast surgery for postoperative analgesia. This study is similar to our study. They compared 50 patients in two groups (ESP group and control group). Total morphine requirement in the block group decreased by 65% at 24 h compared with the control group (5.76 ±3.80 vs. 16.60±6.92 mg), but they observed no statistically significant difference between the groups in terms of NRS scores [18].

However, ESPB is convenient to perform and a comparatively safe method in which the transverse process acts as an anatomic barrier and avoids needle insertion to the pleura, decreasing the risk of pneumothorax as well as direct spinal cord injury, epidural hematoma, and central infection. The safety margin could make it possible to perform in a ward or in an outpatient clinic setting. In our study, complications were seen in three (5%) patients. A 21-year-old female who underwent ESPB posted for mitral valve replacement became hemodynamically unstable, restless, and developed seizures 5 min after the block; her vitals were pulse, 144 bpm and blood pressure, 65/40 mmHg. She was immediately induced and surgery began; the postoperative period was uneventful. It is probably due to that the patient developed LA toxicity. We suspect LA toxicity because patients developed seizures immediately after the block and she had not any history of seizures and neurological abnormality in the past. The other two patients complained of dizziness 5 min after the block may be due to hypotension because of dexmedetomidine (Table 3).

Table 3 Complications after erector spinae plane block

Variables	Group A (30)	Group B (30)	P value
Nausea and vomiting	0	0	1.000
Dizziness	2	0	0.472
Itching	0	0	1.000
Urinary retention	0	0	1.000
Pneumothorax	0	0	1.000
LA toxicity (seizure)	1	0	0.99

LA, local anesthetic.

A study by Yao *et al.* [19] found that incidences of PONV and dizziness in the ESPB group were less. No episodes of clinically significant hypotension or bradycardia were reported in their study.

Limitations

There were a few limitations to the study, relatively a small sample size; patients with weight more than 65 kg were not included in the study, hence the results of our study may not be applicable in obese patients and thus, further trials including obese patients need to be done. We did not include pediatric patients. A fixed amount of LA was used irrespective of the weight of the patients. We did not check the dermatomal sensory blockade in our patients.

Conclusion

ESPB is a safe regional anesthetic technique without significant complications. It is a very effective technique to provide postoperative analgesia and hence recommended to be included as a part of routine postoperative analgesia in patients undergoing cardiac surgery. Within the capacity of

this study, ESPB delayed the need for rescue analgesia postcardiac surgery.

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Conflicts of interest
There is no conflicts of interest related to all author of this study.

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