

Augmentative compression plating versus exchanging reamed nailing for nonunion of femoral shaft fracture after intramedullary nailing : A retrospective cohort study

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Aim of the present study was to compare the outcomes between exchanging reamed nailing (ERN) and augmentative compression plating (ACP) in treatment of femoral shaft nonunion after intramedullary nailing (IMN) retrospectively.

A retrospective, multicentre study was performed with 188 patients (190 cases)with femoral shaft nonunion after IMN, who received therapy with either ERN (n = 92) for 44/92 (47.8%) cases of nonisthmal nonunions and 48/92 (52.2%) cases of isthmal nonunions or ACP (n = 98) for 48/98 (49%) cases of nonisthmal nonunions and 50/98 (51%) cases of isthmal nonunions. Operation time, intraoperative blood loss, time to union, union rate, postoperative draining volume and complication rate were compared between ERN and ACP group.

After a mean follow-up of 4.6 years (range 1-8.1 years), the bone union occurred in 98/98 (100%) cases in total ACP group versus 80/92 (87%) cases in total ERN group [odds ratio (OR) = 3.34, 95% confidence interval (CI) 0.8-1.6]. Twelve cases with re-nonunion in the total ERN group included 10/12 (83.3%) cases of nonisthmal nonunions and 2/12 (16.7%) cases of isthmal nonunion with cortical bone defect > 3 cm. The average time to union, the intraoperative blood loss and the complication rate in total ERN group were also both significantly more than that in total ACP group (p = 0.031, p = 0.042, p = 0.028). No significant difference was found in the average operation time between the two total groups (p = 0.213). However, for nonisthmal nonunions, the mean opera-

No benefits or funds were received in support of this study. The authors report no conflict of interests. tion time for ERN group was 126.8 ± 19.6 min in comparison to ACP group (88.6 ± 15.2 min), significant difference was found between ERN group and ACP group (p = 0.021).

ACP could obtain the higher bone union rate and shorter time to union than ERN in the treatment of femoral shaft nonunion after failed IMN. Especially for nonisthmal femoral shaft nonunions or isthmal

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nonunions with larger bone defect, ACP could bring more advantages to patients than ERN. A prospective observational study is needed.

Keywords : femoral fracture ; intramedullary nailing ; nonunion ; exchanging reamed nailing ; augmentative compression plating.

INTRODUCTION

Nowadays, although a number of surgical strategies have been suggested for aseptic femoral shaft nonunions after failed IMN including ERN, ACP, internal fixation after hardware removal, only bone grafting (BG), and dynamization of static interlocking nails, ERN tends to yield better outcomes in the treatment of these nonunions with the union rate of 72-100% (4.11.14.18.20.25.26). Nevertheless, several studies have revealed that ERN could not achieve satisfactory clinical outcomes in the treatment of femoral nonunions after failed IMN for comminuted femoral shaft fracture with or without obvious bone defects, and nonisthmal femoral fracture etc (1,24,27). On the contrary, ACP has increasingly shown to have more advantages, which include less injury, shorter operation time and no requirement of IMN removal, than ERN surgery. More importantly, a postoperative bone union rate up to 100% can be achieved by ACP surgery for femoral nonunions after failed IMN (15). Yet, it remains unclear whether ACP can bring more advantages to patients with femoral nonunions after failed IMN than ERN regardless of any anatomical sites. As a result, the debate between advocates of ACP and ERN is likely to continue until a long-term follow-up study reveals the clinical outcomes and indications of ERN surgery and ACP surgery respectively. The current study aimed to analyze and compare the clinical outcomes between ERN and ACP in treatment of femoral shaft nonunion subsequent to failed IMN.

METHODS

Study design

Between 2001 and 2013, 188 patients (190 cases) with femoral shaft nonunion after IMN received therapy

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with either ERN (n = 92) or ACP (n = 98). Patients were identified by queries of computerized records databases. According to the anatomic features of isthmus and extraversion of the metaphysis, the femoral shaft was divided into isthmal and nonisthmal (supraisthmal and infraisthmal) sections (15,27). Of all cases, ERN surgery was selected for 44/92 (47.8%) cases of nonisthmal nonunions and 48/92 (52.2%) cases of isthmal nonunions, and ACP surgery for 48/98 (49%) cases of nonisthmal nonunions and 50/98 (51%) cases of isthmal nonunions. A nonunion was defined as a radiolucent line without signs of callus formation around femoral shaft fracture treated by interlocking IMN for at least six months. It was characterized as persistent pain at the fracture site which might get worse by mobilization or weight-loading. X-ray films of all patients displayed sclerotic margins without continuous callus spanning the fracture site or no callus at least three cortices (7). For patients with femoral shaft nonunions after failed IMN treated with ERN or ACP, only patients aged between 19-60 years or with aseptic nonunions were included. Patients with open fractures at the initial injury, pathologic fracture, suspected latent infection, leg length discrepancy of more than 1.5 cm, severe cardiovascular disease or a recent administration history of corticosteroids and immunosuppressive drugs were excluded. This was a retrospective, multicentre study, the sample size of which was calculated and which was approved by the institutional review board at all centres.

Surgery

For ERN surgery (n = 92), the IMN was removed by C-arm X-ray positioning and monitoring using the original incision. The sclerotic margins and fibrous tissue fillings in the fracture gap were removed throughly. The diameter of reamed medullary cavity was increased by 1-2 mm to insert the exchanged IMN. Excessive proximal reaming should be avoided because it was possible to result in mechanical instability. In this group, the diameter of exchanged IMNs was 1-2 mm larger than original ones. Of all cases, 75 cases had replaced the nails with antegrade femoral IMN (Synthes, USA), and 17 cases with retrograde ones (Synthes, USA). For the patients with atrophic nonunions or nonunions of cortical bone defect > 1 cm (length in cm around the nail), autologous iliac grafting was performed using cancellous bone to fill in the fracture gap. For larger defects, a portion of cortical bone was applied mixed with cancellous bone. The average weight of BG in this group was 4.49 ± 0.27 g (range 0-11 g).

For ACP surgery (n = 98), dissection of periosteum or muscles was minimized to avoid blood supply damage. In 98 cases (97 patients) of this group, 44 cases received treatment with 7-11 hole locking compression plates (Synthes, USA), and the other 54 cases with 6-10 hole dynamic compression plates (Synthes, USA). To prevent the drill breakage, 3-3.5 mm Kirschner wires were used to enable the screws to travel through the cortical bones completely. A certain range of angle adjustment was allowed for the screws to avoid IMN baffle, Three to four pieces of locking screws or ordinary cortical screws were fixed on distal and proximal ends of the plate. Autologous iliac grafting, with an average weight of 8.61 ± 0.37 g (range 7-12 g), was applied to all patients in this group.

The drainage tubes were placed for 1-2 days postoperatively. The patients started to mobilize hip and knee joints with assistance of Continuous Passive Motion (CPM) machine to avoid the stiffness of joints. Meanwhile, the patients were encouraged to take isometric and isotonic training of quadriceps actively. Eight weeks after operation, the patients could gradually have partial weight-bearing walk dependent of crutches, followed by full weight bearing walk once obvious continuous callus appeared in X-ray films.

Data collection and outcome measurement

Data collection included demographics (ages, gender, side, comminution grade, interlocking mode of nail, previous number of operations, nonunion type, cortical bone defect, intervals from injury), operation time, intraoperative blood loss, time to union, union rate and postoperative draining volume and related complications. Outpatient follow-ups were carried out at 1, 2, 3, 4, 6, and 12 months after surgery and then once every year. Radiological examinations included femoral plain radiographs in 2 views (anteroposterior view and lateral view) to monitor callus growth. Follow-ups at interval of a month was carried out for those without obvious progression of healing four months after surgery. Operative time and intraoperative blood loss were recorded along with any related complications during the study. In data collection, the operation time referred to the duration from skin open to wound closure. Intraoperative blood loss was calculated by hematocrit changes (theoretical value) with extra transfusion volume. The calculation was made according to following formulas : total volume of blood loss = preoperative blood volume × (preoperative hematocrit – postoperative hematocrit). $PBV = kl \times height (cm) +$ $k2 \times weight (kg) + k3 (male kl = 0.3669, k2 = 0.03219,$ k3 = 0.6041; female kl = 0.3561, k2 = 0.03308, k3 = 0.1833) (9). Postoperative draining volume referred to the actual volume in postoperative wound drainage bag together with nettly – increased weight of gauze pad. The data were extracted through patient chart review and computerized records that were linked to patient records in the community and other hospitals.

Statistical Analysis

Data were analyzed with SPSS version 18.0 statistical software (SPSS Inc, Chicago, Illinois). Descriptive frequencies and percentages were tabulated. Pearson's chisquare test or Fisher's exact chi-square test, as appropriate, was used to detect differences in nonparametric variables, Unadjusted odds ratios (ORs) with 95% confidence intervals (CIs) are presented. Continuous variables were compared using the t-test or the Mann-Whitney Utest, as appropriate. All tests were two-tailed and $P \le 0.05$ was considered statistically significant (power 80%).

RESULTS

A total of 188 patients (190 cases) with femoral shaft nonunion after IMN were identified, who received therapy with either ERN (n = 92) for 44/92 (47.8%) cases of nonisthmal nonunions and 48/92 (52.2%) cases of isthmal nonunions or ACP (n = 98) for 48/98 (49%) cases of nonisthmal nonunions and 50/98 (51%) cases of isthmal nonunions. No significant difference in demographics of patients was showed between ERN group and ACP group (P > 0.05) (Table I).

After a mean follow-up of 4.6 years (range 1-8.1 years), the bone union occurred in 98/98 (100%) cases in total ACP group versus 80/92 (87%) cases in total ERN group [odds ratio (OR) = 3.34,95% confidence interval (CI) 0.8-1.6] (Fig. 1). Twelve cases with re-nonunion in the total ERN group included 10/12 (83.3%) cases of nonisthmal nonunions and 2/12 (16.7%) cases of isthmal non-union with cortical bone defect > 3 cm, of which two patients with nonisthmal nonunion achieved the final healing 3 and 5 months after subsequent cast immobilization of the affected limb respectively who declined next operation for the reason of economy, and the others eventually achieved bone union after secondary autologous BG (Fig. 2). The

Tuble 1. Demographic enaluciensites of eases					
	Nonisthmal (N = 92)		Isthmal (N = 98)		
	ERN (N1 = 44)	ACP (N2 = 48)	ERN (N1 = 48)	ACP (N2 = 50)	
Age (years)	46.6 (range 19-56)	48.3 (range 24-60)	48.8 (range 22-54)	47.8 (range 19-60)	
Males/females	23/21	26/21	28/19	27/23	
Side, n (%)					
Left	24 (54.5%)	27 (57.4%)	29 (61.7%)	27 (54%)	
Right	20 (45.5%)	19 (40.4%)	17 (36.2%)	23 (46%)	
Bilateral	0 (0)	1 (2.2%)	1 (2.1%)	0 (0)	
Comminution Grade, n (%) ^a					
0-I	16 (36.4%)	18 (37.5%)	19 (39.6%)	17 (34%)	
II-III	20 (45.4%)	23 (47.9%)	23 (47.9%)	23 (46%)	
IV	8 (18.2%)	7 (14.6%)	6 (12.5%)	10 (20%)	
Cortical bone defect, median (cm, range)	1 (range 0-2.5)	1.5 (range 0-4)	1.5 (range 0-4.5)	1 (range 0-3)	
Interlocking mode of nail, n (%)					
Static	26 (59.1%)	30 (62.5%)	30 (62.5%)	29 (58%)	
Dynamic	18 (40.9%)	18 (37.5%)	18 (37.5%)	21 (42%)	
Previous number of operations, median (range)	2 (range 0-4)	1.5 (range 0-2)	1.5 (range 0-2)	2 (range 0-3)	
Nonunion type, n (%) ^b					
Hypertrophic	20 (45.5%)	25 (52.1%)	26 (54.2%)	22 (44%)	
Atrophic	24 (54.5%)	23 (47.9%)	22 (45.8%)	28 (56%)	
Interval from injury, median (yrs, range)	1.5 (range 0-3.5)	1 (range 0-2)	1 (range 0-2)	1.5 (range 0-3)	

Table I. —	Demographic	characteristics	of cases

ERN/ACP, exchange reamed nailing/augmentation compression plating.

^aWinquist-Hansen classification.

^bWeber-Cech classification.

time to union and the intraoperative blood loss in total ERN group were also both significantly more than that in total ACP group (p = 0.031 and p = 0.042). No significant differences were found in the average operation time and postoperative draining volume between the two total groups (p = 0.213 and p = 0.176) (Table II).

In the treatment of nonisthmal nonunions, there was no significant differences in postoperative draining volume between ERN group and ACP group (p = 0.512). However, the mean operation time, intraoperative blood loss, time to union for ERN group was $126.8 \pm 19.6 \text{ min}$, $786.8 \pm 98.7 \text{ ml}$, $9.8 \pm 2.3 \text{ months}$ respectively in comparison to ACP group ($88.6 \pm 15.2 \text{ min}$, $362.4 \pm 84.8 \text{ ml}$, $5.2 \pm 0.8 \text{ months}$, respectively), significant differences

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was found between ERN group and ACP group (p = 0.021, p = 0.031 and p = 0.037). The bone union occurred in 48/48 (100%) cases in ACP group versus 34/44 (77.3%) cases in total ERN group [odds ratio (OR) = 3.69, 95% confidence interval (CI) 0.5-1.5] (Table III).

In the treatment of isthmal nonunions, there was no significant differences in postoperative draining volume, intraoperative blood loss, time to union and union rate between ERN group and ACP group (p = 0.248, p = 0.132, p = 0.768 and p = 0.201).

However, the mean operation time $(86.5 \pm 11.2 \text{ min})$ in ERN group was less than that $(131.9 \pm 27 \text{ min})$ in ACP group (p = 0.026) (Table III).

After surgery, two patients in ACP group had delayed wound infection after bone healing whose



Fig. 1. — a. A 48-year–old-male patient with bilateral superaisthmal femoral shaft nonunions 9 months after antegrade IMN; b. Instant x-ray filming after ACP (9 holes of DCP on the left and 9 holes of LCP on the right); c. Bone union was achieved 5 months (left) and 6 months (right) after ACP respectively. d. X-ray demonstrated complete bone healing after implant removal.

wounds healed successfully after hardware removal. The complication rate in total ERN group significantly was higher than the total ACP group (p = 0.024). Likewise, in the treatment of nonisthmal nonunions, significant difference was found in the complication rate between the two groups (p = 0.021) (Table II, III). No patients had experienced failure of internal fixation, neurovascular injury, angular or rotational malunion or other complications.

DISCUSSION

ERN tends to yield better outcomes in the treatment of these nonunions with the union rate of 72-100% (4,11,14,18,20,25,26). Court-Brown *et al* (23) suggested that reaming could increase periosteal blood circulation to stimulate periosteal to generate new bones . In addition, Bhandari *et al* (2) found that IGF I/IGF II antibodies and indomethacin could reduce bone formation after reaming ; thus it was conceivable that activated growth factors played a critical role in reamed bone formation due to weakened inflammation and immune system response, which can decrease the production of IGF I/IGF II antibodies and indomethacin. The mechanical advantage of ERN lies in applying the thicker and longer IN after reaming to increase the contact area between the nails and cortex. As a consequence, the mechanical stability, particularly anti-rotation stability (ARS) of the fracture ends could increase, which was consistent with bone healing mechanisms. Nevertheless, some investigators raised doubts on the effectiveness and indications of ERN (1,24,27). In a study by Banaszkiewicz et al (1), only bone healing rate of 58% was achieved in ERN-treated femoral shaft nonunions after failed IN. Similarly, a study by Park et al (15) reported retrospectively that 5 out of 7 patients with femoral shaft nouunion after failed IMN did not achieve bone healing after ERN surgery once again, with the non-union rate of 72%. It was concluded that patients with non-isthmal nonunions could not gain more effective contact area and thus had poor ARS after ERN surgery, yet biomechanical studies on this aspects remain absent currently. On the contrary, ACP has increasingly shown to have more advantages, which include less injury, shorter operation time and no requirement of IMN removal, than ERN surgery. More importantly, a postoperative bone union rate up to 100% can be achieved by ACP surgery for femoral nonunions after failed IMN (7). Yet, it remains unclear whether ACP can



Fig. 2. — a. A 39-year-old male patient with infraisthmal femoral shaft nonunion 9 months after retrograde IMN; b. Bone union was not achieved 7 months after ERN; c. Obvious bone calus was formed 3 months after secondary autologous bone grafting. d. Final bone healing was completed 6 months after bone grafting. e. X-ray demonstrated complete bone healing after implant removal.

bring more advantages to patients with femoral nonunions after failed IMN than ERN regardless of any anatomical sites. As a result, the debate between advocates of ACP and ERN is likely to continue until a long-term follow-up study reveals the clinical outcomes and indications of ERN surgery and ACP surgery respectively. Thus, clinical orthopedic surgeons had put further insights into causes for high failure rate of ERN to ensure the indications of its use.

In the current study, the bone union occurred in 98/98 (100%) cases in total ACP group versus 80/92 (87%) cases in total ERN group [odds ratio (OR) = 3.34, 95% confidence interval (CI) 0.8-1.6].

Table II. Comparison of outcomes between the total EII (group and the total Tier group				
	total ERN group (N = 92)	total ACP group (N = 98)		
Mean operation time (min), mean ± SD	116.8 ± 19.5	105.6 ± 17.3		
Mean intraoperative blood loss (ml), mean ± SD	589.6 ± 102.3 °	343.6 ± 88.9 °		
Mean postoperative draining volume (ml), mean ± SD	181.2 ± 51	173.7±46		
Mean time to union (mons), mean ± SD	8.9 ± 2.3 b	5.2 ± 0.9 ^b		
Union rate, n (%)	80 (87%)°	98 (100%)°		
Complication rate, n (%) ^d				
Infection	0 (0)	2 (2%)		
Re-nonunion	12 (13%)	0 (0)		

Table II. — Comparison of outcomes between the total ERN group and the total ACP group	able II. — Comparison of	utcomes between th	he total ERN grout	and the total ACP group
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 $^{a}P = 0.042.$

 ${}^{\rm b}P = 0.031.$

 $^{\circ}P = 0.044.$

 ${}^{d}P = 0.028.$

In the treatment of nonisthmal nonunions, the bone union occurred in 48/48 (100%) cases in ACP group versus 34/44 (77.3%) cases in total ERN group [odds ratio (OR) = 3.69, 95% confidence interval (CI) 0.5-1.5]. However, for isthmal nonunions, there was no significant differences in union rate between ERN group and ACP group (p = 0.201). The result showed that ACP could obtain the higher

bone union rate than ERN in the treatment of femoral shaft nonunion after failed IMN and bring more advantages to patients with nonisthmal femoral shaft nonunions or isthmal nonunions with larger bone defect especially. Poor ARS may be mainly responsible for low union rate after ERN surgery, yet larger studies and further biomechanical studies are needed to fully validate these results.

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	Nonisthmal (N = 92)		Isthmal (N = 98)		
	ERN group	ACP group	ERN group	ACP group	
	(N1 = 44)	(N2 = 48)	(N1 = 48)	(N2 = 50)	
Mean operation time (min),	126.8 ± 19.6 a	88.6 ± 15.2 °	$86.5 \pm 11.2^{\circ}$	131.9 ± 27 °	
$mean \pm SD$					
Mean intraoperative blood loss (ml), mean ± SD	$786.8\pm98.7^{\mathrm{b}}$	362.4 ± 84.8 ^b	473.6 ± 93.4	323.5 ± 51.1	
Mean postoperative draining volume (ml), mean \pm SD	159.6 ± 54	169.7 ± 49	160.4 ± 35.6	164.8 ± 39	
Mean time to union (mons), mean ± SD	$9.8 \pm 2.3^{\circ}$	5.2 ± 0.8 °	7.7 ± 1.3	6.2 ± 0.9	
Union rate, n (%)	34 (77.3%) ^d	48 (100%) ^d	46 (95.8%)	50 (100%)	
Complication rate, n (%)					
Infection	0 (0)	1 (2%)	0 (0)	1 (2%)	
Re-nonunion	10 (22.7%)	0 (0)	2 (4.2%)	0 (0)	

Table III. - Comparison of outcomes between ERN group and ACP group according to different sites

 $^{a}P = 0.021.$

 ${}^{\rm b}P = 0.031.$

 $^{\circ}P = 0.037.$

 ${}^{\rm d}P = 0.024.$

 $^{\circ}P = 0.026.$

Interestingly, this study showed a relatively higher bone healing rate for ERN surgery compared to what was reported by Park *et al*. The possible interpretation was that autologous iliac grafting was performed in this study for patients with atrophic nonunions or nonunions with cortical bone defect > 1 cm, whereas only closed surgery without autologous BG was performed for patients in the ERN group by Park *et al* (15).

In a study by Ueng et al (21,22), ACP surgery in combination with autologous bone grafting was firstly reported to lead to 100% bone healing rate for femoral nonunions after failed IMN, and poor ARS was thought to be the main cause for femoral shaft non-unions after failed IMN. The mechanical advantages of ACP surgery include its axial stability and bending resistance due to retaining original IMN as a prerequisite, reinforcement of ARS at the broken ends of fracture via augmentive plating, and correction of rotational deviation. As a result, indispensable mechanical supports are provided for formation of local callus bridging. In addition, for nonisthmal nonunions, dual cortical screws fixation for ACP surgery could provide a mechanical stability as the blocking screws. In a cadaveric fracture model study by Park et al (16), the augmentive plate group had a 3.3-fold increase in torsional stiffness and 2.6-fold increase in bending stiffness, compared with interlocking IMN group. Moreover, the involved biological mechanism in ACP surgery was to stimulate bone remodeling at the fracture ends through successful bone autografts with osteogenesis, osteoconduction, and osteoinduction (21,22). Numbers of studies have shown that ACP surgery has many advantages over ERN in the treatment of long bone nonunions after failed IMN, which include minimal invasion, short operation time, high bone healing rate and satisfactory outcomes (3,5,6,8, 10,12,13,17,19,21,22,28). However, a major drawback of ACP lies in its additional invasiveness requiring an augmentive incision. In addition, for isthmal femoral nonunions after failed IMN, screws fixiaton have greater difficulties in ACP surgery. The effectiveness of 2 surgical methods (ACP and ERN) for femoral shaft nonunion subsequent to failed IMN at different anatomical sites need to be clinically compared.

The present study demonstrated that no significant differences were found in the average operation time between the two total groups (p = 0.213). However, in the treatment of isthmal nonunions, mean operation time in ACP group $(131.9 \pm 27 \text{ min})$ was longer than that $(86.5 \pm 11.2 \text{ min})$ in ERN group (p = 0.026). Its cause may be related to difficult insertion and fixation of screws due to blocking of IMN in ACP surgery. Although two ACP-treated patients suffered from delayed wound infection, success wound healing was achieved after hardware removal. It was thought that the delayed wound infection in this patient may result from such affective factors as skin scar, stiff joints, and poorly systemic immune functions. Moreover, the result of this present study indicated that the intraoperative blood loss in total ERN group were also significantly more than that in total ACP group (p = 0.042). The possible causes for increased blood loss after treated with ERN may lie in reaming-related destruction of intramedullary blood supply, and difficult removal of hardwares because according instruments were absent for some patients whose initial surgeries were performed at other hospitals. Thus, this study result demonstrated that, for ERN surgery in combination with autologous BG even, the re-nonunion rate were still high in patients with nonisthmal nonunions or with larger cortical bone defect. In present study, twelve cases with re-nonunion in the total ERN group included 10/12 (83.3%) cases of nonisthmal nonunions and 2/12 (16.7%) cases of is thmal nonunion with cortical bone defect > 3 cm, of which two patients with nonisthmal nonunion achieved the final healing 3 and 5 months after subsequent cast immobilization of the affected limb respectively who declined next operation for the reason of economy, and the others eventually achieved bone union after secondary autologous BG.

In conclusion, ACP could obtain the higher bone union rate and shorter time to union than ERN in the treatment of femoral shaft nonunion after failed IMN. Especially for nonisthmal femoral shaft nonunions or isthmal nonunions with larger bone defect, ACP could bring more advantages to patients than ERN. A prospective observational study is needed.

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