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Original Research

Minimally invasive surgery in the era of step-up approach for treatment of severe acute pancreatitis

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ABSTRACT

Objectives: To assess the minimally invasive surgery into the step-up approach procedures as a standard treatment for severe acute pancreatitis and comparing its results with those obtained by classical management.
Methods: Retrospective cohort study comparative with two groups treated over two consecutive, equal periods of time were defined: group A, classic management with open necrosectomy from January 2006 to June 2010; and group B, management with the step-up approach with minimally invasive surgery from July 2010 to December 2014.
Results: In group A, 83 patients with severe acute pancreatitis were treated, of whom 19 underwent at least one laparotomy, and in 5 any minimally invasive surgery. In group B, 81 patients were treated: minimally invasive surgery was necessary in 17 cases and laparotomy in 3. Among operated patients, the time from admission to first interventional procedures was significantly longer in group B (9 days vs. 18.5 days; $p = 0.042$). There were no significant differences in Intensive Care Unit stay or overall stay: 9.5 and 27 days (group A) vs. 8.5 and 21 days (group B). Mortality in operated patients and mortality overall were 50% and 18.1% in group A vs 0% and 6.2% in group B ($p < 0.001$ and $p = 0.030$).
Conclusions: The combination of the step-up approach and minimally invasive surgery algorithm is feasible and could be considered as the standard of treatment for severe acute pancreatitis. The mortality rate deliberately descends when it is used.

1. Introduction

Acute pancreatitis (AP) remains a serious public health problem in Western countries [1], with an incidence that has increased to 13–14 cases per 100,000 people per year [2–4]. Although most cases are mild and self-limiting [5], mortality in severe acute pancreatitis (SAP) remains high, exceeding 3000 deaths annually in the US [1]. Classically, infection of pancreatic necrosis was considered an absolute indication for urgent surgical debridement, even so mortality rates could reach up to 25–40% [6,7], a percentage that was reduced with medical treatment [8].

When organ failure (OF) and infected pancreatic necrosis are both present it indicates extremely severe disease or critical acute pancreatitis. The main risk factor for death is the infection of pancreatic necrosis and the relative risk of mortality doubles when it includes OF [9,10]. Therefore, currently the main indication for surgical treatment in SAP remains the infection of pancreatic or peripancreatic necrosis, especially if associated with OF [11].

However, the diagnosis of infected necrosis alone is not an absolute indication for surgical treatment [12,13]. Conventional open necrosectomy (ON) is associated with a high rate of postoperative complications, reoperations and mortality, as well as a high rate of postoperative diabetes [14–17]. The earlier the surgery is performed during the evolution of the disease, the poorer the results [16,18] and, in fact, surgical treatment has proved insufficient for adequate control of the systemic inflammatory response in early stages of SAP [16,19,20]. Nevertheless, if surgical debridement is performed at a late stage, the reoperation rate is lower and the results are highly improved [9,18,21].

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The step-up approach has shown that what matters is not the removal of the necrosis, but it is the control of the septic focus [22]. In cases of sterile SAP associated to persistent organ failure the results of surgery remain poor, so it is only considered in selected cases [11], basically when serious clinical deterioration is presented. The earlier and the more severe the onset of the OF, the worse the prognosis [14].

The various treatments in acute necrotising pancreatitis include the ON and minimally invasive surgery (MIS) have shown good results in both treatment strategies [23]. The use of the step-up approach with MIS in SAP is gaining popularity, and the procedure is currently an alternative to ON. Specialist groups routinely use it in over 90% of their patients, with good results [24,25], whereas when ON is manage by some selected expert groups it presents a mortality rate of only 12% [26,27].

The aim of our study is to evaluate the MIS into the step-up approach procedures as a standard method of managing SAP, comparing it with the classic conventional therapy and analysing the evolution of our results in the treatment of SAP.

2. Methods

In July 2010, we adopted the step-up approach/MIS treatment algorithm proposed by the Dutch Pancreatitis Study Group [22,28]. Since then we have attempted to apply this approach in all patients with SAP. Prior to July 2010 some selected patients had undergone MIS, but not as part of a formal treatment strategy.

We designed a retrospective comparative cohort study with two groups of consecutive patients treated with two different SAP management protocols:

- Group A (conventional therapy), from 1/1/2006 to 30/6/2010 (54 months): patients were treated in accordance with current recommendations for classic management of SAP [29,30].
- Group B (step-up approach-MIS), from 01/07/10 to 31/12/14 (54 months): patients were treated using MIS into the step-up approach strategy [22].

The work has been reported in line with the STROCSS criteria [31] and informed consent of treatment was obtained for every patient.

In both periods, the same recommendations were followed with regard to the use of prophylactic antibiotics, enteral nutrition, need for early ERCP and diagnosis by fine-needle aspiration puncture or blood cultures of the pancreatic/peripancreatic infection [13,32–34]. Although patients were managed by a specialist multidisciplinary team in both periods, in group A surgery was carried out as an emergency procedure by the surgeon on call, while in group B, as far as possible, surgery was performed on a semi-scheduled basis by a surgical team specialising in pancreatic surgery.

Only patients with definitive, unequivocal diagnosis of acute pancreatitis were enrolled in the study [32,33]. In addition, the disease had to be the primary or initial cause of admission to our centre, regardless of the etiology. Patients with clinical criteria (OF > 48 h. duration) and/or radiological criteria of severity according to the revised recommendations of Atlanta 2012 [35] were considered as SAP. Pancreatic pseudocyst was considered a late complication of the AP, so no cases were included in the study. We do not show the different scoring systems, although we use them routinely because the same initial clinical and radiological scores can develop a variety of clinical course of disease.

Variables analysed were: age, sex, etiology, days before surgery, Intensive Care Unit (ICU) stay, total stay, need for surgical intervention and type, number of reoperations, presence or absence of infected necrosis, and mortality.

3. Invasive procedures performed

In ON, the incision of choice was a bilateral subcostal laparotomy, and the technique of choice was necrosectomy and postoperative local lavage [29]. In some cases, in view of the intraoperative findings and at the discretion of the surgeon, the abdomen was left open with an ad vacuum therapy system. This system was especially used in re-operations, when the abdominal wall cannot be closed and to decompress and avoid compartment syndrome [36].

The MIS interventions were adapted to each patient. Five different types [37] were considered:

3.1. Percutaneous drainage (PD)

One or more percutaneous drains of at least 8 French are inserted under radiological guidance. The puncture site and route are previously agreed upon with the radiologist, taking into account the intended treatment strategy and bearing in mind the possibility of the need for surgery in the future.

3.2. Transperitoneal laparoscopic approach (TPLA)

A conventional laparoscopic approach is used to access the pancreatic sac via the gastric greater curvature. Debridement of the infected pancreatic/peripancreatic necrosis is performed if required and large caliber drains are then put in place.

3.3. Video-assisted retroperitoneal necrosectomy (VARD)

This procedure is performed as initially described by Horvath [38] and later popularized by van Santvoort [39]. At the end of the intervention, a large caliber drain is left in the debrided area.

3.4. Laparoscopic transgastric drainage (TGLD)

Using a conventional laparoscopic approach, an anterior gastrostomy is performed, through which the area of retrogastric necrosis is located using laparoscopic ultrasounds. A posterior gastrostomy is performed for the evacuation of the infected necrosis into the stomach, and then the anterior gastrostomy is sutured.

3.5. Transgastric endoscopy drainage (TGED)

Through the stomach, two or more transgastric drains are inserted in the area of infected necrosis, which is located using endoscopic ultrasounds.

4. Statistical analysis

For the statistical analysis, SPSS 14.0 software was used. The results are presented as mean and standard deviations, as numbers and percentages or as median and percentiles when confidence intervals were too high. The qualitative variables were analysed with the chi-squared test and the continuous variables with the Student “t” test. For sample sizes below 30, Fisher's exact test and U the Mann-Whitney test were used. Differences with $p < 0.05$ were accepted as statistically significant.

5. Results

Of the 1322 patients admitted to our hospital for AP, 164 with SAP (12.4%) were enrolled in the study.

Table 1 shows patient characteristics and outcomes. No significant differences were found between the two groups regarding to patient features. Patients in group A who underwent surgery did so earlier than those in group B. Although the average intervention in group A was 9

Table 1
Clinical demographic characteristics of patients included in the study.

	Group A (83)	Group B (81)	P
Age (years) †	62 (17.9)	65 (19.1)	0.415
Sex (men) ‡	43 (51.8)	53 (65.4)	0.162
Etiology ‡			
- Biliary	50 (60.2)	53 (65.4)	0.785
- Alcohol	18 (21.7)	16 (19.8)	
- Others	15 (18.1)	12 (14.8)	
Interventional approach ‡	24 (28.9)	20 (24.7)	0.533
Mortality for interventional procedures ‡	12/24 (50)	0/20 (0)	< 0.001
Overall mortality ‡	15 (18.1)	5 (6.2)	0.030
Days from admission to first interventional procedures §	9 [1.5–17.75]	18.5 [8.25–46.75]	0.042
Surgery ‡	23 (27.7)	15 (18.5)	< 0.001
Need > 1 surgery ‡	12/23 (52.2)	5/15 (33.3)	0.123
Length of stay for §			
- Intensive care unit SAP	9.5 [5.75–20.25]	8.5 [3–22.25]	0.719
- Intensive care unit interventional procedures	17 [7.5–32.5]	21 [4–49]	0.105
- All SAP	27 [17–48]	21 [13.5–34.5]	0.090
- Interventional procedures	53 [27.25–78.25]	56.5 [31–112.25]	0.364
Infected/Operated ‡	18/24 (75)	17/20 (85)	0.477

† Mean (SV)
‡ n (%).
§ Median [P25-P75].

days, many of them were operated from the second week whereas others were operated the first 48 h trying to control de multiorganic failure. Mortality was significantly lower in group B especially among operated patients. However no significant differences were observed regarding lengths of stay for interventional procedures, overall and ICU stay.

Table 2 shows mortality rate regarding to pancreatic infection and therapeutic approach. The percentage of patients undergoing surgery for sterile and infected SAP separately, and their mortality in interventional procedures was significantly lower in group B. Sterile cases with SAP that required surgical intervention were basically when serious clinical deterioration was presented.

Fig. 1 and Fig. 2 displays the type of interventional approach used for groups A and B respectively. The surgical procedure of choice in group A was ON. None of the five patients treated with open abdomen survived. The procedure of choice in group B was MIS. The most frequently used MIS approach was VARD, in nine occasions (eight patients); as the initial technique in six, and as re-operation in three. In four of the 17 patients undergoing MIS, more than one technique was required, but none required laparotomy. In two cases a VARD of the right side had to be performed due to peripancreatic involvement of the head of the pancreas – one concomitantly with the left-sided VARD and the other subsequently. In the only patient initially treated with TGED, a definitive TGLD was required at a later date. Five patients were treated only with PD. In three patients in group B, a laparotomy was performed: one for a massive hemoperitoneum due to spontaneous rupture of the spleen, another for ischemic necrosis of the left colon requiring a left hemicolectomy; and another as a finding during an emergency exploratory laparotomy performed for acute abdomen. It is known the intestine is subject to ischemic injury in SAP. This injury is often subclinical but sometimes requires an intervention that contributes to improving the severity of pancreatitis. Makes evident the interaction of pancreas and intestine to drive the outcomes of AP [40,41]. The patient with the left hemicolectomy was later re-operated upon with VARD for infection of pancreatic necrosis, which had not presented at the time of colonic ischemia. None patients in group B, underwent interventional procedures died.

Table 2
Flow chart in patients submitted to interventions in group A and B.

	Group A (83)	Group B (81)	P
STERILE	60	60	0.796
Interventional procedures †	6/60 (10)	3/60 (10)	0.012
Mortality sterile interventional patients †	4/6 (67)	0/3 (0)	< 0.001
No interventions †	54/60 (94)	57/60 (95)	0.298
Mortality No interventions †	2/54 (3.7)	4/57 (7)	0.373
Total Mortality sterile †	6 (10)	4 (6.7)	0.509
INFECTED	23	21	0.796
Interventional procedures †	18/23 (78.3)	17/21 (81)	0.477
Mortality infected interventional patients †	8/18 (44.4)	0/4 (0)	< 0.001
No interventions †	5/23 (21.7)	4/21 (19)	0.562
Mortality No interventions †	1/5 (20)	1/4 (25)	0.722
Total Mortality infected †	9/23 (39.1)	1/21 (4.8)	0.010

† n (%).

6. Discussion

The routine implementation of the step-up therapeutic algorithm is feasible in most patients with infected SAP associating MIS, in certain patients without previous percutaneous drainage. The main concept around the intervention for necrotising pancreatitis is that there is no optimal and unique treatment for all patients and hence it is necessary to individualise the cases according to their evolution. The step-up approach allows optimization of the patients critical condition, controls the septic focus and planning of the surgical procedures, mostly MIS, on semi-elective cases. Moreover, this procedure dramatically reduces the mortality and morbidity rates [42,43].

In 1998, Freeny et al. published promising results for the management of infected SAP with the use of PD alone, reporting a success rate of 47% [44]. Recently, other authors have obtained similar results, with success rates ranging from 18% to 79% [45]. Since the publication of the PANTER study [22], interest has been growing in the application of a step-up approach for SAP. It seems that the triad: control of the initial acute inflammatory process; control of sepsis; and delay of surgical treatment are the keys to successful management of these patients [18,46,47]. The later the necrosectomy is performed, the more defined and mature the necrosis will be, the more effective its removal, and the lower the likelihood of reoperations. Active measures for delaying possible early necrosectomy are the use of systemic antibiotics, the insertion of PD in infected collections and enhanced resuscitation and intensive care as a cornerstone. Therefore, a definitive operation can be carried out with a more controlled and localized infectious focus thanks to the significantly improved specialization of surgeons dedicated to pancreatic surgery. As far as possible, patients should not be operated in the early stages of the disease [11,16,19,48,49]. Our experience shows that the implementation of the step-up approach linked to MIS is feasible in most patients and allows surgery to be delayed by up to two weeks. This has reduced the rates of reoperation and mortality in operated patients and overall.

One of the surgical treatment most often used today remains ON [29,30], the technique used routinely in group A in our series. In fact, in a recent review of the Cochrane database, no evidence suggested that the minimally invasive step-up approach resulted in fewer adverse events, less organ failure to open necrosectomy [23].

In the second stage of our study, MIS techniques were introduced in conjunction with the implementation of the step-up approach, and laparotomy was only considered in the case of other intra-abdominal complications due to the SAP. These critical patients still have a high mortality rate regardless of the surgical technique used [50]. Although some recent studies report mortality rates below 12% in patients undergoing ON [26,27], in our series this figure was 50%, however in group A ON was not performed in conjunction with the step-up

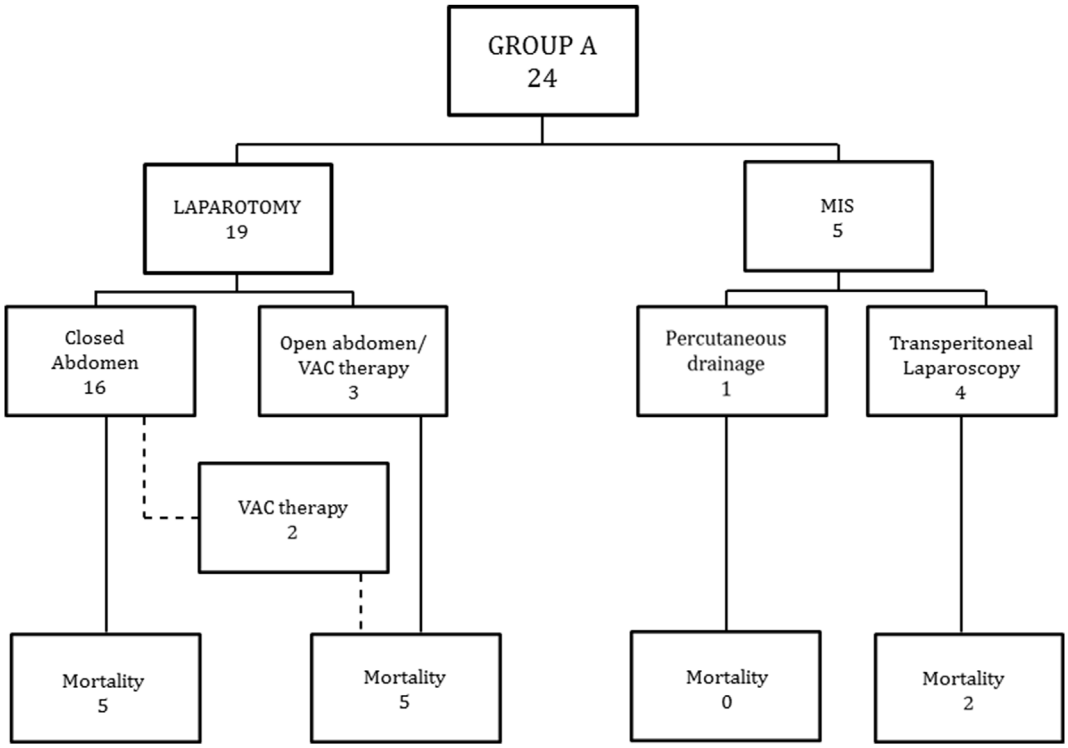

Fig. 1. Interventional procedures used in group A.

algorithm. To determine the real advantages of MIS it would be interesting to compare these patients with others undergoing ON in the context of a step-up algorithm. At present, however we do not consider, as published in the PANTER study [22] it is not appropriate to carry out this kind of study given the obvious advantages of MIS and the good results obtained. It is well known with any retrospective and not randomized review, this study has several limitations.

A key point for success is the choice of the most appropriate MIS

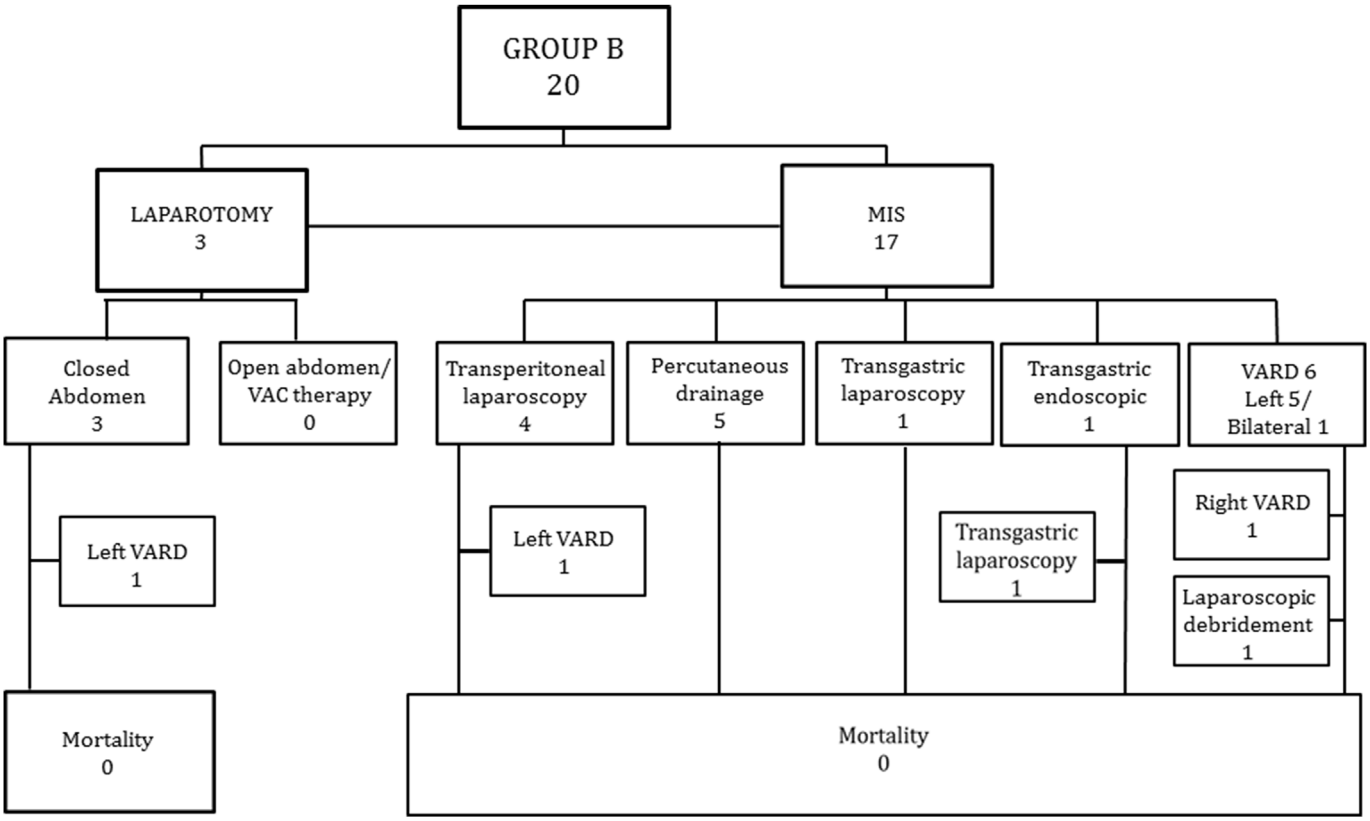

Fig. 2. Interventional procedures used in group B.

approach in each patient. Basically the decision is made according to the location of the necrosis. However it is difficult to standardize an algorithm because it each patient has to be treated individually, we usually follow our previously reported algorithm [37]. In our case, we opted for VARD when the necrosis predominantly affected the tail of the pancreas and the left renal space; transgastric drainage (TGLD/TGED) if it predominated in the lesser sac and bulged in the back of the stomach; and TPLA when it affected several peripancreatic areas or if the above procedures could not be performed. In the transgastric approach we prefer endoscopy if the collection is mainly liquid and laparoscopy if it is mainly solid. Another advantage of MIS approaches is that different procedures may be performed sequentially if necessary, without the first procedure compromising the later ones, and the percutaneous drainage has to be the first step; in contrast, reoperations after ON usually present additional morbidity because access is obtained via the laparotomy itself. In our series, there was no mortality in operated patients in group B, and the five deaths recorded were in older patients who we rejected any type of invasive treatment due to severe associated pre-existing chronic disease which was directly related to mortality. In our point of view, a decisive factor in the improvement in the results is the fact that with the step-up approach, surgical procedures are no longer performed as emergency by surgeons on call, but can be performed on a semi-elective basis by specialist pancreatic surgeons. We know that this fact could produce a bias in terms of management and decision making of the therapeutic attitude between the two groups.

7. Conclusion

Patients suffering from clinical severe acute pancreatitis should be individually treated in reference centers by multidisciplinary specialized teams. The combination of the step-up approach and minimally invasive surgery algorithm is feasible and could be considered as the standard of treatment for severe acute pancreatitis. The mortality rate deliberately descends when it is used.

Ethical approval

The ethical committee of the Hospital did not require an approval for this study. Without alteration in the accomplishment of the medical practice.

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Author contribution

All of the present author's, has been involved in the design, acquisition analysis, critically revising, final approval of the version to be published and all of us we are agreement to be accountable for all aspects of the work. We are all responsible for all aspects of the work.

1 Study conception and design, acquisition analysis or interpretation of data for the work: O.Morató, I.Poves, L.Ilzarbe, A.Radosevic, A.Vázquez, J.Sánchez, F.Burdio, L.Grande
2 Drafting the work or revising it critically for important intellectual content: O.Morató, I.Poves, L.Ilzarbe, A.Radosevic, A.Vázquez, J.Sánchez, F.Burdio, L.Grande
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4 Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: O.Morató, I.Poves, L.Ilzarbe, A.Radosevic, A.Vázquez, J.Sánchez, F.Burdio, L.Grande

Conflicts of interest

This manuscript describes original work and has not been published and is not under consideration by any other journal, demonstrating our will to be published in your prestigious journal. All authors; Olga Morató Redondo, Ignasi Poves Prim, Lucas Ilzarbe Sanchez, Aleksandar Radosevic, Antonia Vázquez Sánchez, Juan Sánchez Parrilla, Fernando Burdío Pinilla and Luis Grande Posa have approved the manuscript and this submission to **International Journal of Surgery**. All of them declare no financial and conflict of interest.

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