ITalian Excluder Registry and results of Gore Excluder endograft for the treatment of elective infrarenal abdominal aortic aneurysms

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Background: **To report the midterm results of elective endovascular aortic repair (EVAR) of abdominal aortic aneurysms (AAAs) in a multicenter, clinical unsponsored registry using the Gore Excluder endograft.**

Methods: **This study is a retrospective analysis of a multicenter, prospective registry that involved nine centers in Italy. Periodic clinical and radiographic follow-up with computed tomography scans were performed at 1, 6, and 12 months after the procedure, and on a yearly basis thereafter.**

Results: **A total of 872 patients underwent elective EVAR. Primary technical success was 97.5%, and hospital mortality was 1.0% (9/872). At least 816 (93.6%) patients underwent a follow-up control. Freedom from all-cause death was estimated to be 97.9% at 1 year, 93.4% at 3 years, and 88.5% at 5 years. Aneurysm-related mortality was 1.6% (n = 13) with only two late AAA-related deaths observed at 21 and 36 months. Significant predictors of all-cause mortality included age ($P < .001$) and AAA maximum diameter ($P = .027$). Overall conversion rate was 2.3% (n = 19). Mean elapsed time from initial intervention to surgical conversion was 23 ± 18 months (range, 0-52 months). Late rupture was detected in four (0.5%) cases: two of these patients died after conversion. The rate of any reintervention was 9.4% (n = 77); most of them were required within the first 24 months. The leading cause of reintervention was endoleak (n = 41; 5.0%). Limb thrombosis occurred in nine (1.1%) cases. Freedom from reintervention at 1, 3, and 5 years of follow-up were 98.6%, 94.6%, and 86.5%.**

Conclusions: **The ITalian Gore Excluder Registry is the largest clinical unsponsored registry using a single device, with the longest follow-up period so far. The present experience confirms the effectiveness of EVAR using the Gore Excluder with low rates of mortality, migration, reintervention, and limb thrombosis. (J Vasc Surg 2014;59:52-7.)**

During the last two decades, endovascular aortic repair (EVAR) gained popularity for abdominal aortic aneurysm (AAA) repair.[1,2] There is no longer debate about the early benefits of EVAR, including shorter hospital stays, less blood loss, shorter operating times, and lower early morbidity and mortality.[3,4] In contrast, randomized clinical trials have raised concerns about late outcomes of EVAR, including complications, loss of survival benefit, and need for reinterventions.[5,6] The design and conduct of these trials may not reflect "real-world" practice, so the outcomes may not be applicable to the general population. In contrast, registries report more realistic results as they are obtained from a range of clinical institutions with varying levels of expertise and experience, and there is evidence to support their validity.[4]

Concomitant with the increased EVAR utilization has been the availability of a variety of endograft (EG) designs and configurations to treat AAAs, each of them evaluated in pivotal studies against primary endovascular outcomes.[7-9]

The aim of this report is to present the 3-year follow-up results of an Italian multicenter registry (ITER, ITalian Excluder Registry) using the Gore Excluder EG.

METHODS

This report describes the results of a multicenter, prospective registry of EVAR for infrarenal AAA using the Gore Excluder (W. L. Gore & Associates Inc, Flagstaff, Ariz) bifurcated EG. The registry was a single device registry of elective EVAR that involved nine centers in Italy (participating investigators are listed in the Appendix, online only). All the centers had experience of at least 40 cases with this type of EG. Generally, indication for AAA treatment with this device included:

- An intact AAA diameter of ≥50 mm, or any aneurysm with an increase of ≥5 mm in two consecutive diagnostic evaluations, symptoms, or radiologic findings of impeding rupture;
- Patent, adequate femoral-iliac access vessels to accept introducer sheaths of 18 F for the main body and 12 F for the contralateral iliac extension;

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- An infrarenal aortic neck diameter range of 19 to 29 mm and a minimum aortic neck length of 15 mm;
- A proximal aortic neck angulation ≤60°;
- Iliac artery treatment diameter range of 8 to 18.5 mm and iliac distal vessel seal zone length of at least 10 mm.

Patient management. Preoperative investigation consisted of spiral/computed tomography (CT) angiography scans, whereas operative risk assessment was stratified accordingly to the classification of the American Society of Anesthesiologists.[10] In all centers, EVAR was performed in an operating room equipped with endovascular capabilities, meaning the availability of a mobile C-arm, an automatic injector, and a wide inventory of EGs. The time period included two different versions of the Gore Excluder: the original device and the enhanced EG, that with the new polytetrafluoroethylene microstructure redesigned to reduce porosity and fluid transmigration. Clinical and radiographic follow-up with CT scans were performed at 1, 6, and 12 months after the procedure, and on a yearly basis thereafter. Angiography, Doppler ultrasound, and plain X rays were performed in selected cases. Endoleaks or enlargement correction (regardless of endoleak status) were intensively studied and considered for reintervention or conversion to conventional repair. This consideration included the local principal investigator's and attending physician's assessment of an individual subject's comorbidities, life expectancy, and the subject's personal choices.

Definition and outcomes. Comorbidities and risk score were defined prospectively accordingly to the guidelines of the Society for Vascular Surgery/American Association for Vascular Surgery.[11,12] Technical success was defined as no type I or III endoleak at the conclusion of the procedure; further primary end points were operative (<30 days) mortality, aneurysm rupture, aneurysm-related mortality, conversion to open repair, reintervention, and device-related adverse events (migration, thrombosis, or kinking). Changes of ≥5 mm in the minor axis were considered significant for either enlargement or shrinkage.

Statistical analysis. All clinical and procedural data were prospectively collected and recorded into a computerized database registry. Extracted database variables were tabulated using Microsoft Excel (Microsoft Corp, Redmond, Wash), and statistical analysis was computed using SAS Version 9.2 (SAS Institute, Cary, NC). Life-table estimates were provided for mortality and reintervention. Results are expressed as mean ± standard deviation for continuous variables and frequencies for the categorical ones. A P value less than .05 was considered statistically significant. Formal cost analysis was not performed; as well, we did not perform comparison between the original device and the enhanced EG, that with the new polytetrafluoroethylene microstructure redesigned to reduce porosity and fluid transmigration.

RESULTS

Between October 1998 and December 2006, a total of 872 patients underwent elective EVAR and were enrolled into the registry. We treated 802 (91.9%) males; mean age was 72.7 ± 8.5 years (range, 52-95 years). Comorbidities are listed in Table I: cardiovascular risk factors were present in the majority of patients, and most (n = 517; 59.3%) had a high operative risk (American Society of Anesthesiologists scale III-IV). Main AAA features are depicted in Table II: a neck length of <15 mm was present in 82 (9.5%) patients. Mean angle of the proximal aortic neck was 26.2 ± 15.1 degrees (range, 0-75 degrees). The original permeability device was used in 656 (75.2%) patients, and the low permeability device in 216 (24.8%).

Perioperative outcomes. Primary technical success was achieved in 850 (97.5%) patients. Regional anesthesia was utilized in 462 (52.9%) patients, general anesthesia in 275 (31.5%), and local anesthesia with sedation in 135 (15.6%). Total percutaneous intervention was never performed. Mean procedure time was 113 ± 83 minutes (range, 30-480 minutes), with a mean fluoroscopic time of 26 ± 14 minutes. Contrast agent averaged 144 ± 104 mL. Blood loss averaged 234 mL (range, 0-3000 mL). Length of hospitalization was 6 days (median, 4 days). Operative mortality was 1.0% (9/872). The most frequent complication involved access vessels (n = 11; 1.3%). EG-related complications were observed in four (0.4%) cases: kinking of an iliac limb (n = 3; 0.3%) was treated with additional percutaneous transluminal angioplasty (PTA) stent, and migration (n = 1; 0.1%). Conversion to open repair was performed in three (0.3%) cases for persisting type I endoleak (n = 2), and the previously mentioned migration (n = 1).

Follow-up and survival. As of December 2009, at least 816 (93.6%) patients underwent one follow-up visit and CT scan. All-cause mortality was 8.7% (n = 71): most late deaths were caused by cardiovascular events (n = 13, mainly acute coronary syndrome). Freedom from all-cause death was 97.9% at 1 year, 93.4% at 3 years, and 88.5% at 5 years (Fig 1). Significant predictors of all-cause mortality included age ($P < .001$) and AAA maximum diameter ($P = .027$). Aneurysm-related mortality was 1.6% (n = 13). Most (11/13) AAA-related deaths occurred within the initial hospital admission and included: cardiovascular events (n = 5), multiple organ failure (n = 2), acute kidney injury (n = 2), and pulmonary complications (n = 2). Subsequent AAA-related deaths were observed in two cases only, at 21 and 36 months. Estimated freedom from AAA-related death was 98.5% at 1 year, 98.3% at 3 years, and 97.9% at 5 years (Fig 2).

Aneurysm rupture. Postoperative ruptures (n = 4) occurred between 1 and 20 months. An endoleak was detected in all the cases (type I, n = 3; type II, n = 1). Urgent conversion with the EG explantation and graft replacement was performed in all the cases. Two of the four patients died either of the rupture itself or subsequent complications thereof.

Conversion to open surgical repair. Overall conversion rate was 2.3% (n = 19). The indication for conversion to open surgical repair included endoleak with sac enlargement (n = 14) or persistent endoleak and/or migration,

Table I. Comorbidities and risk factors of the population

	No. (%)
Demographics	
Age, years	72.7 ± 8.5
Males	802 (91.9)
Comorbidities	
Hypertension	625 (71.7)
Chronic obstructive pulmonary disease	467 (53.6)
Coronary artery disease	428 (49.1)
History of smoking	420 (48.1)
Dyslipidemia	339 (38.8)
Hostile abdomen	300 (34.4)
Cerebrovascular disease	173 (19.8)
Peripheral arterial disease	164 (18.8)
Diabetes	128 (14.7)
Renal dysfunction	100 (11.5)
Operative profile	
ASA I-II	355 (40.7)
ASA III-IV	517 (59.3)

ASA, American Society of Anesthesiologists; *SD,* standard deviation.
Continuous data are presented as mean ± standard deviation and categoric data as number (%).

Table II. Morphology and sizing of the abdominal aortic aneurysms (*AAAs*)

Parameter	*Size, mm*
AAA diameter	52.4 ± 3.0
≤50 mm	44 (5.0)
Proximal neck diameter	27 ± 12
Proximal neck length	26 ± 13
≤15 mm	83 (9.5)
Neck α-angle, °	26 ± 15
Right common iliac diameter	13.7 ± 9.9
Left common iliac diameter	12.9 ± 9.1

SD, Standard deviation.
Continuous data are presented as mean ± standard deviation and categoric data as number (%).

aneurysm rupture (n = 4) patients, and infection (n = 1). Three (0.3%) conversions occurred at the indexed intervention: the mean elapsed time from initial implantation to surgical conversion was 23.2 ± 18 months (range, 0-52 months). Predictors for conversion were not identified.

Reintervention. During the follow-up, a total of 79 reinterventions were performed in 74 patients, resulting in a 9.7% incidence of any reintervention. The mean interval from the indexed intervention was 20 months, but most (n = 55; 71.4%) were performed within 24 months. Endoleak (n = 41; 5.0%) was the leading cause for reintervention, followed by limb thrombosis (n = 9; 1.1%). EG migration occurred in four cases. Reintervention was catheter-based in 50 (63.2%) cases and included proximal or distal extension (n = 26; 52%), embolization (n = 20; 40%), and PTA (n = 4; 8.0%). Open procedures included conventional aortic graft replacement (n = 19), graft limb thrombectomy (n = 3), extra-anatomic bypass for limb occlusion (n = 3), iliac-femoral bypass (n = 2), laparoscopic ligation of the inferior mesenteric artery (n = 1), and repair of common femoral artery pseudoaneurysm (n = 1).

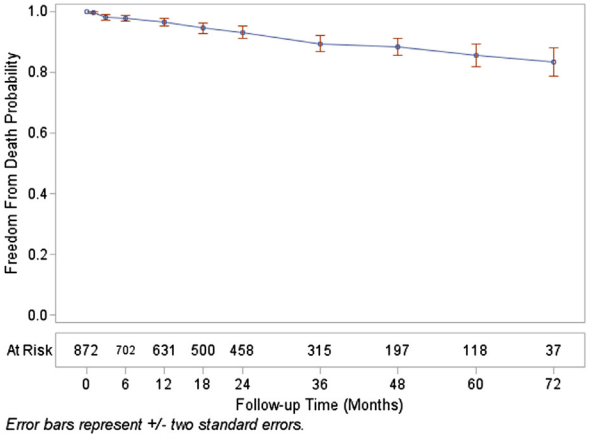

Fig 1. Freedom from all-cause death.

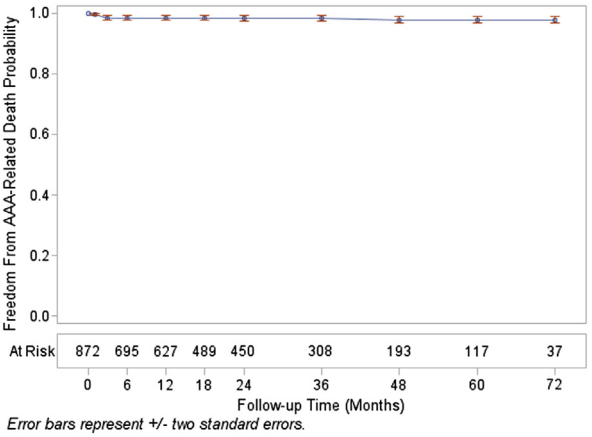

Fig 2. Freedom from abdominal aortic aneurysm (*AAA*)-related death.

Freedom from reintervention at 1, 3, and 5 years of follow-up were 98.6%, 94.6%, and 86.5% respectively (Fig 3). Predictors for reintervention were not identified.

Limb thrombosis. There were nine (1.1%) graft limb thrombosis at a mean 20.6 months (range, 6-48 months). Five occurred in the first 12 months. Three were treated with a femoro-femoral by-pass, three with thrombectomy, and the remaining three using thrombolysis and additional PTA stenting.

Endoleak. Endoleaks at each intervals of follow-up are represented in Table III. At 1-year follow-up, the aneurysm sac was stable or decreased in 94.8% (635/670) of the cases, whereas enlargement was noted in 5.2% (n = 35) of patients. Estimated freedom from endoleak was 82.5% at 1 year, 75.8% at 3 years, and 71.5% at 5 years (Fig 4). The maximum AAA diameter (P = .007) was a significant predictor of sac enlargement.

DISCUSSION

ITER is the largest prospective, unfunded clinical registry of elective EVAR using a single device. The most

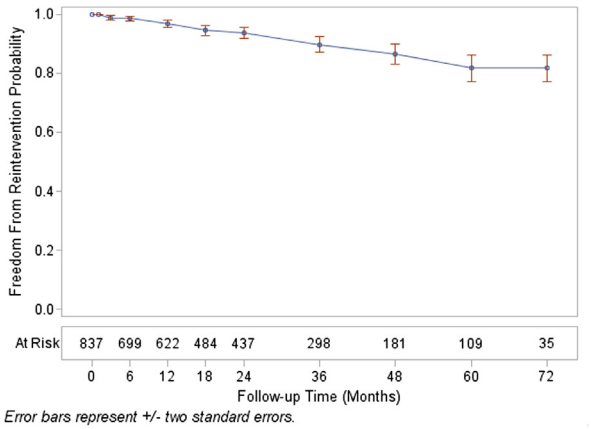

Fig 3. Freedom from reintervention.

important findings of the registry are the low rates of migration, reintervention, and iliac limb thrombosis with the use of the Gore Excluder.

Few registries have been published in literature reporting the outcomes of a single device; even more importantly, mid- to long-term follow-up has not been consistently reported.[13,14] Other registries have enrolled hundreds of patients, but results were reported in the range of 30 days to 6 months only. The most consistent registry available at this time is Talent Unidoc Retrospective Italian Study (TAURIS),[15] a multicenter study that involved 10 centers in Italy. It recruited 557 patients overall with a mean follow-up of 25 months, and 349 were available with a CT control at 12 months. Considering these data, at this moment, ITER is the largest registry available, including 670 patients with a CT scan at 1-year and a follow-up mean of 28 months. Our registry compares well with the results of the combined IDE cohort of the Gore Excluder that included 565 patients overall: we can confirm the low complications rate using this EG either in the early or in the midterm follow-up.[8] The most important difference with that cohort is the 3-year survival of 93.4% rather than the 82% reported in the IDE. This unanticipated data could be explained by the different age at treatment and the better operative risk profile of our patients. Despite these significant differences, we had similar satisfactory results when considering the primary outcomes such as open conversion, AAA secondary ruptures, migration, and EG-related complications.

Through the last decade, Gore Excluder implantation showed a high success rate: Bush et al[16] reported an 89% primary technical success rate. This is probably the lowest reported rate, but it refers to the early experience with the original permeability device. More recently, Ghotbi et al[17] reported full success in the first 100 cases of their single-center experience. Some authors tested different EGs in device-specific outcome analysis, including the Gore Excluder: Pulli and coworkers[18] achieved a 98% success rate with no increased need of adjunctive procedures and no intraoperative migration with the Gore Excluder. Actually, our study compares well with these data and could have been even better: the 97.5% we reported in this registry could have been a full success because an intraoperative migration occurred for a technical inaccuracy, a complication that, although typical of the long run, has remained very low at the 3-year analysis (sustaining <1%). These data are supported by the results of the EUROpean collaborators on Stent-graft Techniques for abdominal aortic Aneurysm Repair (EUROSTAR) registry.[19] In that analysis, despite the Gore Excluder being the second most utilized EG, as well as the most frequently utilized in more hostile anatomies, it had the lowest rate of migration: these results confirmed the safety and effectiveness of the device.

Since its advent, the primary aim of EVAR has been considered the prevention of rupture. In this sense, two randomized clinical trials raised concerns about the long-term safety of EVAR because most of the reported late deaths have been ascribed to secondary rupture.[20] However, it should be said that most of these ruptures should have been charged to use of early-generation EGs and might have been averted by an appropriate reintervention at an appropriate interval. Our results can support the safety of EVAR in daily practice: the 1.6% AAA-related death experienced in our registry is similar to the 1.6% to 1.8% range reported in several single-center data, as well as the 1.9% rate in the EUROSTAR registry.[19] This does not mean that we should minimize the problem, partly because the mortality after secondary rupture remains considerable despite prompt diagnosis, as occurred in our experience.[3,8,9]

Preventing rupture has been intended the real rationale of EVAR, but the prevention of secondary intervention with particular attention to open conversion is no less important.[18,21] The incidence of secondary procedures was commonly reported in the 10% to 15% range.[18,19,22-24] In particular, among the different devices included in the EUROSTAR registry,[19] the Gore Excluder annual freedom from reintervention rate was the lowest at 3.5%. A low reintervention rate is important not only for the patients, but also for the overall safety and cost-effectiveness of the procedure. The freedom from reintervention at 5 years was 86.5% in our registry; that is favorable if compared with previous analyses ranging from 65% to 82% at 5 years.[18,22,24,25] Equally important, we had no adjunctive mortality after secondary procedures. In reference to these same studies, the fact that we were not able to replicate the data in which a large AAA diameter is a predictor for reintervention deserves a comment. In fact, a larger diameter has been more frequently associated with EVAR treatment outside the instructions for use in these studies.[22,24] Our unexpected finding could be a further significant aspect to attest the reliability of the registry data and one that confirms the homogeneous adherence to the inclusion criteria.

Previous reports have also raised concerns about limb thrombosis, and implicated it in being a leading cause of secondary interventions.[19,22,25-27] No specific device-related analysis has been performed so far. In our registry,

Table III. Summary of endoleaks by period

	Follow-up period					
Subjects assessed	*1 month (n = 863), No. (%)*	*12 months (n = 670), No. (%)*	*24 months (n = 482), No. (%)*	*36 months (n = 394), No. (%)*	*48 months (n = 257), No. (%)*	*60 months (n = 160), No. (%)*
Any endoleak	94 (10.9)	78 (11.7)	54 (11.3)	41 (10.5)	20 (7.8)	4 (2.5)
Type I	14 (1.6)	7 (1.1)	4 (0.9)	3 (0.7)	0 (0.0)	0 (0.0)
Type II	67 (7.8)	61 (9.1)	46 (9.5)	27 (6.9)	15 (6.0)	0 (0.0)
Type III	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Unknown	13 (1.5)	10 (1.5)	4 (0.9)	10 (2.6)	5 (1.8)	4 (2.5)
No endoleak	769 (89.1)	592 (88.3)	428 (88.8)	353 (89.6)	237 (92.4)	156 (97.5)

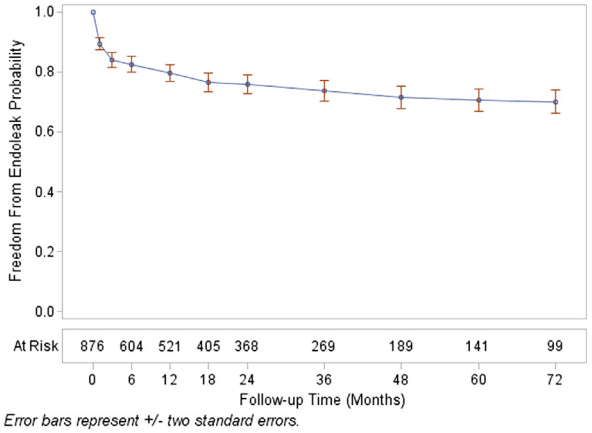

Fig 4. Freedom from all types of endoleak.

limb thrombosis was quite low and almost nonexistent after 36 months: of note, this is an aspect that was not reported in detail in the IDE cohort, and finds support in previous experiences. In their device-specific outcome analysis involving four different EGs, Pulli and coworkers[18] reported the lowest limb thrombosis rate using the Gore Excluder. In a similar study, Abruzzese et al[22] performed an anatomically stratified device-specific analysis to evaluate the performance of three different EGs. Despite the Gore Excluder being implanted more frequently in women, more frequently outside the indications for use, it had the lowest limb thrombosis rate with no difference in terms of migrations or disconnections.[22]

Another important finding that testifies to the reliability of our registry data is the confirmation of age as a predictor of postoperative survival.[28-31] In a review of their first decade of EVAR, Brewster et al[23] confirmed that age was an independent predictor of survival especially in the long run; since they had good long-term overall outcomes with EVAR, they suggested it could be used as a reasonable alternative to conventional open repair in a broad range of patients with suitable anatomy, including younger and lower risk individuals. We had similar findings: these should not be considered a definitive statement, but the concept of this study outlines that the association of a suitable anatomy and a good perioperative risk profile could have positively influenced either technical or clinical outcomes in our registry cohort.[8] Also, the diameter of the AAAs have been identified as an independent risk factor for long-term outcomes. Zarins et al[32] showed that patients with large aneurysms (≥6 cm) were older and more likely to need a secondary procedure during the 5-year follow-up period, and comparison of the Kaplan-Meier curves showed that they had a significantly shorter life expectancy than those with smaller AAAs. Lomazzi et al[29] evaluated a large cohort of EVAR patients and identified that AAA diameter was one of the most important variables to predict decreased survival. Our study is not different: diameter was a predictor of endoleak and survival in the long run, and several papers already published supported our data.

There are some limitations in the present study. Mainly, our study design is retrospective; although data were prospectively collected, they certainly include potential confounding variables such as selection bias and data collection. However, similar design is present in other studies, and our results are in consonance with them; although the incidence of complications and mortality related to the AAA could be higher due to the number of patients lost to follow-up.

CONCLUSIONS

The ITER is the largest clinical unsponsored registry using a single device, with the longest follow-up period so far.

The present experience confirms the near-term effectiveness of EVAR using the Gore Excluder with low mortality rate, as well as the 3-year high rate of technical success and the low rate of EG-related complication.

At an interim 3-year analysis, EVAR with the Gore Excluder is confirmed to have a low migration rate, a low reintervention rate, and a low limb thrombosis rate.

AUTHOR CONTRIBUTIONS

Conception and design: CP, PC
Analysis and interpretation: CP, GPi, GPr, PC
Data collection: GPi, GPr
Writing the article: CP, GPi, GPr, PC
Critical revision of the article: CP, GPi, GPr, PC
Final approval of the article: CP, GPi, GPr, PC
Statistical analysis: CP, GPi, GPr, PC

Obtained funding: Not applicable
Overall responsibility: PC

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APPENDIX (online only).

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