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Prospective Comparative Analysis of Colour-Doppler Ultrasound, Contrast-enhanced Ultrasound, Computed Tomography and Magnetic Resonance in Detecting Endoleak after Endovascular Abdominal Aortic Aneurysm Repair CME

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Abstract *Objectives:* To assess the accuracy of colour-Doppler ultrasound (CDUS), contrast-enhanced ultrasonography (CEUS), computed tomography angiography (CTA) and magnetic resonance angiography (MRA) in detecting endoleaks after endovascular abdominal aortic aneurysm repair (EVAR).
Design: Prospective, observational study.
Materials and methods: From December 2007 to April 2009, 108 consecutive patients who underwent EVAR were evaluated with CDUS, CEUS, CTA and MRA as well as angiography, if further treatment was necessary. Sensitivity, specificity, accuracy and negative predictive value of ultrasound examinations were compared with CTA and MRA as the reference standards, or with angiography when available.
Results: Twenty-four endoleaks (22%, type II: 22 cases, type III: two cases) were documented. Sensitivity and specificity of CDUS, CEUS, CTA, and MRA were 58% and 93%, 96% and 100%, 83% and 100% and 96% and 100% respectively. CEUS allowed better classification of endoleaks in 10, two and one patients compared with CDUS, CTA and MRA, respectively.

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Conclusions: The accuracy of CEUS in detecting endoleaks after EVAR is markedly better than CDUS and is similar to CTA and MRA. CEUS seems to be a feasible tool in the long-term surveillance after EVAR, and it may better classify endoleaks missed by other imaging techniques.

Endovascular abdominal aortic aneurysm repair (EVAR) is an effective alternative treatment to open repair,[1] and the number of EVAR procedures carried out worldwide is continuously growing. Incomplete exclusion of the aneurysm sac from the circulation, defined as endoleak, is the most frequent complication after EVAR occurring in 10—45% of cases,[2] and it can be associated with aneurysm enlargement and rupture.[3] Thus, lifelong surveillance of aortic stent grafts to detect endoleaks and other forms of device failure is required in patients who undergo EVAR. Standard Duplex ultrasound investigation was first adopted in the follow-up of conventional vascular procedures for reasons of low cost, easy interpretation and performance and no radiation exposure, but it has not achieved reference standard status in the EVAR follow-up because of low diagnostic specificity and sensitivity.[4,5] To date, computed tomography angiography (CTA) is the preferred imaging modality to follow-up patients after EVAR. However, it carries the risks associated with radiation and contrast-media exposure. Magnetic resonance angiography (MRA) and contrast-enhanced ultrasonography (CEUS) have been shown to be more accurate than CTA,[6—13] but, so far, there is no consensus regarding the optimal diagnostic imaging modalities for surveillance after EVAR. The accuracy of these imaging modalities in the detection and characterisation of endoleaks in aortic stent grafts has been investigated in this prospective study.

Materials and Methods

Study population

From December 2007 to April 2009, 123 consecutive patients (92 males and 31 females, mean age 63.0 $\pm$ 7.3 years), who have undergone EVAR for abdominal aortic aneurysm (aneurysm baseline mean diameter 5.4 $\pm$ 0.5 cm, range: 3.9—8.7 cm), were prospectively recruited in the present study. The EVAR devices employed in these patients were the Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA) in 50 patients, the Talent (Medtronic, Santa Rosa, CA, USA) in 55, the Powerlink (Endologix, Irvine, CA, USA) in 12 and the Jomed (Jomed International AB, Helsingborg, Sweden) in six patients.

Patients underwent regular follow-up at our institution at 1, 6 and 12 months and only some of them at 24 months, with imaging procedures including colour-Doppler ultrasound (CDUS) and CEUS on the same day, and, within 1 week, CTA and MRA.

The radiologists were blinded to the results of any previous examination. DSA was performed in case of contradictory results at different modalities. Furthermore, the cases positive for endoleak and considered for possible re-intervention underwent also digital subtraction angiography (DSA) study and were eventually treated.

Ethical Committee approved this study and all patients signed the informed consent. The authors did not receive any outside funding for this study. There are no conflicting interests inherent in this study.

CEUS protocol

Patients were suggested to have a low residual diet the day before the ultrasound study and to fast in the morning of the investigation. CDUS and CEUS examinations were performed by two radiologists (P.R. and V.C. with 20 and 10 years of experience in this particular field, respectively) with Aplio XV, (Toshiba Vx, Zoetermeer, the Netherlands) and Technos MPX ultrasound (ESAOTE Biomedica, Genoa, Italy) equipments, using a 3—5 MHz probe, with longitudinal and transversal scans with the patient lying in a dorsal or lateral position. In a single patient, one radiologist performed CDUS and the other CEUS, but this assignment (which examination by whom radiologist) was at random for each case. The entire abdominal aorta was scanned from the diaphragm to the iliac arteries and the entire sac was analysed to detect possible pulsatility colour flow within the aneurysm sac. The aneurysm sac size was measured in both anterior—posterior and transverse dimensions at its widest point and the mean of these measurements was used for the purposes of this study. Arterial flow haemodynamics were documented throughout the stent graft with spectral Doppler velocity measurements. Colour-Doppler was adjusted for optimum sensitivity to slow flows, and the entire stent graft and aneurysm sac were scanned to detect any endoleak that might have been present. Any suspected endoleak was further documented for flow characteristics with spectral Doppler velocities. Subsequently, patients underwent CEUS with a 3—5-MHz probe and with a low mechanical index (varying from 0.06 to 0.10; about 35—45 kPa), with real-time tissue harmonic imaging (contrast-tuned imaging CnTI using Technos MPX, Esaote) and contrast harmonic imaging (pulse subtraction) (Aplio, Toshiba Corp, Tochigi, Japan). These imaging techniques enable selected tuning of the signal from the contrast-agent microbubble resonance, notably filtering tissue echoes. A second-generation contrast agent (SonoVue, Bracco, Milan, Italy) consisting of sulphur hexafluoride gas microbubbles in a phospholipid membrane, which presents a longer persistence in the bloodstream under insonation by low acoustic power, was injected intravenously in all cases. A single bolus of 2.4 ml of the contrast agent was injected in all patients into an antecubital vein followed by 5 ml of saline. Images obtained in all patients were recorded in digital form for subsequent analysis. CEUS scanning was performed for at least 5 min after injection and assessed the presence of contrast enhancement within the aneurysm sac, with monitoring of the time of appearance (synchronous or delayed with respect to graft enhancement) and persistence (wash-out) to inflow and outflow vessels.

CT protocol

CTA was performed with 64-slice CT scanner (Somaton Sensation Siemens Medical Solutions, Erlangen, Germany). A triple-phase CT protocol was carried out with an unenhanced, an arterial (with bolus-tracking) and a delayed phase at 120 s (with 130 ml of non-ionic contrast media: Iomeron, Bracco, Milan, Italy, flow 4 ml s^{-1}). Other scan parameters were as follow: acquisition thickness 1.2 mm; reconstruction with soft kernel algorithm (B30), 1.5 and 3 mm with 1.5 of recon increment; pre-contrast scans with low tube current (120 mA); for other phases, 120 kVp and 200 mAs.

Magnetic resonance protocol

All MRA examinations were conducted on a high-performance 1.5-T scanner (Magnetom Avanto, Siemens Medical System, Erlangen, Germany) with gradient strength of 45 mT m^{-2} and slew rate of 200 T $m^{-1}s^{-1}$ and with a multichannel phased array coil. Scout images were obtained by acquiring fast true fisp imaging with steady precession (FISP) sequences in the caudocranial direction at the abdomen's level.

Sequential pre-contrast images were obtained in the caudocranial direction, using axial three-dimensional (3D) fast low-angle shot (FLASH) sequences with integrated parallel acquisition technique (IPAT) optimised for high spatial resolution and short acquisition time (TR (time of repetition) 3.5 ms, TE (time of echo) 1.18 ms, FA (flip angle) 30°, voxel size 1.3 mm $\times$ 0.9 mm $\times$ 0.9 mm, matrix 256 $\times$ 512, TA (time of acquisition) 16 s, IPAT factor $\times$2), acquired in breath-hold. The protocol was repeated in the craniocaudal direction after a single biphasic administration of contrast medium through a dual-head injector: 0.2 mmol kg^{-1} of gadolinium benzyloxyproprionic tetraacetic acid (Gd-BOPTA, Bracco, Milano, Italy) was administered as a single bolus with a biphasic injection protocol (first phase at a rate of 1 ml s^{-1} and second phase at 0.5 ml s^{-1}), with 25 ml saline solution bolus chaser at a rate of 0.5 ml s^{-1}. The optimal delay between contrast injection and sequence acquisition was calculated by using the bolus-tracking technique, with the start of image acquisition synchronised with the arrival of contrast material in the left cardiac cavities. The pre-contrast images were automatically subtracted from the post-contrast images to increase the contrast between the vasculature and the background. Another scan was performed in the abdominal area 120 s after contrast administration. The CTA and MRA images were analysed in an independent dedicated work station (Aquarius, TeraRecon, San Matteo, CA, USA) using the common post-processing techniques. The images were reviewed in consensus by two radiologists (CC and AN, both of them with 15 and 8 years of specific experience, respectively). We have evaluated the aneurysm sac size, the attachment and integrity of the prosthesis and the presence and type of any endoleak.

DSA

DSA was performed with a fluoroscopy machine (Integris 5000, Philips Medical System, the Netherlands). A percutaneous femoral approach was carried out. After insertion of a 4Fr introducer sheath (Radifocus,Terumo, Tokyo, Japan) a 4Fr pig-tail catheter(Cordis Endovascular, Miami Lakes, FL, USA) was advanced into the abdominal aorta just above the origin of the renal arteries where a DSA was performed, after the injection of 20 ml of iodinated contrast media at a flow rate of 20 ml s^{-1}. The correct sealing of the endoprosthesis at the level of the proximal neck was evaluated. Afterwards, a selective catheterisation of the superior mesenteric artery was done, using a Sim1 catheter (Cordis Endovascular, Miami Lakes, FL, USA) to evaluate the collateral flow within the Riolano arcade and the excluded inferior mesenteric artery. If no endoleaks were detected, a selective injection was also performed at the level of both internal iliac arteries to evaluate sac revascularisation through the ileolumbar arteries. Treatment of the endoleak was performed according to its type and site by using different embolic agents (coils and glue) or cuffs.

Statistical analysis

Statistical analysis was performed using a Statistical Package for Social Sciences (SPSS) statistical software (SPSS v. 16.0.1, SPSS Inc., Chicago, IL, USA). The maximal external transverse aneurysm sac diameter was measured with all diagnostic techniques and data were expressed as mean $\pm$ standard deviation. Variables herein evaluated were changes in the maximum diameter of the aneurysm sac as well as presence and type of endoleak, if detected. Sensitivity, specificity, accuracy and negative predictive values were estimated for each of these diagnostic methods. Spearman's correlation test was used to estimate the correlation between measurements by different imaging methods. Wilcoxon's test was employed to estimate the extent of aneurysm sac shrinkage. A $p < 0.05$ was considered statistically significant.

Results

Of the initially recruited 123 patients, 15 patients were excluded from this study because of the following reasons: eight patients could not undergo MRA (claustrophobia, no. 2; pace-maker, no. 6), three patients because of renal failure, one patient because of the allergy to iodine and three because of presence of severe co-morbidity (heart failure and severe pulmonary disease). Thus, the present study includes 108 patients.

At the time of stent-graft evaluation, the mean follow-up after EVAR was 13 months (range, 1–24 months). All patients completed the protocol, and no adverse events were recorded during CEUS, CTA and MRA examinations. Among these patients, 24 endoleaks have been detected.

The mean diameters of the abdominal aortic aneurysm sac at follow-up were 5.2 $\pm$ 1.2, 5.1 $\pm$ 1.1 and 5.2 $\pm$ 1.1 cm for CDUS/CEUS, CTA and MRA, respectively. Aneurysm sac size at baseline and at control as measured by ultrasound significantly correlated with CTA measurements (rho 0.903 and rho 0.813, respectively) and MRA measurements (rho 0.870 and rho 0.781, respectively). During follow-up, the aneurysm sac shrank by 0.3 $\pm$ 0.4 cm (range, $-$1.4–0.8 cm, Wilcoxon's test: $p < 0.0001$). The aneurysm sac shrank in 77

(71.3%) patients, did not change in size in 24 (22.2%) patients and increased in size in seven (6.5%) patients. Change in the aneurysm sac size was -0.4 ± 0.3 cm (range 1.4—0.0 cm) among those patients without any endoleak (84 patients), whereas it was 0.0 ± 0.5 cm (range -1.2—0.8 cm, Mann—Whitney's test: $p = 0.002$) in those with endoleak (24 patients). In all patients without endoleak at the standard of reference, the aneurysm sac always decreased or remained unchanged, without any complication. Therefore, no diagnosis of endotension was made.

Twenty two of the detected endoleaks were of type II, 18 due to retrograde flow into the aneurysm sac through the lumbar arteries and four from the inferior mesenteric artery. Two type III endoleaks were detected as well.

All examinations visualised graft patency and graft integrity in all patients. Three out of four patients in whom CTA was not able to identify any endoleak were treated because the diagnosis of endoleak based on CEUS and MRA findings was confirmed by angiography, and it was associated with growth of the aneurysm sac. More in detail, CDUS examinations suggested 20 endoleaks, seven of which were false positives, whilst endoleak was not detected in 10 cases, due to the patient's physical constitution and stent's metallic artefacts.

CTA detected endoleak in 20 patients and did not identify four small type II endoleaks (Fig. 1). Sixteen type II endoleaks detected at CTA examination were low-flow endoleaks as identified at the delayed phase.

All but one of the endoleaks was correctly identified by the CEUS and MRA examinations; no false positive occurred with these imaging methods. CEUS better classified two endoleaks identified at CTA and one at MRA. At CTA, the two incorrectly classified endoleaks were one type II instead of type III endoleak, and one type III instead of type II endoleak. The case detected at MRA as type III endoleak was shown to be a type II endoleak at CEUS as confirmed by angiography. The accuracy of these diagnostic methods in detecting endoleaks is summarised in Table 1.

According to these results, CEUS was markedly more accurate than CDUS in the identification of leaks and its accuracy was also slightly better than CTA and similar to MRA. It is worth noting that CEUS allowed better classification of endoleaks in 10, two and one cases compared with CDUS, CTA and MRA, respectively. The four cases of missed endoleak at CTA could be explained by the metallic artefact resulting in suboptimal imaging, and because the endoleaks were too small.

Overall, DSA and treatment of the endoleak were performed in 10 patients. Two patients with type III endoleak were successfully treated by covering the defect with a stent-graft extension. Six patients with important type II endoleaks with progressive increase of the aneurysmal sac

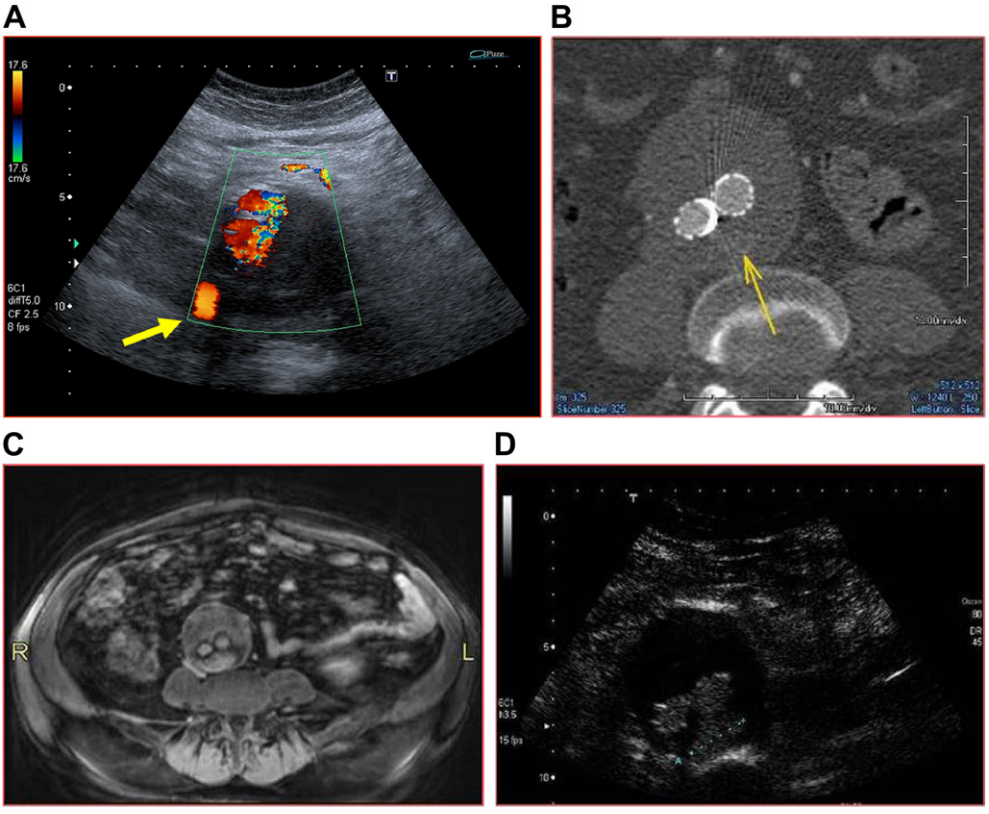

Figure 1 Figures summarizing the findings according to four different imaging methods of a type II endoleak after endovascular repair of an abdominal aortic aneurysm: A) Colour-Doppler ultrasound: no flow signal is detected within the aneurysm sac (arrow indicates a hypertrophic lumbar artery); B) computed tomography angiography: no focal contrast-enhancement within the aneurysm sac (arrow indicates the place where the endoleak is not evident due to artefacts; C) magnetic resonance angiography and D) contrast-enhanced ultrasound: focal contrast-enhancement behind the iliac branches during arterial phase consistent with endoleak.

Table 1 Accuracy of four diagnostic methods in detecting endoleak after endovascular repair of abdominal aortic aneurysm.

Imaging modality	True positives	False positives	False negatives	True negatives	Sensitivity	Specificity	Accuracy	Negative predictive value
CDUS	14	6	10	78	58%	93%	85%	89%
CEUS	23	0	1	84	96%	100%	99%	99%
CTA	20	0	4	84	83%	100%	96%	95%
MRA	23	0	1	84	96%	100%	99%	99%

CDUS: Colour-Doppler ultrasound; CEUS: contrast-enhanced ultrasound; CTA: computed tomography angiography; MRA: magnetic resonance angiography.

were treated with coil embolisation. The two remaining patients were not treated as the degree of endoleak was very small and a watchful, waiting strategy was indicated.

Discussion

EVAR is widely used as it is less invasive than open repair.[1,14–17] Surveillance of patients after EVAR is crucial for evaluating its technical success and possible complications such as endoleaks.[17] When indicated, endoleaks should be treated to avoid the risk of aneurysm rupture.[18,19]

Endoleak has been reported in as many as 44% of EVAR cases,[20] type II endoleak having been reported in 6–30% of patients.[3,21] Most of type II endoleaks resolve spontaneously within 6 months since detection,[22] whereas type I and type III, although being uncommon, are significantly related to a high risk of aneurysm rupture, and should be treated as soon as detected.[3,21]

This prospective multimodality evaluation for EVAR was performed to settle the controversy on the optimal follow-up method of EVAR patients.[7,23] The imaging method of choice should be cheap, repeatable, safe, non-invasive and accurate. CDUS is safe, cheap, and repeatable, but in our and other authors' experience,[4,5,9] it performed poorly in detecting endoleaks. This is mainly due to the burden of artefacts detected at CDUS.

CTA is the most used modality as it is widely available, with rapid acquisition and high diagnostic value.[23,24] However, it carries the risk of contrast-induced nephrotoxicity, radiation exposure and increased costs. Moreover, the definition of flow direction of endoleaks and feeding arteries by CTA is difficult. Stavroupoulos et al.[25] found that conventional angiography was much more sensitive than CTA. There is no general consensus on the CTA protocol for endoleak detection, and some authors advocate the importance of arterial phase[26] or delayed phase.[27] We use a triple-phase protocol with a low-dose unenhanced phase, normal dose arterial and delayed phase, and this method showed a high specificity and sensitivity.

MRA has been evaluated in the follow-up of EVAR patients due to the absence of radiation exposure and a lower risk of nephrotoxicity. However, it is considered time consuming, costly and not universally available.[28] A few studies suggested that MRA may be more sensitive than CTA for the detection of endoleaks.[10–12] However, these studies used single-detector and multidetector CT (MDCT) and standard gadolinium chelates for MRA for endoleak detection. Gadolinium-BOPTA (gadobenate dimeglumine, Multi- Hance®, Bracco, Italy) has a weak protein interaction, leading to an almost two-fold increase in relaxivity compared with conventional Gd chelates.[29] This property might be useful for the detection of low-flow endoleaks, where inadequate opacification with contrast medium represents a major limitation. Recently, Alerci et al.[13] reported the results of a prospective, intraindividual comparison between contrast-enhanced MRA, with a high-relaxivity MR contrast medium and 16-slice multidetector CTA. They showed superior sensitivity of MRA for the detection of endoleaks compared with CTA. However, this finding did not translate into therapeutic consequences for the patients, as none of the endoleaks undetected on CTA were associated with an increase of aneurysm size. A potential drawback is that stainless steel stents are ferromagnetic and, therefore, at risk of migration by the strong magnetic field.[30] Furthermore, they cause extensive artefacts. For example, the elgiloy stents (an alloy of cobalt, chromium and nickel), may obscure the stent lumen. Therefore, only patients with MR-compatible nitinol stent grafts should be considered for MRA surveillance. Endoleak detection in patients with MR imaging-compatible stents is relatively more sensitive as showed in previous studies[11,13,31] as confirmed by the findings of our study.

In the present study, CEUS was significantly more sensitive and specific than CDUS in the identification of leaks ($p < 0.001$), somewhat more accurate than CTA and of similar accuracy to MRA. CEUS allowed better classification of endoleaks in 10, two and one cases compared with CDUS, CTA and MRA, respectively. It is noteworthy that four cases of missed endoleak at CTA or endotensive endoleak were probably due to metallic artefact in two cases, and in the remaining two cases because of the small extent of endoleak. CEUS detected these two endoleak late after 80 s.

Regarding the classification of endoleaks, CEUS classified in two cases that were misdiagnosed by CTA and MRA as type III endoleak by the clear evidence of inflow vessels such as hypertrophic lumbar arteries. Moreover, CEUS has the advantage over CTA to provide haemodynamic information on blood flow and direction, in addition to the morphological evaluation, with the possibility of comparing in real time, on the same screen, the baseline and contrastographic images.

CEUS was performed with one bolus of 2.4 ml of second-generation contrast agent followed by 5 ml of saline in agreement with Iezzi et al.,[9] who showed that 2.4 ml should be preferred to 1.2 ml because it provides significantly better results in intensity and duration of contrast enhancement and, consequently, in visualisation. The need

for a second bolus should be limited to better characterise endoleak in difficult cases. Furthermore, US contrast media in this as well as in previous studies proved to be safe. Contrary to the findings reported by Iezzi et al.,[9] in our study, all patients treated with 'low permeability' design Gore Excluder endoprostheses were studied with sonographic imaging (CDUS as well as CEUS) at 1 month after EVAR, although the only case in whom CEUS failed to detect the endoleak was one treated with this type of device.

Despite the large number of patients participating in this study, we have observed a small number of endoleaks. This might have led to a potential bias on the evaluation of the diagnostic accuracy of the present methods. Furthermore, we encountered only type II and III endoleaks, which are the most frequent types of endoleaks. Therefore, not all types of endoleaks were represented in this investigation. We suggest that future studies with a larger number of subjects should be performed to confirm the role of these imaging modalities, particularly the CEUS, in the follow-up of EVAR patients.

In conclusion, CDUS is inadequate for the surveillance of patients after EVAR. The results of the present study showed that CEUS is an effective tool for surveillance after EVAR as it is fast, cheaper but equally accurate compared with CTA or MRA, and can be repeated frequently even at bedside, also in the immediate postoperative period. The limitations of CEUS are mainly due to its operator dependence and patients' habitus. Based on these findings, we do believe that CEUS is a valuable adjunctive imaging modality to CTA and MRA in detecting endoleaks after EVAR.

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Conflict of Interest

None.

Ethical Approval

None declared.

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