Treatment of failing arterio-venous dialysis graft by angioplasty, stent, and stent graft: Two-years analysis of patency rates and cost-effectiveness

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Abstract. The objective of this prospective randomized single-center study was to compare primary and secondary patency rates, number of percutaneous transluminal angioplasty (PTA) interventions and cost-effectiveness among PTA, deployment of a stent, or a stent graft in the treatment of failing arteriovenous dialysis grafts (AVG) due to restenosis in the venous anastomosis or the outflow vein. Altogether 60 patients with failing AVG and restenosis in the venous anastomosis or the outflow vein were randomly assigned to either PTA, placement of a stent (E-Luminexx®) or stent graft (Fluency Plus®). After the procedure, patients with stent or stent graft received dual antiplatelet therapy for the next three months. Follow-up angiography was scheduled at 3, 6, and 12 months unless requested earlier due to suspected stenosis or malfunction of the access. Subsequently, angiography was performed only if requested by the clinician. During a median follow-up of 22.4 (IQR=5.7) months patients with PTA, stent, or stent graft required 3.1±1.7, 2.5±1.7, or 1.7±2.1 (P=0.031) secondary PTA interventions. The primary patency rates were 0, 18 and 65% at 12 months and 0, 18 and 37% at 24 months in the PTA, stent, and stent graft group respectively (P<0.0001). The cost of the procedures in the first two years was €7,900±€3,300 in the PTA group, €8,500±€4,500 in the stent group, and €7,500±€6,200 in the stent graft group (P=0.45). We conclude that the treatment of failing dialysis vascular access by the deployment of a stent graft significantly improves its primary patency rates and decreases the number of secondary PTA interventions; however, the reduction in costs for maintaining AVG patency is not significant.

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Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; CI, confidence interval; DA, dialysis access; HR, hazard ratio; IQR, interquartile range; PTA, percutaneous transluminal angioplasty

Key words: vascular access, hemodialysis, angioplasty, stent, stent graft, stenosis, cost-effectiveness

Introduction

Hemodialysis is the most common treatment of patients with end-stage renal disease. In most of them the circulation is accessed through an arteriovenous fistula (AVF) or a graft (AVG) created on the upper limb (1,2). Although there is no better entry point for dialysis than a functional dialysis access (DA) on upper limb, its performance is far from perfect with nearly all patients requiring at least one percutaneous intervention with a subsequent primary patency rate of 23% at 12 months (3-5).

Despite great effort that had been devoted to improving the durability of DA, for long percutaneous transluminal angioplasty (PTA) had been the mainstay of DA stenosis treatment. The proposed deployment of a stent in the stenosis was initially met with little success. Further studies showed that only nitinol stents might deliver improved patency rates (6,7). Further development based on the promising bare nitinol stent was crowned by the design of a covered stent graft. Initial promising results were confirmed in a randomized multicenter trial that showed significant improvement of overall patency rates and freedom from subsequent interventions in short-term (8). The benefit of a stent graft deployment in a stenosed DA had been replicated in further studies and scenarios (9). However, the efficacy of the use of stents or stent grafts in the treatment of DA had been questioned due to the high cost of the devices and a limited number of randomized studies with long-term endpoints (10).

The objectives of this independent study were to compare three options for the treatment of failing AVG due to restenosis in the venous anastomosis or the adjacent segment of the outflow vein by PTA, deployment of a stent, or a stent graft with regard to primary and secondary patency rates, the number of therapeutic interventions (either PTA ± thrombolysis) required to maintain vascular access patency, and the cost of maintaining the vascular access.

Materials and methods

This prospective single-center study was approved by the Ethics Committee of the General University Hospital in Prague (60/12 IGA MZ ČR VFN), it was conducted in accordance with the Declaration of Helsinki, and all patients signed informed consent. Between 2013 and 2015 a total of 60 subjects were randomized in three study groups according to the strategy for treatment of the restenosis in the venous anastomosis or outflow vein of prosthetic AVG. The inclusion criteria were: i) Age above 18 years; ii) AVG located in the upper extremity; iii) restenosis in the venous anastomosis or adjacent segment of the outflow vein up to the axilla; iv) at least 2 previous PTAs during the previous year; v) last PTA of the stenosis <3 months and vi) referral for angiography due to malfunction of the fistula (low flow rate, elevated venous pressure during dialysis, increased intradialytic recirculation). The exclusion criteria were: i) life expectancy <1 year; ii) thrombosed fistula; iii) previous infection of AVG; iv) history of adverse reaction to iodinated contrast material and v) blood coagulation disorder.

The patients were randomly assigned to either continued PTA treatment, placement of a stent or stent graft.

Angiography and intervention. The procedures were performed by three experienced interventional radiologists with 11 to 32 years' experience at a tertiary academic center. In the supine position, after local disinfection, one cannula was placed in the arterial (inflow) segment of the graft in an antegrade direction. Angiography was performed on a standard angiography system (Axiom Artis MP, Siemens AG, Munich, Germany) during injection of 10-15 ml of Iomeron 400 (Iomeprol, Bracco Imaging, Konstanz, Germany) in anterior-posterior and oblique projections centered on the graft and the outflow vein as a digital subtraction angiography with a frame rate of 1/s.

PTA was performed from the same access using a balloon catheter (Optimed, Ettlingen, Germany; Boston Scientific, Marlborough, MA, USA) of appropriate diameter (7.3±0.7 mm; Fig. 1). In the stent group, a self-expanding nitinol stent (E-Luminexx® Vascular Stent, Bard Peripheral Vascular, Tempe, AZ, USA) with a diameter of 8.3±0.9 and length of 55±19 mm (Fig. 2) was implanted. In the stent graft group, a stent graft with similar design additionally covered by carbon-impregnated ePTFE (Fluency® Plus Endovascular Stent Graft, Bard Peripheral Vascular, Tempe, AZ, USA) with a diameter of 7.7±0.6 and length of 79±29 mm was used. If necessary, post-dilatation was performed by a non-compliant balloon catheter. The angiograms were evaluated by one radiologist who measured the diameter of the stenosis before and after PTA and the reference diameter of the adjacent segment.

Follow-up. After implantation of a stent or stent graft, a dual antiplatelet therapy (aspirin 100 mg and clopidogrel 75 mg daily) was administered for the next three months in all patients. If anticoagulation therapy was required for other reasons, it was continued. PTA patients either continued their antiplatelet or anticoagulant therapy or received at least one antiplatelet agent.

Follow-up angiography was scheduled 3, 6, and 12 months after the initial procedure unless requested by the referring physician earlier due to suspected restenosis (ultrasound) or malfunction of the fistula (low flow rate <600 ml/min, elevated dynamic venous pressure during dialysis, increased intradialytic recirculation, prolonged puncture site bleeding after hemodialysis) (11). Later, angiography was performed only if requested by the clinician. During the follow-up procedures, we performed angiography and decided on further treatment (no intervention, PTA, thrombolysis) based on angiographic findings. In one patient, a suspected infection of the stent graft was successfully treated with antibiotic therapy. One patient from the stent group withdrew from the study.

The endpoints were defined as follows: i) primary and secondary patency rates; ii) the number of therapeutic interventions (either PTA ± thrombolysis) required to maintain vascular access patency and iii) the cost of maintaining the vascular access calculated as the cost of the primary procedure (€1,210 for PTA, €2,667 for stent, and €3,475 for stent graft) and subsequent PTAs (€1,210). Primary patency was defined as the time from the index procedure to the first access failure or percutaneous intervention required to maintain its patency. Secondary patency was defined as the time from the index procedure to the abandonment of the AVG.

Statistical analysis. Statistical analysis was performed in SPSS 19 (IBM Corp., Armonk, NY), MedCalc 15 (MedCalc Software, Ostend, Belgium), and GraphPad Prism (GraphPad Software, La Jolla, CA, USA). Normality of the data was tested using D'Agostino's K2 test. To test for statistical significance among the study groups, we used ANOVA (with Bonferroni post hoc tests) or the Kruskal-Wallis test (with Dunns post hoc tests). Dichotomous variables were tested using the Fisher-Freeman-Halton test. Life table analysis was performed using the log-rank test and presented in a Kaplan-Meier estimator. Multivariable analysis was performed by Cox proportional hazard regression model using the forward likelihood ratio method on baseline characteristics and data from the primary interventions. $P<0.05$ was considered to indicate a statistically significant difference.

Results

The patients were 64±12 years old and 41 (71%) were women. There was no significant difference between the groups in the baseline data (Table I). In all patients, the primary intervention was technically successful (Table II). During a median follow-up of 22.4 [interquartile range (IQR)=5.7] months patients with PTA, stent, or stent graft required 3.1±1.7, 2.5±1.7, or 1.7±2.1 ($P=0.031$) secondary PTA interventions, respectively. The primary patency rates were 0, 18, and 65% at 12 months and 0, 18, and 37% at 24 months in the PTA, stent, and stent graft group respectively ($P<0.0001$; Fig. 3). The secondary patency rates were 94, 84, and 89% at 12 months and 94, 84, and 79% at 24 months ($P=0.58$; Fig. 4). The cost of the procedures in the first two years was €7,900±€3,300 in PTA group, €8,500±€4,500 in stent group, and €7,500±€6,200 in stent graft group ($P=0.45$).

Survival analysis showed that patients with stent graft had better primary patency rates ($P<0.0001$; Fig. 3), but there was

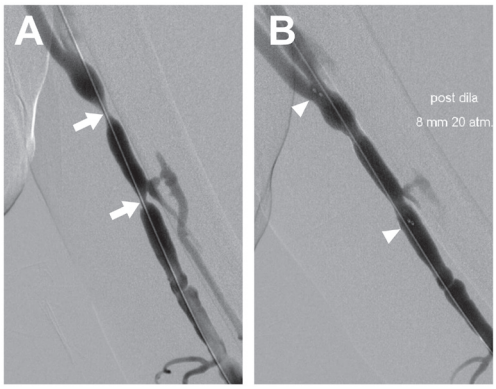

Figure 1. Angiography of AV graft (A) prior to and (B) following deployment of a nitinol stent (diameter, 8 mm; length, 60 mm, arrowheads) with a resolution of two stenoses in the outflow vein (arrows). AV, arteriovenous dialysis grafts.

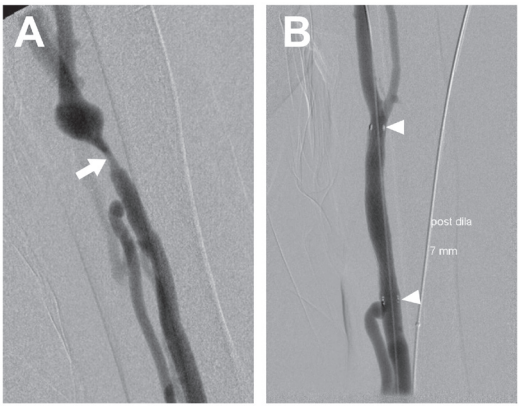

Figure 2. Angiography of AV graft (A) prior to and (B) following deployment of a stent graft (diameter, 7 mm; length, 80 mm, arrowheads) with resolution of a stenosis and aneurysm in the outflow vein (arrow). AV, arteriovenous dialysis grafts.

no difference in the secondary patency rates among the groups (P=0.58; Fig. 4). Multivariable Cox regression analysis identified the following predictors of primary patency: residual stenosis after initial PTA [hazard ratio (HR)=1.048; 95% CI 1.013 to 1.084; P=0.007], diameter of the reference segment adjacent to the stenosis (HR=0.498; 95% CI 0.306 to 0.813; P=0.005), and outflow to the superficial venous system vs. deep venous system (HR=0.457; 95% CI 0.233 to 0.894; P=0.022) with model significance of P=0.005 (Table III).

Discussion

In this study, we compared the mid-term performance of PTA, bare stent, and stent graft in the treatment of restenosis in the venous anastomosis or the adjacent segment of the outflow vein of upper limb AVGs. We showed that patients with stent graft required less subsequent PTA interventions but the reduction in cost was not statistically significant. We further identified predictors of primary patency rate.

Hemodialysis is the most common treatment of patients with end-stage renal disease. Maintaining dialysis access is necessary for all patients undergoing ambulatory hemodialysis on a regular basis. In most cases, a DA is the preferred long-term or permanent solution (1,2). The majority of DA failures occur due to stenosis or occlusion and can be repaired by percutaneous intervention including PTA and local thrombolysis with initial success rates above 90% and primary patency rates of 23% at 12 months (4,5,12,13). The culprit stenosis that leads to malfunction of AVG can be identified in the anastomosis in half of the patients with prosthetic AVGs. In patients with autogenous AVFs it is more common in the outflow vein. Stenosis in failing AVGs is attributed to intimal hyperplasia due to increased wall shear stress and other mechanisms with secondary thrombosis caused by decreased flow velocity and stasis (3).

Maintaining failing DA is a matter of finding a line between the requirement of repeated percutaneous interventions and surgical correction or a redo procedure (14). Nearly all patients with DA require at least one percutaneous intervention (14). Early resolution of DA stenosis improves the functioning of the circuit, but randomized trials were unable to demonstrate its positive effect on DA survival (15,16). Lessons have been drawn from other vascular interventions, and stents and stent grafts have been tested in DAs in the treatment of stenosis, aneurysms and ruptures initially in off-label settings (17).

A percutaneous approach to DA stenosis by PTA has been long established as the best treatment in most cases and used as the gold standard (14,18,19). The primary patency rates after PTA of DA regardless of location (arm, forearm) vary widely in the literature and are about 25-30% for AVG and 67% for AVF at 1 year (3). Up to 70% of patients require a second intervention within one year (5,20). Secondary patency rates usually with multiple interventions are about 82% at one year and 70% at two years (3,8).

Initial attempts to improve patency rates of AVF by placement of bare stents have been disappointing and their hypothesized advantage over PTA alone did not materialize (21,22). Only nitinol stents showed improved flow in the AVF with and better patency rates with a pooled relative risk of 0.79 (2,6,7). Compared to stainless steel, nitinol (nickel-titanium alloy) stents do not shorten during deployment (23).

Further development based on the promising bare nitinol stent resulted in the design of a covered stent graft that was used in a randomized multicenter trial by Haskal *et al* who compared short-term patency rates in 190 patients with venous anastomotic stenosis in a prosthetic AVG (8). In their study, PTA with the placement of a stent graft showed significant improvement in overall primary patency rates of the AVG and freedom from subsequent interventions at six months compared to PTA alone (32% vs. 16%) (8). The advantage of a stent graft over PTA was later confirmed in other studies as well (9). Carmona *et al* compared primary patency rates in patients with failing grafts due to stenosis at the graft to vein anastomosis between PTA and heparin bonded stent graft and reported improved primary patency rates from 9 to 42% and an increased proportion of functional grafts from 36 and 88% at 12 months (24). Both rival stent grafts (nitinol stents covered with ePTFE), the Viabahn® and Fluency® were compared in a study by Schmelter *et al* (25), who did not prove any difference in primary and secondary patency rates in the treatment of stenosed AVGs and AVFs. In their study, the primary

Table I. Study group characteristics at baseline.

Characteristics	PTA n=20	Stent n=19	Stent graft n=20	P-value
Age	61±17	68±11	65±13	0.30
Sex (women)	15	12	15	0.64
Coronary artery disease	4	4	10	0.087
Chronic heart failure	6	1	3	0.13
Diabetes	9	10	7	0.58
Smoker or ex-smoker	7	8	10	0.64
Arterial hypertension	15	18	17	0.27
Hyperlipoproteinemia	8	13	15	0.061
Therapy				
ACE inhibitor	6	6	9	0.62
Statin	6	6	10	0.40
Antiplatelet	14	17	17	0.34
Anticoagulation	12	10	6	0.14
Vascular access since (years)	3.1 (IQR 3.8)	3.3 (IQR 5.4)	4.0 (IQR 3.0)	0.88
Vascular access type				
Loop	12	13	15	0.61
Straight	8	6	5	
Inflow artery				
Brachial artery	16	15	16	1.0
Radial artery	4	4	4	
Outflow vein				
Superficial vein	13	15	16	0.60
Deep system	7	4	4	

PTA, percutaneous transluminal angioplasty; IQR, interquartile range.

Table II. Vascular access, stenosis, primary and secondary interventions.

Characteristics	PTA n=20	Stent n=19	Stent graft n=20	P-value
Reference diameter (mm)	6 (IQR 1)	6 (IQR 1.5)	6.3 (IQR 1)	0.77
Restenosis location				
Venous arm	11	8	4	0.065
Anastomosis	9	11	16	
Stenosis (%)	66±16	67±16	67±9	0.90
Stenosis after PTA (%)	17±12	9±10	11±10	0.054
Follow-up (months)	22.1 (IQR 4.8)	22.3 (IQR 3.8)	23.6 (IQR 15.1)	0.36
Thrombosis	1 (5%)	3 (16%)	1 (5%)	0.60
Infection	0	0	1 (5%)	1.0
Secondary PTA <1 year	2.8±1.4	2.3±1.8	1.4±2.4	0.015[a]
Secondary PTA <2 years	5.5±2.8	4.8±3.7	3.3±5.1	0.037[b]

PTA, percutaneous transluminal angioplasty; IQR, interquartile range. [a]P<0.01 between PTA and stent graft in a post hoc test, [b]P<0.05 between PTA and stent graft in a post hoc test.

patency rates were 31% at 12 months and 19% at 24 months. Our results with 65 and 37% primary patency rates at 12 and 24 months in the stent graft group and only prosthetic AVGs compare favorably with the results from Schmelter *et al* (25). The success rate of the deployment of stents and stent grafts in our study is comparable to other studies that consistently report high rates near 99% confirming the safety of both approaches (8,25).

Table III. Multivariable Cox proportional hazard regression analysis model for primary patency rates-variables retained in the model (P=.005) and their hazard ratios.

Variables	Hazard ratio	95% CI	P-value
Residual stenosis following initial PTA	1.048	1.013 to 1.084	0.007
Diameter of the reference segment adjacent to the stenosis	0.498	0.306 to 0.813	0.005
Outflow to the superficial venous system vs. deep venous system	0.457	0.233 to 0.894	0.022

PTA, percutaneous transluminal angioplasty; CI, confidence interval.

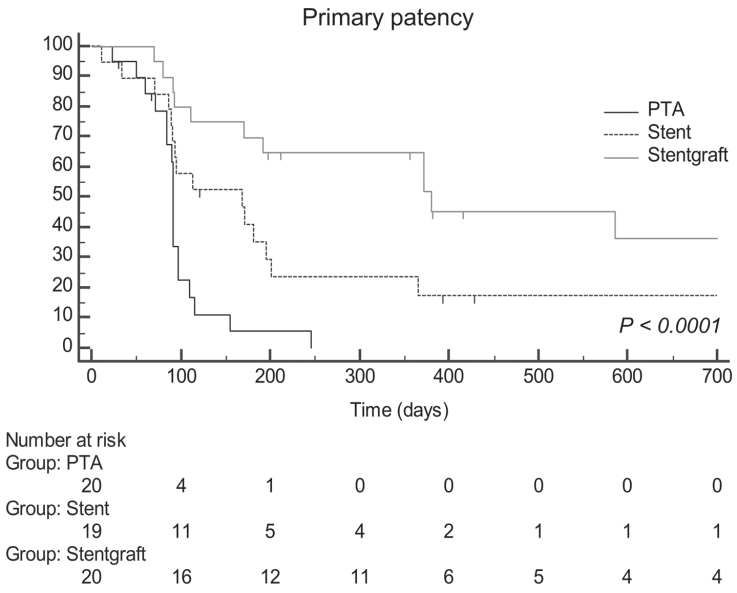

Figure 3. Comparison of primary patency rates among PTA, stent, and stent graft groups in a Kaplan-Meier plot. PTA, percutaneous transluminal angioplasty.

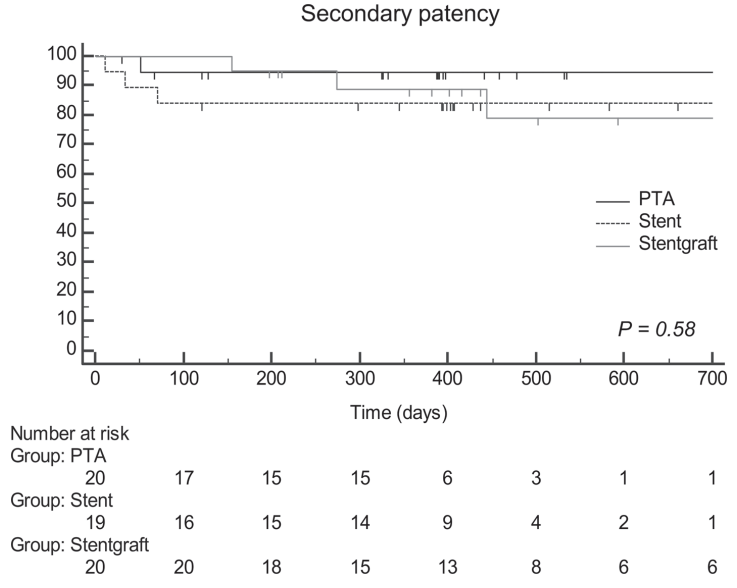

Figure 4. Comparison of secondary patency rates among PTA, stent, and stent graft groups in a Kaplan-Meier plot. PTA, percutaneous transluminal angioplasty.

The effect of antiplatelet agents and their risk to benefit ratio in dialysis patients is poorly understood especially in AVGs and their general use for preventing AVG thrombosis is therefore not recommended due to lack of supporting data (3,26,27). Their use after placement of stent graft in stenosed dialysis access has not been included in the protocol of previous studies

and left on the discretion of the referring physician (8,25). In our study, the protocol required dual antiplatelet therapy after deployment of stent or stent graft. We believe that this might have improved their performance compared to the PTA group.

The comparison of primary and secondary patency rates after intervention should be viewed in the perspective of study design. Intensive follow-up programs with tight monitoring of the vascular access and early intervention artificially decrease the primary patency rates (10). Moreover, lower patency rates can be expected in AVGs, younger DA, in the presence of longer lesions, and residual stenosis after PTA (25,28). The present study confirmed that greater residual stenosis after initial PTA is a risk factor and identified further two factors: Smaller diameter of the reference segment adjacent to the stenosis and the use of a deep vein as the outflow.

Numerous approaches to the management of stenosed or malfunctioning DA have also been compared on the cost-effectiveness basis. The debated intensive surveillance program has an incremental net cost for a modest decline in DA thrombosis and is less efficient than increasing the proportion of autogenous fistulas (13,29). The cost-effectiveness of stents and stent grafts in the treatment of DA stenosis has been questioned due to the high cost of the devices and a limited number of randomized studies with long-term endpoints (10). Our study showed that deployment of a stent graft results in decreased number of subsequent PTAs, but the reduction in cost for maintaining AVG patency in our country was not significant. We estimate that in countries such as the USA or India the deployment of a stent graft in this scenario would reduce the cost of maintaining the access from the payer's perspective by a greater margin due to higher ratio between the procedure reimbursement rates and the price of the stent graft, even more than predicted by Dolmatch *et al* (30). Nevertheless, the sole reduction of the number of PTAs can be regarded as a clear benefit to the comfort of the patient.

In conclusion, this study confirms that treatment of failing dialysis vascular access due to restenosis in the anastomosis or the outflow vein by the deployment of a stent graft significantly improves its primary patency rate and decreases the number of secondary PTA interventions in comparison with PTA and deployment of a stent. The cost analysis showed that the reduction in cost for maintaining AVG patency is not statistically significant. The present study confirmed that greater residual stenosis after initial PTA is a risk factor and identified further two: Smaller diameter of the reference segment adjacent to the stenosis and the use of a deep vein as the outflow. Finally, the safety of all three compared approaches was confirmed.

The present study has several limitations. Firstly, the sample size is relatively small. Secondly, the study groups are heterogeneous in term of the location of the restenosis. Thirdly, only one type of stent graft was used. Fourthly, dual antiplatelet therapy was required in the stent and stent graft groups only, but patients from the PTA group received or continued at least one antiplatelet agent or continued their anticoagulation therapy. Lastly, the cost analysis pertains to the author's country.

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Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Authors' contributions

JKa, JKu, AB and JM conceived and designed the study; JKa, JKu, EC, MS, and PM performed examinations, interventional procedures, and collected the data; JKa, JKu, and LL performed analysis; JKa, JKu, LL, and AB drafted the paper; all authors approved final version of the manuscript.

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki, it was approved by the Ethics Committee of the General University Hospital in Prague, and all patients provided written informed consent.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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