Use of a novel hybrid vascular graft for sutureless revascularization of the renal arteries during open thoracoabdominal aortic aneurysm repair

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Objective: **The aim of this study was to assess the safety and short-term effectiveness of a novel hybrid vascular graft used to address renal revascularization during open thoracoabdominal aortic aneurysm (TAAA) repair, performing a sutureless distal anastomosis.**

Methods: **Between 2012 and 2013, 25 patients (16 men; mean age, 66 ± 8 years) underwent revascularization of one (24 patients) or both (one patient) renal arteries with the Gore Hybrid Vascular Graft (GHVG; W. L. Gore and Associates, Flagstaff, Ariz) during open TAAA repair. Specific indications included remote location of the ostium of the renal artery, severe atherosclerotic wall degeneration, focal dissection, and stenosis. All surviving patients underwent computed tomography angiography and follow-up visit at 1 month. Preoperative characteristics, intraoperative data, and short-term results were compared with those of 49 concurrent TAAA patients operated on within the same period by standard renal revascularization (SRR) techniques.**

Results: **All GHVG target renal vessels (26 of 26) were successfully revascularized without technical concerns. No significant differences were found between GHVG and SRR groups in preoperative and intraoperative data, except for a relative prevalence of aortic dissection (28% vs 6%; $P = .026$) and renal artery stenosis (44% vs 12%; $P = .003$) in the GHVG group and for intraoperative renal bare stenting that was predominantly used in the SRR group (12% vs 28%; $P = .036$). The 30-day mortality was 4% in both groups. Postoperative acute renal failure (doubling of creatinine level and creatinine level >3.0 mg/dL) occurred in two GHVG patients (8%) and seven SRR patients (14%; $P =$ NS). Perioperative peak decrease of estimated glomerular filtration rate was lower in the GHVG group (26 ± 18 mL/min/1.73 m^2 vs 37 ± 22 mL/min/1.73 m^2; $P = .034$). At 1-month computed tomography angiography, renal artery patency was 92% for the GHVG vessels, 91% for the contralateral to GHVG renal vessels, and 92% for the SRR group arteries. No GHVG-related complications requiring reintervention or cases of new-onset renal failure requiring dialysis were observed at follow-up.**

Conclusions: **Renal revascularization during open TAAA repair by the GHVG with distal sutureless anastomosis is feasible, especially in cases of aortic dissection, remote location of the renal vessel, and severe atherosclerotic disease of the ostium. Short-term results are satisfactory, at least comparable to those of SRR. Larger series and longer follow-up are needed to assess clinical advantages and durability of this new device. (J Vasc Surg 2014;60:622-30.)**

Although great strides in morbidity and mortality reduction have been made in the surgical treatment of thoracoabdominal aortic aneurysm (TAAA),[1] perioperative acute renal dysfunction still complicates up to 70% of these procedures even in the most specialized centers.[2] The clinical consequences of postoperative renal impairment are noteworthy: its occurrence has been shown to be the strongest predictor of early mortality and to be associated with permanent long-term chronic kidney disease.[3,4]

Multiple etiopathologic factors are supposed to be involved in perioperative renal dysfunction, but the most important are definitely the time of renal ischemia during artery reattachment and the associated atherosclerotic renal vessel disease, such as ostial stenosis or dissection. These factors account for a significant increase in technical difficulty, prolonged time of anastomosis, and increased global risk of intraoperative renal injury.

Covered self-expanding stents are being used to perform "sutureless anastomoses" on visceral aortic branches (including the renal arteries) during debranching procedures, obviating the need for technically demanding vessel exposure and anastomoses, thereby reducing the duration of flow interruption and simplifying the performance of complex aortic repair.[5] Lachat and colleagues named this method VORTEC (Viabahn Open Revascularization TEChnique), as they used a "standard" covered stent graft (Viabahn; W. L. Gore and Associates, Flagstaff, Ariz).

The Gore Hybrid Vascular Graft (GHVG; W. L. Gore and Associates) is a novel expanded polytetrafluoroethylene (ePTFE) vascular prosthesis that includes a nitinol-reinforced self-expanding section at one of its extremities, allowing a "sutureless" endovascular anastomosis. In this study, we report our initial experience with this graft for

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renal revascularization during TAAA open repair to assess the safety and short-term results of this technique compared with standard renal revascularization (SRR) strategies.

METHODS

We analyzed a single-center series of 25 consecutive patients who underwent elective TAAA open repair, including at least one renal revascularization with the GHVG, between September 2012 and November 2013. During the same period, 49 other patients were submitted to TAAA open repair with SRR techniques because the GHVG was deemed to be contraindicated or not necessary by the operating surgeon.

Data of both groups were prospectively collected in an electronic database. Informed consent of the patient was obtained in all cases. All survivors were followed up 1 month after the operation by means of computed tomography angiography (CTA) and office visit.

Demographics and preoperative risk factors of patients included in the analysis are reported in Table I. Patients were stratified into the five chronic kidney disease stages according to the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative guidelines.[6]

All patients underwent preoperative CTA within 1 month before the procedure. Patients were stratified by aneurysm extension to the Crawford-Safi revised classification. Aneurysm size was determined on the basis of CTA three-dimensional reconstructions by use of the cross-sectional diameter of the aortic centerline. In the GHVG group, all patients had two functioning kidneys with a single patent renal artery at preoperative CTA, for a total of 50 patent renal arteries in this group. In the SRR group, 43 patients had a bilaterally patent renal artery, four patients had only one functioning kidney with a single patent renal artery, and two patients had multiple (double) patent renal arteries for the same kidney, for a total of 96 patent renal arteries in this group. Renal artery stenosis was defined as a >50% lesion as documented by CTA.

Intraoperative variables were recorded and are listed in Table II. Total renal ischemia time was defined as the duration from first aortic cross-clamping to complete bilateral renal revascularization. Isothermic renal distal perfusional time was considered the duration of aortic cross-clamping, with working left-sided heart bypass providing retrograde blood perfusion to the kidneys. Cold renal perfusional time was defined as the duration of cold selective renal artery perfusion after opening of the visceral aortic segment.

Morbidity and mortality were recorded (Table III). Serum creatinine concentration was measured the day before the operation (baseline value) and postoperatively on a daily basis. Acute renal failure was defined as both a doubling of the serum creatinine level and an absolute value above 3.0 mg/dL.[7] Glomerular filtration rate was estimated (eGFR) by the Chronic Kidney Disease Epidemiology Collaboration formula (expressed as mL/min/1.73 m^2).[8] Perioperative peak decrease of eGFR was calculated as the difference from the preoperative eGFR value and the lowest eGFR value measured during the postoperative period.

All CTAs performed at 1 month after the operation were carefully reviewed to ascertain patency of the renal vessels and of the implanted grafts and to identify graft migration, stenosis, kinking or twisting, stent fractures, and instances of bleeding or renal infarctions.

Continuous variables are presented as mean ± standard deviation; those with non-normal distributions are presented as median (interquartile range), and discrete variables are reported as number (and proportion) of patients. To compare preoperative clinical characteristics (Table I), intraoperative surgical data (Table II), and postoperative outcomes (Table III) including cumulative

Table I. Demographics and preoperative risk factors of the 25 Gore Hybrid Vascular Graft (*GHVG*) and the concurrent 49 standard renal revascularization (*SRR*) patients

Variables	*GHVG patients*	*SRR patients*	P
Total	25	49	
Gender, male	16 (64)	39 (80)	NS
Age, years	66.0 ± 8.4	65.0 ± 10.1	NS
Etiology			
Atherosclerotic/degenerative	17 (68)	42 (86)	NS
Chronic type B dissection	7 (28)	3 (6)	.026
Para-anastomotic pseudoaneurysm	1 (4)	0 (0)	NS
Connective tissue disorder	0 (0)	4 (8)	NS
Principal comorbidities			
Hypertension	22 (88)	44 (90)	NS
Diabetes mellitus	6 (24)	9 (18)	NS
Dyslipidemia	13 (52)	27 (55)	NS
Active smoking	7 (28)	14 (29)	NS
COPD	17 (68)	35 (71)	NS
Extracardiac arteriopathy	10 (40)	12 (24)	NS
Coronary artery disease	7 (28)	9 (18)	NS
Cerebrovascular disease	6 (24)	8 (16)	NS
CKD stages			
Stage 1	7 (28)	15 (31)	NS
Stage 2	10 (40)	20 (41)	NS
Stage 3	6 (24)	10 (20)	NS
Stage 4	2 (8)	4 (8)	NS
Stage 5	0 (0)	0 (0)	NS
ASA score	3.6 ± 0.5	3.5 ± 0.5	NS
Classification of aneurysms[a]			
TAAA extent I	0 (0)	2 (4)	NS
TAAA extent II	10 (40)	16 (33)	NS
TAAA extent III	8 (32)	15 (31)	NS
TAAA extent IV	7 (28)	14 (29)	NS
TAAA extent V	0 (0)	2 (4)	NS
Aneurysm maximum diameter, mm	67 ± 21	68 ± 14	NS
Pararenal aortic diameter, mm	60 ± 19	65 ± 13	NS
Associated renal artery stenosis	11 (44)	6 (12)	.003

ASA, American Society of Anesthesiologists; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *NS*, not significant; *TAAA*, thoracoabdominal aortic aneurysm.
Continuous data are presented as mean ± standard deviation and categorical data as number (%).
[a]According to the Crawford-Safi revised TAAA extent classification.

Table II. Intraoperative details of the Gore Hybrid Vascular Graft (*GHVG*) and standard renal revascularization (*SRR*) patients, including technique of revascularization of the renal arteries

Variables	*GHVG patients*	*SRR patients*	P
Total	25	49	
CSF drainage	23 (92)	39 (80)	NS
LHBP	21 (84)	36 (73)	NS
Intercostal/lumbar artery reimplantation	17 (68)	28 (57)	NS
Renal perfusion (4°C Custodiol)	25 (100)	49 (100)	NS
CT/SMA perfusion			
Normothermic blood	21 (84)	36 (73)	NS
4°C Lactated Ringer solution	4 (16)	13 (26)	NS
Total surgical time, minutes	272 ± 87	285 ± 80	NS
Total renal ischemia time, minutes	53 ± 23	59 ± 16	NS
Isothermic renal distal perfusional time, minutes	25 ± 15	25 ± 14	NS
Cold renal perfusional time, minutes	28 ± 13	34 ± 10	.031
Urine output during operation, mL	1485 ± 862	1654 ± 1025	NS
Intraoperative losses	4451 ± 2796	4890 ± 3466	NS
Transfusion requirements, mL			
Packed red blood cells	1104 ± 693	1072 ± 748	NS
Fresh frozen plasma	1498 ± 730	1624 ± 713	NS

Variables	*Renal arteries (GHVG group)*	*Renal arteries (SRR group)*	
Total	50	96[a]	
Technique of reimplantation of the renal arteries			
Carrel patch reimplantation	22 (44)	69 (72)	.001
Presewn multibranched graft	0 (0)	14 (15)	.002
Conventional aortorenal bypass	2 (4)	13 (13)	NS
Left	2 (100)	13 (100)	—
Right	0 (0)	0 (0)	—
GHVG	26 (52)	—	—
Left	17 (65)	—	—
Right	9 (35)	—	—
Renal stenting (non-GHVG vessel)	6 (12)	27 (28)	.036
Renal endarterectomy	0 (0)	2 (2)	NS

CSF, Cerebrospinal fluid; *CT,* celiac trunk; *LHBP,* left-sided heart bypass; *NS,* not significant; *SMA,* superior mesenteric artery.
Continuous data are presented as mean ± standard deviation and categorical data as number (%).
[a]Of the 49 SRR patients, preoperatively 43 patients had a bilaterally patent renal artery, four patients had a single patent renal artery, and two patients had multiple (double) patent renal arteries for the same kidney.

patency at 1 month between the GHVG group and the SRR group, two-tailed Fisher exact test and χ^2 test were used in the case of categorical variables, and two-tailed paired *t*-test (for normally distributed variables) and the Kruskal-Wallis test (for non-normally distributed variables) were used in the case of continuous variables. A two-tailed P value $< .05$ was considered significant.

Table III. Short-term outcomes of the Gore Hybrid Vascular Graft (*GHVG*) and concurrent standard renal revascularization (*SRR*) patients

Variables	*GHVG patients*	*SRR patients*	P
Total	25	49	
Peak serum creatinine, mg/dL	2.0 ± 1.7	2.2 ± 1.1	NS
Perioperative peak decrease of eGFR, mL/min/1.73 m^2	26 ± 18	37 ± 22	.034
Acute renal failure	2 (8)	7 (14)	NS
Temporary hemodialysis	1 (4)	1 (2)	NS
Dialysis at discharge	0 (0)	1 (2)	NS
Respiratory insufficiency	12 (48)	22 (45)	NS
Paraplegia/paraparesis	2 (8)	6 (12)	NS
Ischemic bowel	0 (0)	2 (4)	NS
Stroke	0 (0)	0 (0)	NS
Cerebral hemorrhage	0 (0)	1 (2)	NS
Cardiac complication	3 (12)	8 (16)	NS
Bleeding requiring reintervention	1 (4)	2 (4)	NS
ICU time, days	2 (1-4)	2 (1-3)	NS
LOS, days	7 (5-12)	9 (7-11)	NS
Operative mortality	0 (0)	1 (2)	NS
In-hospital mortality	1 (4)	2 (4)	NS
30-day mortality	1 (4)	2 (4)	NS

eGFR, Estimated glomerular filtration rate; *ICU,* intensive care unit; *LOS,* length of stay; *NS,* not significant.
Continuous data are presented as mean ± standard deviation and median (interquartile range), and categorical data are presented as number (%).

Device description, indications, and surgical technique. We previously reported our standard surgical techniques and outcomes for TAAA open repair and renal vessel management.[9]

The GHVG received U.S. Food and Drug Administration approval in March 2010 and obtained the CE Mark in July 2012. This device is currently commercially available in the United States, Europe, Russia, and a few Middle Eastern countries. It is an ePTFE vascular prosthesis that has a distal section reinforced with nitinol (Fig 1). The nitinol-reinforced section is partially constrained to allow easy insertion and deployment into a vessel. Its lumen is continuous with the CARMEDA BioActive Surface (Medtronic, Minneapolis, Minn), consisting of a stable covalently bonded, reduced molecular weight heparin of porcine origin. An embedded low-permeability film provides a barrier to ultrafiltration. The graft is available with a nitinol-reinforced section length of 5 and 10 cm and diameter of 6, 7, 8, and 9 mm.

In this initial experience, our indication for the use of the GHVG was generally limited to renal vessels that were not considered suitable for inclusion in an aortic patch because of their anatomic location or the poor quality of the surrounding aortic wall. We favored the GHVG over a standard aortorenal bypass graft in cases of anatomically

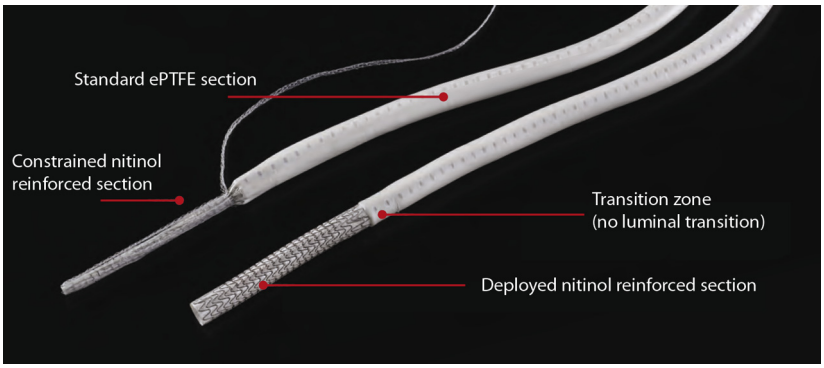

Fig 1. The Gore Hybrid Vascular Graft (GHVG). *ePTFE*, Expanded polytetrafluoroethylene.

challenging location of the renal artery ostium and in cases of severe atherosclerotic disease of the proximal tract of the renal artery (including the presence of highly calcified or disrupted plaque, critical stenosis, or local dissection). The choice to use the GHVG was guided by the intention to decrease technical complexity and duration of the distal anastomosis, to reduce accidental damage to the arterial wall, concurrently to treat stenotic or dissected arteries, and to prevent early kinking of bypassed renal vessels during viscera derotation.

Sizing of the nitinol-reinforced section was performed with a 10% to 20% oversizing compared with the diameter of the target renal vessel as measured at preoperative CTA and confirmed by intraoperative findings. The distance between the origin and the bifurcation of the renal artery was always measured at preoperative CTA to avoid unintentional coverage of renal artery branches during GHVG deployment.

Contraindications to use of the GHVG included target renal artery diameter <5 mm or >8 mm, anomalous major collaterals of the target renal artery originating in its proximal tract, and severe stenosis of the distal tract of the target renal artery.

With the patient on cerebrospinal fluid drainage, placed in a right lateral decubitus position, thoracophrenolaparotomy is performed and the thoracoabdominal aorta is exposed following our standard surgical technique.[9] After institution of left-sided heart bypass, the proximal anastomosis is performed, and critical intercostal arteries are reattached by a sequential clamping technique. The distal clamp is then moved below the renal arteries, and the visceral aorta is opened. Visceral normothermic hemoperfusion is then delivered by the pump with 9F irrigation-occlusion catheters (LeMaitre Vascular, Burlington, Mass) into the celiac trunk and the superior mesenteric artery (400 mL/min). Selective perfusion of the renal arteries is performed with cold (4°C) crystalloid solution enriched with histidine-tryptophan-ketoglutarate (Custodiol).[10] Visceral arteries that are not deemed to require a separate reattachment are usually first reimplanted by means of a Carrel patch. The distal aortic anastomosis is then performed, and the aortic clamps are removed.

After identification of the GHVG target renal vessel, the perfusion catheter is temporarily removed. A flexible steerable J-tip guidewire (usually 0.035 inch) is inserted into the renal artery. The constrained stented segment of the GHVG is gently placed into the artery for 2 to 3 cm, with respect to the distances measured at preoperative CTA, with the deployment line facing upward. The stent is released, pulling the deployment line parallel to the vascular graft section (Fig 2). Care must be taken to hold it firmly in place during this maneuver. Stent post-dilation is performed in all cases after GHVG distal segment deployment by a 5- to 6-mm noncompliant balloon advanced on the guidewire through the conduit. The cold renal perfusion catheter is then immediately reinserted into the graft to reduce renal ischemia. The GHVG is then sewn in place with at least four single circumferential monofilament polypropylene stitches. Finally, the proximal anastomosis to the main aortic graft is completed in the usual fashion after the proximal unstented section of the graft is cut at the proper length.

After blood flow restoration, protamine is administered to completely reverse heparin. Red blood cells, platelets, and plasma transfusions are aggressively used to correct severe thrombocytopenia and coagulation derangements. Anastomoses are carefully checked for bleeding and reinforced when needed. Mild initial bleeding from ePTFE needle holes usually resolved spontaneously after a few minutes. In case of major suture hole bleeding, hemostasis is obtained by manual compression with surgical gauze and oxidized cellulose pads.

Antiplatelet therapy (usually aspirin) is routinely initiated by the third postoperative day if it is not contraindicated. Double antiplatelet therapy (adding ticlopidine or clopidogrel) is then started by the tenth postoperative day and continued after discharge for at least 1 month.

RESULTS

In the GHVG group, all patients presented two patent renal arteries at preoperative CTA, for a total of 50 renal arteries to be revascularized during TAAA open repair. A >50% stenosis at the ostium of 11 renal vessels was detected at preoperative CTA; in another 28 arteries,

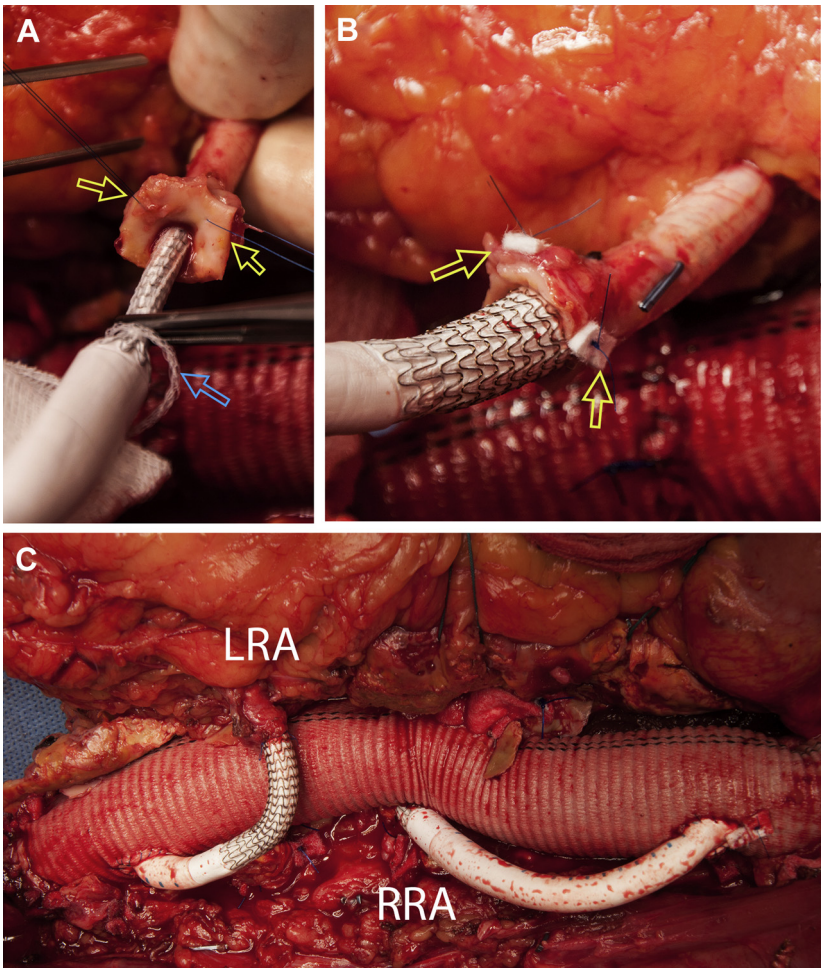

Fig 2. Sequence of Gore Hybrid Vascular Graft (GHVG) deployment during distal "sutureless" anastomosis of a left aortorenal bypass. **A,** During insertion of the device, the origin of the renal artery is suspended with separate stitches (*yellow arrows*). With the GHVG firmly held, the stent is released by pulling the deployment line (*blue arrow*). **B,** After release of the nitinol-reinforced section, the device is fixed, sewing the circumferential stitches (*arrows*). **C,** Final result after aortic reconstruction and bilateral renal revascularization with two GHVGs. *LRA,* Left renal artery; *RRA,* right renal artery.

significant calcification, thrombus, or mild (<50%) stenosis was found. Twenty-six renal arteries were revascularized with the GHVG (17 left and nine right) and 24 with standard surgical techniques (22 by means of Carrel patch reimplantation and two by means of conventional aortorenal bypass). Indications for the use of the GHVG included intraoperative detection of a remote location of the ostium of the renal artery (20 cases; 77%), severe atherosclerotic wall degeneration or dissection (23 cases; 88%), and renal artery stenosis (seven cases; 27%).

No significant differences were found between the GHVG group and the SRR group in preoperative characteristics (Table I), except for a relative prevalence of aortic dissection (28% vs 6%; $P = .026$) and renal artery stenosis (44% vs 12%; $P = .003$) in the GHVG group.

Intraoperative data are summarized in Table II. Surgical techniques for renal revascularization differed significantly between the GHVG and SRR groups, resulting in a relative prevalence of Carrel patch reimplantation and use of presewn multibranched graft in the SRR group (44% vs 72%; $P = .001$, and 0% vs 15%; $P = .002$, respectively).

All intended target renal vessels were treated without technical concerns with the GHVG. No significant bleeding from ePTFE needle holes or from the graft anastomoses was observed. Total surgical and total renal ischemia times were slightly shorter in the GHVG group compared with SRR, but this difference did not reach statistical significance (272 ± 87 minutes vs 285 ± 80 minutes; P = NS; and 53 ± 23 minutes vs 59 ± 16 minutes; P = NS, respectively). Cold renal perfusional time was significantly shorter in the GHVG group (28 ± 13 minutes vs 34 ± 10 minutes; $P = .031$).

No adjunctive unplanned endovascular or surgical procedures were required on the GHVG-treated vessels. Before revascularization, a balloon-expandable stent was

directly implanted at the ostium of six renal arteries in the GHVG group (contralateral to the GHVG target vessel) and in 27 renal arteries in the SRR group, resulting in a significant prevalence of renal artery bare stenting in the SRR group (12% vs 28%; $P = .036$).

The 30-day mortality was 4% in both groups (Table III). In the GHVG group, one patient died on postoperative day 6 of myocardial infarction. In the SRR group, one patient died intraoperatively of acute ascending aortic dissection with left main coronary artery occlusion; another patient died on postoperative day 26 of multiorgan failure.

No significant differences were found between groups in regard to perioperative complications. Acute renal failure occurred in two GHVG patients. The first patient experienced perioperative paraparesis; postoperative creatinine level reached 4.51 mg/dL but returned to 2.87 mg/dL after 6 days and did not require dialysis; 1-month CTA revealed occlusion of the right aortorenal conventional bypass. The second patient had a history of bilateral renal polycystic disease, with a baseline creatinine value of 3.86 mg/dL; he required temporary dialysis during the first and second postoperative days and then returned to baseline renal function; 1-month CTA revealed regular patency of both renal arteries. The rate of acute renal failure showed an increased trend in the SRR group (14%) compared with the GHVG group (8%), but this difference was not statistically significant. Perioperative peak decrease of eGFR was significantly lower in the GHVG group (26 ± 18 mL/min/1.73 m^2 vs 37 ± 22 mL/min/1.73 m^2; $P = .034$).

Follow-up CTA was available in 24 GHVG patients (all patients except for the one who died perioperatively), including 25 renal arteries revascularized with the GHVG and 23 revascularized with standard techniques. In the SRR group, only 32 follow-up CTAs were available for analysis, for a total of 62 revascularized renal arteries. No significant stenosis, migration, stent fracture, kinking, or twisting of the GHVG was observed. No areas of renal infarction were observed in patients with patent aortorenal grafts. Patency rates were 92% (23 of 25) for the aortorenal grafts performed with the GHVG, 91% (21 of 23) for the contralateral renal arteries revascularized with standard techniques in the same group (one renal artery occlusion after Carrel patch reimplantation and one occlusion of conventional aortorenal bypass), and 92% (57 of 62) for revascularized renal vessels in the SRR group. No renal complications requiring reintervention or cases of new-onset renal failure requiring dialysis were reported at follow-up in both groups.

DISCUSSION

Open repair of thoracoabdominal aortic disease is durable, with well-defined and acceptable long-term survival.[11] Its applicability covers the widest range of aortic anatomies as well as different underlying aortic diseases, including dissections and connective tissue disorders. Despite specific renal protection strategies, acute kidney dysfunction secondary to ischemia-reperfusion injury remains one of the most serious complications of TAAA open repair, with about 6% to 10% of patients requiring postoperative hemodialysis.[3,12] If lesser grades of postoperative kidney injury are also considered, an elevation in baseline creatinine level up to 50% may be observed in more than 70% of patients.[2] Most important, in a recent study reviewing all the published data of the past decade (2000-2010) for open TAAA surgical repair,[1] the rate of postoperative renal complications did not seem to decrease compared with a similar review published in 1995, regardless of medical and surgical advances.[13]

Major causes of intraoperative renal damage include temporary ischemia during aortic cross-clamping and visceral vessel repair, arterial embolism, and stenosis or dissection of the reattached renal vessel.[14-16] These harmful mechanisms are known to develop especially when the quality of the arterial wall is poor, with severe atherothrombotic vessel degeneration, and when the surgical reattachment of the renal artery is demanding because of its anatomic location.

Traditional methods of renal artery revascularization during TAAA open repair include direct reattachment on the aortic graft with the inclusion technique described by Crawford et al[17] (usually together with other visceral vessels, or even by direct single-vessel reimplantation) and the use of a single aortorenal bypass.

The inclusion in a visceral aortic patch (VAP) is relatively simple and has the advantage of decreasing the global number of anastomoses and the duration of organ ischemia. However, a fragile aortic wall can cause difficulties with bleeding control, the suture line may become too long in case of considerable distances between the visceral arterial ostia, and the aortic patch tissue may result in subsequent aneurysmal degeneration in time.[18] The last one is considered the main disadvantage of the VAP technique; we previously demonstrated that a large VAP including four visceral vessels is associated with VAP aneurysm formation[18] and that consequent corrective surgery is associated with high morbidity and mortality.[19]

To reduce the VAP size, separate reattachment of distant visceral vessels, namely, the left renal artery, may be employed, directly or interposing a graft. Aortorenal graft interposition allows better bleeding control, may accommodate several anatomies, and presents reduced risks of late aneurysmal degeneration. Its major disadvantage is that two anastomoses are required for each vessel revascularization, often making this option time-consuming and occasionally challenging. Alternatively, the use of presewn aortic branched grafts has the advantage of reducing the number of total anastomoses to be performed, consequently decreasing operative times.[20] However, branches are presewn to the aortic graft in a fixed position and may not adapt well to the patient's anatomy, leading to subsequent kinking or twisting after viscera derotation. Finally, customized branched aortic graft may be employed, in which prosthetic ramifications are sewn during the operation before aortic cross-clamping, taking into account the variable anatomy of each single patient.[21]

Although this strategy may theoretically represent a valuable alternative to reduce the visceral ischemia time (but definitely increasing total operative time), we found it quite difficult to predict a priori how the aortic graft will arrange after the proximal, distal, and intercostal patch anastomoses are performed.

Previous studies using lactated Ringer solution have demonstrated the protective effects of selective cold crystalloid perfusion on renal function during renal ischemia time. Perfusion with isothermic and cold blood failed to support the hypothesis that blood perfusion is more effective than cold crystalloid in renal protection.[2,22] In the current series, selective renal perfusion was carried out with cold (4°C) crystalloid solution enriched with histidine-tryptophan-ketoglutarate (Custodiol). We recently found that the use of Custodiol was safe and provided improved perioperative renal function compared with lactated Ringer solution.[10]

Patients with TAAAs often have occlusive disease involving the visceral branches, either related to atherosclerotic disease or caused by aortic dissection. The presence of visceral arterial occlusive disease is a significant predictor of renal complications after TAAA repair.[23] Furthermore, the presence of calcification and thrombus at the origin of the renal artery is associated with the risk of plaque disruption and dissection during vessel reattachment, leading to kidney malperfusion.[24] Thus, renal artery endarterectomy may be required before revascularization to remove ostial plaques and to improve patency rates. This maneuver, however, has important limitations, including the risk of vessel thrombosis or distal dissection related to an unsatisfactory end point. Also, perforation of the friable endarterectomized wall is possible during vessel manipulation or during the insertion of balloon catheters that are used to deliver renal perfusion.[25]

To overcome this problem, several groups started to use bare stents during TAAA open repair, positioned and expanded within the renal artery under direct vision, both to address arterial stenosis or dissection, avoiding endarterectomy, and to tack down an unsatisfactory end point after visceral endarterectomy.[9,26,27]

The use of covered self-expanding stents for sutureless anastomoses in challenging anatomies has been reported by several authors and in different vascular fields. Lachat et al[5] first reported the concept of a Viabahn-assisted (W. L. Gore and Associates) sutureless anastomosis in the so-called VORTEC technique, used for visceral revascularization during debranching procedures for hybrid complex aortic repair. The distal end of the covered stent was inserted over a guidewire into the visceral vessel, whereas the proximal end was sutured end to side directly with the main feeding graft or fixed into an interposition branch graft on the main bypass. In 2009, the same group published the results of 58 patients submitted to hybrid repair of TAAA or pararenal aortic aneurysm with use of the VORTEC technique to revascularize 98 renal and 15 visceral arteries, reporting an overall primary patency rate of 97% at 22 months.[28] They also applied this technique to debranching procedures of supra-aortic trunks, reporting a midterm 91% patency rate without implantation-related complications.[29] Similar techniques of sutureless anastomosis with the Viabahn covered stent graft were used for femoropopliteal revascularization by several groups.[30,31]

The GHVG represents the natural evolution of these procedures. The tubular heparin-bonded ePTFE graft is preconnected to the nitinol stent-reinforced section, guaranteeing in-line flow while avoiding flow turbulence. The device was released by Gore in 2012 in the European market and approved for hemodialysis access, lower limb bypass grafting, aortic arch debranching, and visceral revascularization.[32] Only three case reports of the use of this novel graft have been published to date, excluding the literature regarding hemodialysis access. Levack et al[33] reported its use for rapid left common carotid revascularization during aortic arch debranching. Nigro et al[34] used the GHVG to perform a sutureless distal anastomosis during surgery for a high-lying internal carotid artery aneurysm. Bornak et al[35] reported a modified use for celiac trunk and superior mesenteric artery revascularization during a visceral debranching procedure, with satisfying early patency.

Our study is the first, to the best of our knowledge, reporting the results of the GHVG in renal revascularization during TAAA open repair. Our limited experience showed that this technique was technically feasible in all planned cases, irrespective of renal artery anatomic location and quality. As a matter of fact, the GHVG group included more patients with type B dissection and associated renal artery stenosis compared with our SRR cohort.

Some of the supposed advantages of this approach were confirmed during this initial experience, such as the ability to perform the aortorenal bypass in a timely fashion (thanks to the distal sutureless anastomosis), reducing renal ischemia time during cold perfusion. Also, we were satisfied by the high technical success rate in reaching remote arterial ostia without the need of extensive exposure of the artery (typically of the *right* renal artery) and by the aptitude to avoid kinking or twisting of the revascularized vessel (especially the *left* renal artery) after viscera derotation (Fig 3). Also, the GHVG performed well in stenotic or dissected vessels, allowing simultaneous arterial ballooning-angioplasty and avoiding the need of additional surgical (endarterectomy) or endovascular (bare stenting) procedures. Of course, the use of the GHVG comes at an added cost to the procedure, but this can be compensated by the relatively lower use of renal bare stents, as was found in our experience.

A well-known problem with ePTFE grafts is the potential for prolonged needle hole bleeding from the anastomosis, which may be exacerbated by heparin, hypothermia, thrombocytopenia, and coagulopathy in TAAA open repair. Suture-line bleeding has been reported to potentially increase operative time, overall blood loss, and risk of infective complications and may require the use of a variety of topical hemostatic agents or sealants.[36] In our experience, mild initial bleeding from ePTFE needle holes resolved spontaneously after a few minutes in most cases. In case of

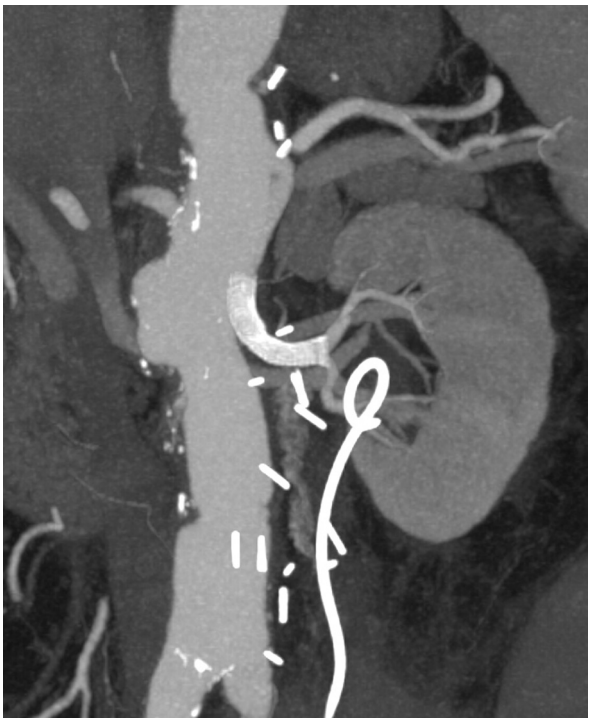

Fig 3. Computed tomography angiography (CTA) reconstruction 1 month after open thoracoabdominal aortic aneurysm (TAAA) repair, showing patency of a left aortorenal bypass performed with the Gore Hybrid Vascular Graft (GHVG).

major bleeding, we rapidly obtained hemostasis by manual compression with surgical gauze and oxidized cellulose pads. At the same time, complete reversal of heparin and aggressive transfusions are required to correct thrombocytopenia and coagulation derangements.

CONCLUSIONS

In this limited series, renal function appeared to temporarily decrease during the first postoperative days, consistent with our previously published results[10,37] and with the most recent literature data.[12,38] In considering the perioperative peak decrease of GFR, GHVG patients seemed to present a lesser grade of renal dysfunction compared with SRR patients. These data may obviously be the result of a multimodal approach to preserve renal function after TAAA open repair, including a number of intraoperative and postoperative adjuncts, and can be highly influenced by other confounding factors that are not addressed by the current group analysis.

The present comparison between GHVG and SRR patients has to be considered together with its important limitations, related to the small number of cases and to the relative heterogeneity of considered patients. The groups were matched with the only purpose of getting an impression of how the GHVG behaved compared with our historical cohort. We definitely cannot draw any conclusion about a possible relationship between the use of the GHVG and perioperative renal function preservation on the basis of these limited data. However, technical feasibility and short-term patency rate of the GHVG for renal revascularization during TAAA open repair were satisfactory, and we hope that this novel graft will represent an additional step forward in the fight against perioperative kidney injury.

This is the first report describing renal revascularization during TAAA open repair with the GHVG. Our initial results indicate that this technique is feasible also in challenging anatomies, with several potential technical advantages. Short-term clinical and radiologic outcomes were satisfactory. Larger series and longer follow-up are needed to confirm the safety and durability of the proposed technique.

AUTHOR CONTRIBUTIONS

Conception and design: RC, AK, YT, GM
Analysis and interpretation: RC, AK, DM, YT, EC, GM
Data collection: AK, DM, EC
Writing the article: RC, AK, DM, GM
Critical revision of the article: RC, AK, YT, EC, GM
Final approval of the article: RC, AK, DM, YT, EC, GM
Statistical analysis: AK, DM
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Overall responsibility: RC

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