Arterio-arterial synthetic loop graft as a reliable alternative for type 3 end-stage vascular access

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Objective
Arterio-arterial synthetic loop graft (AASLG), also known as arterio-arterial prosthetic loop, is an alternative hemodialysis (HD) option in a specific group of patients where other HD conventional arteriovenous (AV) access and tunneled central venous catheters are not technically feasible (type 3 end-stage vascular access). The aim of this study is to report our experience with AASLG in this cohort of fragile patients and contrast the outcomes and risks with other artificial dialysis access solutions.

Patients and methods
A prospective study was conducted on patients who underwent axillary or femoral AASLG using polytetrafluoroethylene graft after exhaustion of all conventional AV access options in these patients with end-stage renal disease undergoing HD. The patients were prospectively observed for graft primary and secondary patency and graft-related complications. Outcomes were reported according to the recommended standards for reporting AV HD accesses.

Results
Between January 2018 and July 2020, 16 patients (median age, 58.76 years; range, 52–68 years) underwent 19 AASLG access placements. Procedures were done under general anesthesia in 18 occasions, whereas one was done under local anesthesia. A total of 15 patients had 18 axillary AASLG, whereas one had femoral AASLG. Central vein occlusion was present in all patients. Patients were followed up for 3–24 months (mean, 16 months).
The technical success of the procedure was 100% despite two cases of postoperative hematoma development, and there were no 30-day perioperative mortalities. Primary patency at 6 months was 78.9%, and the achieved secondary patency rate was 89.5%. At 12 months, the primary and secondary patency rates were 42.2 and 68.4%, respectively. Two procedures were complicated with early postoperative bleeding that required surgical intervention, but no blood transfusion was required. Three procedures were complicated with pseudoaneurysm formation at puncture sites that were repaired surgically by interposition grafts. During follow-up, five AASLGs were thrombosed, three of which had a successful graft thrombectomy and one had a contralateral axillary AASLG done. Two patients developed graft infection, and the graft was excised and replaced by a contralateral axillary AASLG.

Conclusion
Our early experience with AASLG showed that this procedure has a high early success rate with a considerable risk of complications. This procedure could be offered to patients with end-stage renal disease when other AV access options are not feasible. For long-term outcome assessment, further follow-up is needed.

Keywords:
arterio-arterial, hemodialysis, loop graft

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Introduction

End-stage renal disease (ESRD), and the maintenance of hemodialysis (HD) access, is a significant public health burden that has reached almost epidemic trends in the whole world. In 2017, there were 7 46 557 prevalent cases and 1 24 500 new cases of ESRD in the United States [1]. This has increased more than 10-folds since 1980, and it has expected that this will continue to increase, with estimated prevalent and incident counts of 7 84 613 and 1 50 772, respectively, by the end of 2020 [2]. Approximately two-thirds of patients with ESRD in United States are on HD [2].

The optimum HD access choice is a mature arteriovenous (AV) autogenous conduit that is associated with minimal complications [3]. Maintaining the patency and the function of such an access is a real challenge [4]. When peripheral veins are exhausted, tunneled central vein catheters and arteriovenous grafts (AVG) are considered acceptable alternatives.

Occurrence of stenosis and/or occlusion of central veins can be treated by angioplasty or surgically to establish sufficient outflow [5], but the 1-year primary patency rates are usually less than 50%, restenosis rates are significantly high, and long-term results are uncertain [6]. Moreover, not all lesions are amenable for angioplasty, and not all the patients are fit for surgical venous reconstruction.

Some of the patients with ESRD have significant cardiac insufficiency that is intolerable to the additional cardiac load of a high-flow AV access. Creation of an AV access would expose them to the risk of exacerbation of congestive heart failure.

Arterio-arterial synthetic loop graft (AASLG) positioned either on the chest or thigh is an alternative HD access. However, experiences with interarterial approaches for dialysis are limited, and to our knowledge, few data have been published about this treatment option that was described in details and published in 2005 [7,8].

Patients and methods

Patients

This is a prospective study to report our initial experience of the utility of AASLG in patients with ESRD undergoing chronic HD after exhaustion of all conventional AV access options. The AASLG graft used was polytetrafluoroethylene (PTFE) graft interposed in the continuity of the axillary or femoral artery that can be used as the vascular access for HD.

The scientific and ethical committee of Ain Shams University approved the study protocol. Data were collected prospectively according to recommended standards for reporting dealing with AV HD accesses [9].

Primary end point was graft patency, whereas secondary end points were graft-related complications – namely, graft thrombosis, infection, and pseudoaneurysm formation – and mortality.

From January 2018 and July 2020, 16 patients underwent 19 AASLG procedures for HD. All these patients had signed a consent form. Intended procedure was explained in details with all possible complications and alternatives.

Indication

AASLG was offered only to patients with ESRD who have central venous occlusion and/or severe cardiac insufficiency after exhaustion of all conventional AV access options in these patients. Full details of inclusion and exclusion criteria are shown in Table 1.

Preoperative preparation

A consultant nephrologist and a vascular surgeon initially assessed each patient. A consultant cardiologist assessed the patient only if she/he is known to have heart failure. Preoperative evaluation included careful assessment of the vascular anatomy.

Table 1 Inclusion and exclusion criteria of the end-stage renal disease patients included in the study.

Inclusion criteria	Exclusion criteria
Patients who do not have patent large deep veins (defined as the subclavian, internal jugular, external iliac and femoral veins). A vein is considered unsuitable if there is an occlusion or high-grade long stenosis (>70% in diameter, >4 cm long) of the vein or of the venous outflow (defined as the innominate veins, superior vena cava or inferior vena cava) and could not be treated by any method of intervention	Patients in whom hemodialysis can be replaced by peritoneal dialysis in centers well experienced in this form of dialysis and patients who are considered candidates for unconventional sites for tunneled dialysis catheter placement (defined as transthoracic superior vena cava catheters or translumbar or transhepatic inferior vena cava catheters)
Patients who have significant cardiac insufficiency that is intolerable to the additional cardiac load of a high-flow AV access and the risk of exacerbation of congestive heart failure as instructed by an expert cardiologist	Brachial artery is excluded if it has systolic pressure >15 mmHg less than the contralateral limb or the patient has symptoms or signs of upper limb ischemia
Suitable patent noncalcified axillary or femoral artery	Lower limb is excluded if ABPIs <0.8 or if there is any symptom or sign of critical lower limb ischemia
Healthy noninfected tissues at the site of the intended procedure	Upper or lower limb was excluded if it was exposed to previous radiotherapy or extensive scarring due to a previous surgery

ABPI, ankle brachial pressure index; AV, arteriovenous.

Arterial examination included pulse assessment, bilateral upper extremity blood pressure measurement, and ankle brachial pressure indices. Side of the AASLG was chosen according to the higher systolic brachial pressure in the upper limbs or better ankle brachial pressure indices in lower limbs. The skin – where the incision is intended to be made – was examined to ensure it is healthy and free from infection. In case clinical preoperative evaluation was considered inadequate to assess the arterial tree, arterial duplex was performed.

Duplex mapping of the veins and supplementary contrast venography or computed tomographic venogram were essential for defining inadequacy of deep veins and were performed in all patients.

Operative technique

All patients have received preoperative renal dose adjusted intravenous broad-spectrum third-generation cephalosporin before the start of the procedure. They received 5000 IU of intravenous conventional heparin after creation of the graft tunnel and before the placement of arterial clamps. All procedures were done under general anesthesia except one. We used PTFE grafts (6–8 mm according to the native artery diameter) as a conduit for all patients.

For axillary AASLG, a standard infraclavicular incision is made and the axillary artery is identified after separation of the fibers of the pectoralis major muscle and transection of the pectoralis minor muscle just below the coracoid process, and the brachial nerve plexus is carefully spared. After division of the axillary artery, the PTFE graft is interpositioned following creation of a subcutaneously tunneled loop on the chest. The loop graft is anastomosed end to end to the proximal and distal cut-ends of the axillary artery.

For femoral AASLG, a transverse groin incision is made, and the common femoral artery with its bifurcation is identified. After division of the proximal superficial femoral artery (SFA), the PTFE graft is interpositioned after configuration of a subcutaneously tunneled loop in front of the groin. The loop graft is anastomosed end to end to the proximal and distal cut-ends of SFA artery.

Postoperative surveillance

Patients were followed up by a vascular surgeon every 2 weeks in the outpatient clinic for the first month postoperatively then on 3 monthly basis thereafter. All grafts were examined by Duplex to assess changes in the peak systolic velocity (optimum velocity >125 cm/s). Urgent cases were seen and assessed in emergency department, and prompt intervention was provided as needed. The loop conduit was allowed to mature for at least 2 weeks before puncture.

The dialysis team members were informed about the unique different characteristics of this access. They were advised to compress the puncture sites for 20 min after the removal of the needle, to adjust the temperature of the reinfused blood, to continue to administer heparin until 30 min before finishing HD, and to refrain from infusion of medications into the access (intraarterial injection).

Statistical analysis

Statistical analysis was performed using the IBM SPSS 24 version (IBM). Data was analyzed by using SPSS Statistics for Mac, Version 24.0 (IBM SPSS Statistics, Version 24.0 Armonk, NY: IBM Corp). Descriptive statistics were used for patients' demographics and preoperative medical conditions, as well as follow-up parameters. Kaplan–Meier survival curves were used to calculate primary patency and secondary patency.

Results

From January 2018 and July 2020, 16 patients underwent AASLG for HD. Axillary AASLG was done in 18 patients and femoral AASLG in one patient. Table 2 shows the different patients' demographic data and preinterventional medical conditions.

Table 2 Demographics of patients included in the study

	Mean±SD	Range
Age (years)	58.76±4.53	52–68
Duration of dialysis (months)	175.76±42.49	120–240
Number of previous attempts of surgical arteriovenous access	10±4	6–14
Female sex [*n* (%)]	13 (68.4)	
Diabetes [*n* (%)]	9 (47.4)	
Hypertension [*n* (%)]	16 (84.2)	
Ischemic heart disease [*n* (%)]	9 (47.4)	
History of stroke [*n* (%)]	6 (31.6)	
Smokers [*n* (%)]	3 (15.7)	

A total of 19 operations were undertaken in the 16 patients comprising our series. In three patients, the axillary AASLG was excised due to graft infection and thrombosis followed by a contralateral axillary AASLG creation. Operation details can be found in Table 3.

The indication for intervention was central vein occlusion in all 16 patients. Central vein occlusion affected the following veins in the study group among the 19 procedures: subclavian vein (n=10), innominate vein (n=6), superior vena cava (n=3), bilateral iliofemoral deep vein occlusion (n=16), and inferior vena cava (n=3).

Of note, the physiologic thrill used to confirm the adequacy of the access was never present because of the arterio-arterial configuration. Instead, a pulse could be easily palpated on the chest.

Fortunately, no mortalities were seen in the first 30 days following the procedure. Early postoperative bleeding requiring surgical intervention occurred in two (10.5%) cases. Bleeding was derived from the pectoralis minor muscle bed, and no blood transfusions were needed, and there were no early access thrombosis.

Despite instructions provided to the dialysis team, the needle puncture was performed in only two small areas in most patients. As a result, consecutive destruction of the graft led to pseudoaneurysm formation of the main body of the graft. We encountered three cases that developed pseudoaneurysm of the graft that required repair by interposition bridge graft to salvage the access.

Graft infection leading to subsequent graft excision occurred in three patients at 6, 12, and 7 months after access creation. These grafts were excised, and a contralateral axillary AASLG was created. Five grafts developed thrombosis, and consequently thrombectomy was undertaken and resulted in continued functionality in three patients out of five thrombosed grafts. One patient had repair of the axillary artery, graft excision, and a contralateral axillary AASLG and one patient was left untreated (Table 4).

Regarding the time to death after the procedure in this patient series, the cumulative survival at 18 months postoperatively was 63.2%; all deaths were due to causes unrelated to the access.

The achieved primary patency rates at 6 and 12 months are shown in Fig. 1, being 78.9% at 6 months and 42.2% at 12 months, whereas the achieved secondary patency rates at 6 and 12 months were 89.5% and 68.4%, respectively.

Table 3 Operative details of nineteen arterio-arterial synthetic loop procedures

	n (%)	
Site of the procedure		
Right side chest wall	7 (36.8)	
Left side chest wall	11 (57.9)	
Right thigh	1 (5.3)	
Graft material		
PTFE 6 mm standard wall	10 (52.6)	
PTFF 8 mm standard wall	7 (36.8)	
PTFE 6 mm stretch	2 (10.5)	
Site of central vein occlusion		
Subclavian vein	10 (52.6)	
Innominate vein	6 (31.6)	
SVC	3 (15.8)	
Operative time (min) [mean±SD (range)]	137.5±26.4	93–184
Hospital stay (days) [mean±SD (range)]	3.06±1.63	1–7
Time till first cannulation (weeks) [mean±SD (range)]	4.06±1.43	2–6
Follow-up duration [mean±SD (range)]	16.12±6.63	3–24

PTFE, polytetrafluoroethylene.

Discussion

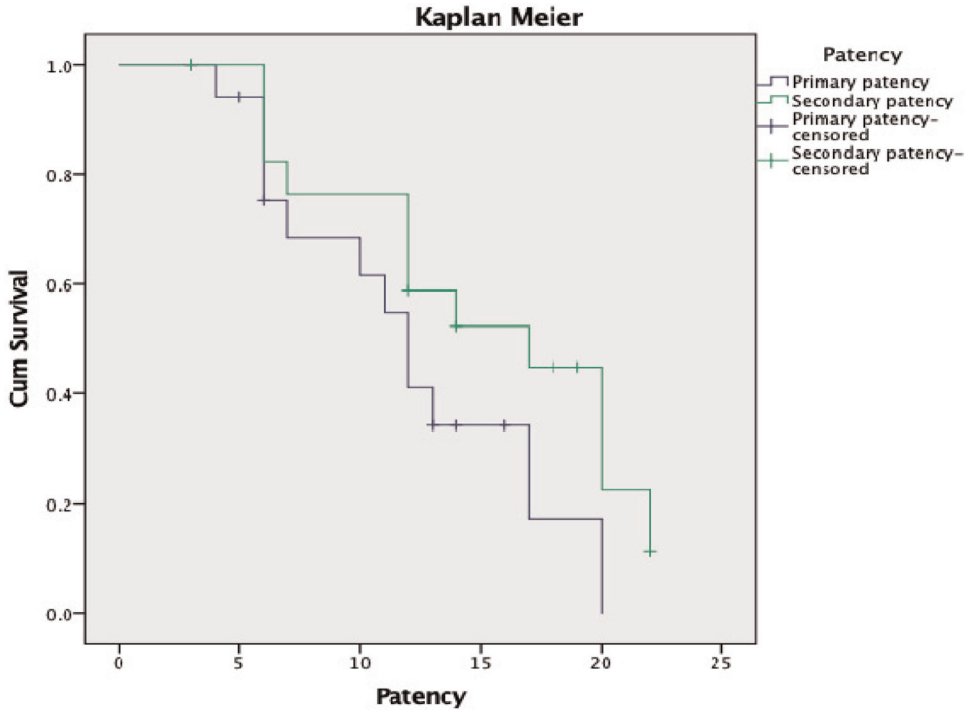
Chronic renal impairment has been increasing in prevalence, and 13.4% of the world's population is estimated to be affected, 10.6% of which range between stages 3 and 5 [10]. Accordingly, HD-dependent patients are increasing in number, reaching up to 121/million population in Europe [11]. With the recent update in international KDOQI guidelines recommending an AV fistula first catheter last approach, the pursuit to increase AV fistula preservation is of paramount importance [12].

Renal transplant cannot be offered to most of the Egyptian patients with ESRD owing to multiple ethical, logistic, and religious limitations. This might

Table 4 Complications detected along the study

Complications	*n* (%)
Ischemic complications	1 (5.3)
Hematoma formation	2 (10.5)
Graft Infection	3 (15.8)
Nerve injury	0
Graft thrombosis	5 (26.3)
Pseudoaneurysm formation	3 (15.8)
Re-exploration	3 (15.8)

Figure 1



Kaplan–Meier curve for primary and secondary patency rates.

explain why we are encountered nowadays with a bigger and older cohort of patients with ESRD who had the disease for longer periods. Many of these patients have exhausted vascular access options in upper and lower limb veins with central venous occlusion. Failure of recanalization of the central veins of these patients using different endovascular procedures or bypassing the occluded vein leaves our options very limited when it comes to offering them a reliable and durable dialysis access. Accordingly, the term 'end-stage vascular access' (ESVA) was introduced and classified by Al Shakarchi *et al.* [13] into no upper limb vascular access option, no lower limb vascular access option, and no options at any site stages that are further subdivided according to laterality and the site of occlusion throughout the venous system.

In 1964, Nayman [14] described the idea of an arterio-arterial shunt for HD. Settmacher *et al.* [15] created two femoral AASLGs between common and profunda femoris arteries in 1998.

Brittinger *et al.* [16] (Mannheim, Germany) in 1969 published the idea of superficial repositioning of the artery (SRA) to be used as a permanent vascular access. They used the SFA for this purpose successfully in 17 patients who were followed for 16 months. SRA was then used in different sporadic case series utilizing SFA, brachial, and radial arteries [17–21]. The biggest case series to our knowledge is the one done by Yasunaga *et al.* [17] who performed 42 SRA procedures from 1986 to 1993. Weyde *et al.* [20] performed SRA of the radial artery in seven patients with satisfactory results as well. SRA procedure is traumatic, exposes the native artery to considerable risk of complications, and can be used only in noncalcified arteries. In late seventies of last century, surgeons started to create a subcutaneous synthetic arterial bypasses such as femoro-popliteal graft for the purpose of HD [21–23].

Right atrial bypass grafting [24] and axillo-renal AVG [25] were described as well, but both procedures are very traumatic and require general anesthesia. Many patients with ESRD would not be considered fit for such a long procedure. Transthoracic superior vena cava [25], translumbar [25,26], or transhepatic [27] inferior vena cava tunneled catheters were prescribed in different series; however, they lack the durability and the longevity needed for HD access. They have a high rate of obstruction, thrombosis, and displacement, which are associated with high morbidity and mortality; therefore, they are by no means considered an ideal alternative method for dialysis access.

Attempts for other unusual bypass grafts for dialysis were also pursued. Jakimowicz *et al.* [28] performed 19 axillo-iliac, 14 axillo-axillary bypasses, and 16 conduits from the arm fistula to the jugular (nine conduits) or subclavian

(seven conduits) vein for HD purposes. At 12 months, the primary, primary assisted, and secondary patency rates were 85.4, 89.6, and 95.8%, respectively. They did not however perform interarterial loop grafts for fear of peripheral ischemia [28].

Recently, Hemodialysis Reliable Outflow (HeRO) grafts were introduced (FDA approved in May 2008) as a more reliable alternative to tunneled central venous catheters that carry the benefits of a subcutaneous AVG and overcome the obstacles met with occlusion or stenosis in the axillary or distal or even proximal subclavian vein, by using IJV or any patent segment in the subclavian vein as a venous outflow. Al Shakarchi *et al.* [29] performed a systematic review to assess outcomes of the HeRO graft and the efficacy of its usage in complex HD patients with central venous stenosis. A total of 409 HeRO grafts from eight different studies were pooled in their systematic analysis. They calculated the mean 1-year primary and secondary patency rates to be 21.9% (9.6–37.2%) and 59.4% (39.4–78%), respectively. The rate of steal syndrome in the six papers that reported its incidence was 6.3% (1–14.7%), and device-related bacteremia ranged between 0.13 and 0.7 (per 1000 days) in six studies that reported it out of the eight. The rate of interventions required to maintain HeRO patency ranged between 1.5 and three procedures per year [29].

HeRO devices, however, remain unavailable for use in many countries, including Egypt, in addition to their high cost and low patency rates compared with AASLGs.

In 2004, Talaiezadeh and Haghighi [30] published their early results of 20 AASLG procedures in mid arm. Two of the procedures did not succeed, whereas another two failed after few sessions of HD. The remaining 80% were patent for more than 6 months.

In 2005, Zanow *et al.* [7] reported their experience with AASLG in details as an efficient approach for HD access. They highlighted that the basics of performing AASLG procedures compared with a standard AVG are absence of a suitable and patent vein as a limitation for the procedure, while preserving the reliability and durability of a bypass procedure compared with peritoneal dialysis. Moreover, the distal perfusion is not decreased during dialysis and the cardiac load is not increased.

They described this procedure in the form of either axillary or femoral AASLG. They performed 36 AASLGs in 34 patients as vascular access between April 1996 and September 2004, either as an axillary chest loop (n=31) or as a femoral loop (n= 5). They showed primary patency of 73% and secondary patency of 96% at 1 year, whereas these rates at 3 years were 54 and 87%, respectively.

In the same year, Bunger *et al.* [8] published their experience in axillary AASLG in 20 patients done between May 2001 and December 2004 under general anesthesia and followed up the patients for 7.4 months. The primary and secondary patency rates were 90 and 93%, respectively, at 6 months.

More recent case series were published with better primary and secondary patency results owing to the advancements in graft surveillance and endovascular access salvage procedures [31,32].

Lei *et al.* [32] did 18 procedures in the form of femoral AASLG between April 2005 and June 2014 (median age, 66 years; range, 43–96 years). All the patients were followed up for 3–38 months (mean, 24 months). Primary and secondary patency rates at 6 months were 94.5 and 88.8%, respectively, and at 3 years were 61 and 72%, respectively.

A recent study done in Egypt by Atta *et al.* [31], who performed AASLG for 20 patients with exhausted vascular access options, showed that the primary patency rates were 100, 100, 95, 90, and 80%, respectively, and the secondary patency rates were 100, 100, 100, 95.0, and 95.0% at 1, 3, 6, 9, and 12 months, respectively [31].

Khafagy *et al.* [33] reported their early results of brachial AASLG. Between January 2011 and December 2014, 35 brachial AASLGs were created. The age of patients ranged between 27 and 72 years, with a mean age of 52.8 years. The primary patency rates were 87.9, 70.4, and 38.8% at 12, 24, and 36 months, respectively. The secondary patency was 90.7, 80.3, and 67.6% at 12, 24, and 36 months, respectively.

In our series, we performed 19 AASLG procedures in 16 patients. AASLG was reserved only for patients who lacked the possibility for the construction of a conventional AV access. All our patients had axillary AASLG except one who had femoral AASLG. Three axillary AASLGs were infected, excised, and a contralateral axillary AASLG was created. Five grafts were thrombosed; three had a successful graft thrombectomy, whereas one had a contralateral axillary

AASLG. The achieved primary patency at 6 and 12 months were 78.9 and 42.2%, respectively, whereas the achieved secondary patency rates at 6 and 12 months were 89.5 and 68.4%, respectively.

From initial experience of Zanow *et al.* [7] with AASLG, it was noted that the patency rate of this cohort of patients was influenced by a high mortality rate among them; however, this is a general problem of vascular access surgery but more profound in AASLG patients.

AASLG cannulation during HD exposes patients to all possible complications of cannulation of an artery or AVG. These complications include thrombosis, infection, bleeding, aneurysm formation, and distal embolization. Axillary AASLG is preferred to femoral AASLG as its thrombosis is more tolerable by patients and has a lower infection rate. Zanow *et al.* [7] reported 42% of their AASLG had a graft thrombosis during the follow-up period. Nine patients had repeated thrombectomy procedures, whereas thrombectomy was combined with the reconstruction of an anastomotic stenosis in seven patients. Bunger *et al.* [8] had 20% axillary graft thrombosis, whereas Khafagy *et al.* [33] experienced 34% thrombosis of brachial AASLG. Lei *et al.* [32] had 28% thrombosis of femoral AASLG. In our series, we had 26.3% graft thrombosis, whereas Moncef [34] reported 22% early thrombosis.

We experienced pseudoaneurysm formation in 15.3% of cases and graft infection in also 15.3%. However, despite these risks, associated complications are still comparable to synthetic AVG complications rate, especially that this cohort of patients does not have any alternative means for dialysis other than peritoneal dialysis [35,36].

Inston *et al.* [37] performed a systematic review of literature comparing AASLGs with translumbar and transhepatic central venous catheters as a final resort to patients with ESVA. They observed that regarding transhepatic or translumbar central venous catheters performed for 189 patients with 439 catheter placements reported in literature, very few technical complications were encountered. Two deaths (<1%) occurred owing to hemorrhage: one with a retroperitoneal bleed and another from a hepatic bleed [38]. Infection rates were reported by Liu *et al.* [38] showing catheter-related infection in 36% with catheter-related bacteremia in 31% and site infection in 5%. Regarding patency, 6-month patency ranged from 25 to 83%, and 1-year patency ranged between 7 and 73.2%. On the contrary, pooled patency data from 174 cases of AASLG procedures reported in seven different studies in literature showed primary patency ranging from 67 to 94.5% at 6 months, 61.7 to 87.9% at 12 months, and 38.8 to 61% at 36 months. Secondary patency rates were 83–93% at 6 months, 83–96% at 12 months, and 67.6–87% at 36 months. The incidence of graft thrombosis ranged from 20 to 42%; none of the axillo-axillary arterial loop grafts required revascularization, but one femoro-femoral arterial loop grafts required restoration of arterial flow to the limb [7]. Regarding graft infection, the rate of infection was low with late infection seen in four (11.7%) out of 34 cases and one (5%) out of 20, and one (2.9%) out of 34 cases in the studies that reported it [7,8,33]. Moreover, concerns of arm ischemia associated with AASLG are not supported by published evidence [38].

AASLG is still considered a new HD access in Egypt, and most of HD centers are not familiar with it. We believe that using AASLG with the usual precautions would prolong the patency of this type of graft and minimize complications. Good patient hygiene, complete aseptic cannulation, usage of different sites for cannulation, and adequate compression at the puncture site may reduce the associated risks and possible complications.

This study reports our initial experience with AASLG as a safe efficient alternative HD access with acceptable and comparable rate of complications with respect to AVGs as well as tunneled central venous catheters, and even superior to transhepatic and translumbar catheters regarding patency and convenience. We need to follow-up our patients for a longer period and to include more patients in the future. However, we still believe that this type of HD vascular access should be created only when all other types of AV access are not feasible.

Conclusion

Our early experience with AASLG showed that this procedure has a high early success rate with an acceptable risk of complications. This procedure could be offered to patients with ESRD when other AV access options have been exhausted and different types of tunneled catheters are not feasible (type 3 ESVA). For long-term outcome assessment, further follow-up is needed.

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Conflicts of interest

There are no conflicts of interest.

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