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Lower Extremity Bypass Using Bovine Carotid Artery Graft (Artegraft): An Analysis of 124 Cases with Long-Term Results

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Abstract

Introduction Although biological grafts have been utilized as a vascular conduit in leg bypass for many years, reports of a bovine carotid artery graft (BCAG) in lower extremity revascularization have been scarce. This study analyzed the outcome of lower leg bypass using BCAG.

Methods A retrospective review of a prospectively collected database of all patients undergoing lower extremity bypass using BCAG from 2002 to 2017 was performed. Clinical outcomes including graft patency and limb salvage were evaluated.

Results A total of 124 BCAG (Artegraft, North Brunswick, NJ) were implanted in 120 patients for lower extremity revascularization. Surgical indications included disabling claudication in 12%, rest pain in 36%, tissue loss in 48%, and infected prosthetic graft replacement in 3%. Autologous saphenous vein was either inadequate or absent in 72% of patients. BCAG was used in 46 patients (37%) who had a prior failed ipsilateral leg bypass. Distal anastomosis was performed in the above-knee popliteal artery, below-knee popliteal artery, and tibial artery in 30 cases (25%), 32 cases (26%), and 48 cases (39%), respectively. Distal anastomotic patch was created in all tibial artery to allow BCAG-tibial reconstruction. The yearly primary patency rates in 5 years were 86.5, 76.4, 72.2, 68.3, and 67.5%, respectively. The corresponding yearly secondary patency rates were 88.5, 84.7, 82.4, 78.5, and 75.6%, respectively. The limb salvage rate at one year was 83.6% and at five years was 86.2% for patients with critical limb ischemia. Multivariate analysis showed poor runoff score ($P = 0.03$, 95% CI, 1.3–5.3; OR, 1.6) was independently associated with graft occlusion.

Conclusion BCAG is an excellent vascular conduit and provides good long-term results in lower extremity bypass.

Introduction

The ideal bypass conduit for infrainguinal arterial reconstruction has been a subject of debate for decades. While most clinicians agree that autogenous saphenous vein graft should be considered as the conduit of choice in lower leg surgical revascularization, this option frequently is not available in many patients due to factors including sclerotic vein segment, inadequate vessel caliber, or prior harvest for coronary artery bypass. As a result, it is necessary to consider options of a non-autogenous graft conduit for leg arterial reconstruction.

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An ideal non-autogenous graft conduit, whether is prosthetic or biological in nature, should be compliant, thromboresistant, durable, and easy to handle with surgical manipulation and suturing. One of the most studied prosthetic graft conduits is polytetrafluoroethylene (PTFE) graft in which many studies have shown favorable clinical outcomes in above-knee femoropopliteal artery bypass with shorter operative time, faster recovery, and similar patency compared to saphenous vein graft [1]. However, the clinical results of below-knee popliteal or tibial artery prosthetic bypass grafts are markedly inferior compared to vein graft [2, 3]. Other graft conduit such as human umbilical vein (HUV) has also been investigated in lower extremity arterial reconstruction [4, 5]. Although studies have shown favorable patency rates compared to saphenous vein graft, its high rate of graft-related aneurysmal formation has dampened surgeons' enthusiasm in its clinical adaptation [5].

Clinical studies have highlighted the clinical benefit of bovine carotid artery graft (BCAG) as a dialysis access conduit [6, 7]. Its structural elasticity with ease of handling of sutures combined with durable clinical outcomes has gained increased acceptance as an dialysis graft conduit [6–8]. However, clinical reports of BCAG in infrainguinal arterial reconstruction remain limited. In this report, we analyzed our clinical experience of bovine carotid arterial graft in lower extremity arterial reconstruction.

Patients and methods

Clinical records of patients who underwent lower extremity bypass using BCAG (Artegraft, North Brunswick, NJ) from 2002 to 2017 were retrospectively analyzed using a prospectively collected database. Appropriate institutional review board approval was obtained for the study. Data extracted from the database included demographic information, presenting symptoms, comorbid medical conditions, relevant physical examination findings, laboratory and radiographic examinations, surgical treatment approach, treatment outcome, and follow-up visits. Follow-up information was obtained from a variety of sources which included outpatient clinic visit records, subsequent hospital admission records, and telephone interviews.

Bovine artery grafts used were either 5 or 6 mm in internal diameter. For femorotibial artery bypass which required a graft length greater than 40 cm, two bovine grafts containing a 6-mm proximal graft and a distal 5-mm graft were routinely joined in an end-to-end fashion. In all tibial artery bypasses, a distal anastomotic patch was created with either an autogenous saphenous vein patch or bovine pericardial patch (Cryolife, Kennesaw, GA) using technique previously described [9]. This was followed by BCAG to the tibial artery patch anastomotic reconstruction in an end-to-side fashion. If the distal bypass target vessel was the distal superficial femoral artery or popliteal artery, the BCAG was connected directly to the femoropopliteal vessel in an end-to-side fashion.

Patients were seen for follow-up at one month for postoperative wound check. Patients were followed up at one month, three months, and every 6 months with physical examination, surveillance graft duplex ultrasound, ankle brachial indices and pulse volume recordings. Graft failure was diagnosed when ABI deterioration was associated with Duplex scan evidence of graft thrombosis. Angiography with endovascular intervention was indicated when the recurrence of critical limb ischemia (CLI) or acute limb ischemia occurred. Follow-up results were analyzed in terms of primary and secondary graft patency, limb salvage, and survival rate. Statistical analysis was performed to determine the association between relevant risk factors and graft occlusion with Fisher's exact test or Pearson's Chi-square test in categorical variables. Wilcoxon rank-sum test was used to test for differences in continuous variables. Kaplan–Meier method was used to assess survival rate. A multivariate model was analyzed with factors found to be significantly associated with graft occlusion based on univariate analysis results. In all analyses, we only considered variables with at least 80% of the data present or recorded. All statistical analysis was performed using a statistical software program (SAS Institute, Cary, NC). All values were expressed as mean $\pm$ SEM. Statistical significance was accepted with a P value of less than 0.05.

Results

A total of 124 lower leg bypasses using BCAG in 120 patients were included in this analysis. The mean age was 74.6 years. Relevant demographic characteristics and clinical history of these patients are summarized in Table 1. Indications for bypass grafting included disabling claudication in 15 patients (12%), rest pain in 45 patients (36%), tissue loss in 60 patients (48%), and infected prosthetic graft replacement in 4 patients (3%). Autologous saphenous vein was either inadequate or absent in 89 patients (72%). BCAG was used in 46 patients (37%) had a prior failed ipsilateral leg bypass. Eighteen patients (15%) were immunocompromised due to either immunosuppressive therapy or immunodeficiency. The majority of the patients had prior endovascular interventions with either stenting or balloon angioplasty (66%), failed bypass operation with either autogenous or prosthetic graft (43%), or a combination of these treatments (35%).

The severity of limb ischemia based on Rutherford disease classification and distal runoff vessel status is

Table 1 Patient demographic information and clinical variables

Characteristics	No. (%)
Age, mean ± SD (years)	68 ± 10.4
Age, range (years)	47–83
Male	71 (57%)
ABI before bypass, mean ± SD	0.53 ± 0.5
ABI after bypass, mean ± SD	0.94 ± 0.4
Comorbidities/risk factors	
Diabetes mellitus	53 (43%)
Hypertension	108 (87%)
Hyperlipidemia	89 (72%)
Coronary artery disease	80 (65%)
Renal insufficiency	53 (43%)
Renal failure requiring hemodialysis	26 (21%)
Prior tobacco usage	83 (67%)
Current tobacco usage	16 (13%)
Previous failed ipsilateral leg bypass	46 (37%)
Previous kidney transplant	10 (8%)
Prosthetic graft infection	4 (3%)
Rutherford disease classification	
Rutherford 2	5 (4%)
Rutherford 3	10 (8%)
Rutherford 4	46 (37%)
Rutherford 5	50 (40%)
Rutherford 6	11 (9%)
Distal runoff vessels	
Single vessel	33 (27%)
Two vessels	48 (39%)
Three vessels	42 (34%)

ABI ankle brachial index, *SD* standard deviation

summarized in Table 1. The mean preoperative ankle brachial index was 0.43. Twenty-four patients (19%) had either an open foot wound or an active leg infection at the time of leg bypass. Seventeen patients (14%) required a concomitant podiatric procedure including wound debridement ($n = 11$, 9%), toe amputation ($n = 4$, 3%), or transmetatarsal amputation ($n = 2$, 2%). Eighteen patients (15%) required postoperative podiatric procedure including wound debridement ($n = 9$, 7%), toe amputation ($n = 5$, 4%), or transmetatarsal amputation ($n = 4$, 3%).

The proximal inflow vessels of the BCAG bypass grafts are shown in Table 2, which included the common iliac artery in 3 cases (2%), the external iliac artery in one case (1%), and the common femoral artery in 100 cases (97%). The target outflow vessels are displayed in Table 2. Distal anastomotic patch was created in 46 cases (37%), which included 39 tibial artery bypass (31%), and seven below-knee popliteal reconstruction (6%). Patch materials included autogenous saphenous vein graft in 11 cases (24%) and

Table 2 Inflow and outflow vessels of bovine artery bypass graft

Bypass type	No. (%)
Iliac to above-knee popliteal artery	2 (2)
Iliac to common femoral artery	1 (1)
Femoral to contralateral femoral artery	11 (9)
Femoral to above-knee popliteal artery	28 (23)
Femoral to below-knee popliteal artery	32 (26)
Femoral to anterior tibial artery	18 (15)
Femoral to posterior tibial artery	16 (13)
Femoral to peroneal artery	14 (11)

bovine pericardial patch in 35 cases (76%). Revascularization was successful immediately after surgical revascularization in all patients. Postoperative 30-day adverse events occurred in five patients (4%), which included two deaths due to myocardial infarction, one groin hematoma which required surgical evacuation, one wound dehiscence, and one renal failure requiring hemodialysis. Postoperative and long-term anticoagulation therapy consisted of single antiplatelet therapy with aspirin in 53 cases (43%), dual antiplatelet therapy in 34 cases (27%), and oral anticoagulants with either Coumadin (Warfarin) or Xarelto (rivaroxaban) in 37 patients (30%). The antiplatelet or anticoagulation agent of choice and treatment duration were determined according to the treating surgeon's discretion.

The mean follow-up time in the series was 26.4 ± 8.6 months, with a median follow-up of 29.4 months. Twenty-four patients died 45–1332 days following the surgery, whose cause of death included stroke, cancer, myocardial infarction, car accident, and natural causes. Two patients (2%) developed graft-related aneurysmal degeneration at 433 and 532 days following the graft implantation, respectively. They were treated with interposition grafting using BCAG, and no subsequent graft degeneration occurred. Fourteen major amputations and seven minor amputations were necessary. The time to amputation ranged from six to 427 days following the bypass procedure. The major amputation rate was 16%, or limb salvage was 84% at five years.

The five-year life-table analysis of primary and secondary patency rates in our patients is shown in Figs. 1 and 2. The yearly primary patency rates in 5 years were 86.5, 76.4, 72.2, 68.3, and 67.5%, respectively. A variety of endovascular treatments were used to maintain the graft patency which included thrombolysis, thrombectomy, balloon angioplasty, and stent placement. A total of 43 endovascular interventions were performed in 37 patients during the follow-up period to maintain graft patency. The corresponding yearly secondary patency rates were 88.5, 84.7, 82.4, 78.5, and 75.6%, respectively. Patency rates for

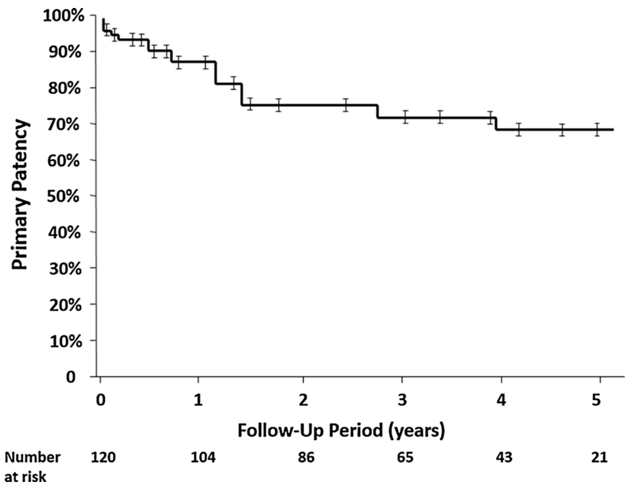

Fig. 1 Life-table analysis of primary patency rates of bovine carotid artery graft (Artegraft) in lower leg bypass

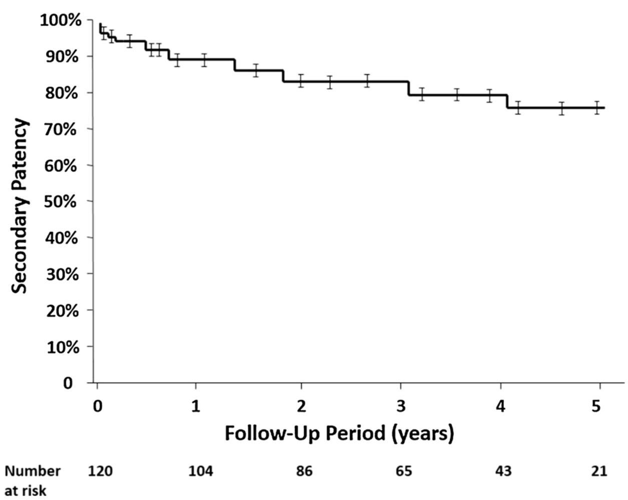

Fig. 2 Life-table analysis of secondary patency rates of bovine carotid artery graft (Artegraft) in lower leg bypass

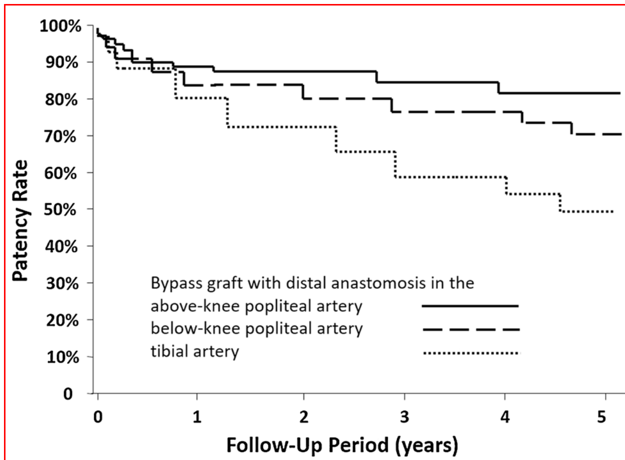

Fig. 3 Comparison of patency rates of bovine carotid artery graft (Artegraft) with the distal anastomosis in the above-knee popliteal artery (*solid line*), below-knee popliteal artery (*long dash line*), and the tibial artery (*short dash line*)

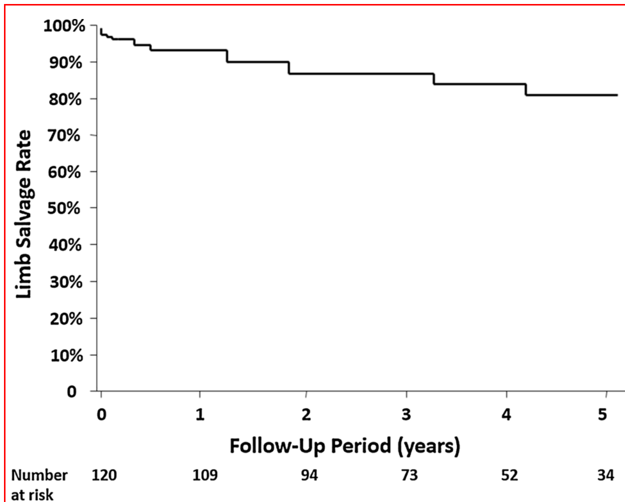

Fig. 4 Kaplan–Meier analysis for estimated 5-year limb salvage rates in patients with critical limb ischemia

BCAG with distal anastomosis at the above-knee popliteal artery, below-knee popliteal artery, and tibial artery are displayed in Fig. 3. The five-year patency rates for the above-knee popliteal graft, below-knee popliteal artery graft, and tibial artery bypass graft were 88.4, 74.6, and 51.7%, respectively. The limb salvage rate at one year was 83.6%, and at five years was 86.2% for patients with critical limb ischemia, as defined by Rutherford disease classification 4 or greater (Fig. 4).

Univariate analysis revealed that patients with prior failed bypass graft, a poor runoff score, and active tobacco significantly affect the long-term primary patency (Table 3). Multivariate analysis showing a poor runoff score was independently associated with poor primary patency ($P < .01$; 95% CI, 1.21–5.4; odds ratio [OR], 2.5, Table 3).

Discussion

Autogenous vein graft has long been regarded as a superior bypass conduit in lower extremity revascularization compared to non-autogenous bypass conduit, due in part to the thromboresistant milieu provided by the confluent lining of luminal endothelial cells which could not be replicated in a prosthetic bypass conduit. While advances in prosthetic graft have led to the heparin coating technology to reduce

Table 3 Univariate and multivariate analyses for primary patency during follow-up

	Univariate analysis				Multivariate analysis		
	Log-rank	*P*	95% CI	OR	95% CI	OR	*P*
Diabetes	0.8	0.8	0.5–2.4				
Chronic renal failure	0.3	0.7	0.3–2.6				
Prior failed graft	5.6	0.02	1.3–5.4	2.75	1.2–4.8	0.7	0.05
Reintervention	1.5	0.4	0.4–1.8				
Above-knee popliteal artery bypass	0.8	0.6	0.8–2.6				
Below-knee popliteal artery bypass	1.2	0.4	0.3–1.5				
Tibial artery bypass	1.9	0.2	0.2–1.7				
Antiplatelet therapy	0.8	0.4	0.6–2.6				
Active tobacco user	6.5	0.05	1.1–4.5	2.15	1.3–5.3	1.6	0.03
Runoff score 0–1	8.9	0.02	0.3–0.9	3.25	0.5–1.1	0.9	0.06
Runoff score 2–3	2.6	0.1	0.5–1.7				
Rutherford class 5–6	0.9	0.8	1.2–3.5				
Foot ulcers	1.2	0.6	0.7–4.2				
Rest pain	1.6	0.7	1.3–3.4				
Claudication	0.05	0.9	0.4–1.9				

CI confidence interval, *OR* odds ratio

the risk of graft-related thrombosis [10], neointimal hyperplasia as triggered by graft-related compliance mismatch remains a significant challenge in maintaining its long-term patency [11]. As an alternative bypass graft conduit, bovine arterial graft has been shown with clinical efficacy in both human studies and experimental investigations [12–15]. This current report provides further evidence regarding the clinical benefit of BCAG as a bypass graft conduit. The finding of our study is notable because it represents one of the largest contemporary clinical series in lower extremity revascularization using BCAG with long-term follow-up results.

In our current study, patency rates with the bovine graft showed excellent long-term outcomes, with an overall 5-year primary and secondary patency rates of 66.7 and 74.6%, respectively. When analyzing the subgroup in our series with the above-knee femoropopliteal bypass grafting, the five-year patency was remarkable at 81.4% (Fig. 3). This compares favorably with the published studies of lower leg bypass using autogenous vein conduits, where primary patency ranged from 68 to 83% at five years [2, 16, 17]. Further analysis of our patient cohort underscores these significant results when considering the complexity of our patients' medical comorbidities. Over one-third of our patients, or 46 patients (37%), underwent a bovine carotid artery interposition bypass grafting due to previously failed lower extremity bypass graft. Additionally, 18 patients (15%) were immunocompromised due to either prior solid organ transplantation which required life-long immunosuppressive therapy or underlying immunodeficiency condition. BCAG was chosen in these challenging patients due to the lower risk of infection associated with a biological graft, an important benefit which has been highlighted by other reports [8, 18, 19].

In contrast to prosthetic vascular graft, biological-based bypass graft has several advantages including reduced risk of graft infection and enhanced graft anastomotic compliance due to its vessel elasticity. The latter property has been attributed to improved graft patency due in part to diminished anastomotic neointimal hyperplasia when compared to prosthetic graft [12, 20]. An example of a biological allograft which has been widely studied in lower extremity revascularization is human umbilical vein (HUV) graft. Eickhoff and associates conducted a prospective randomized trial comparing 105 patients treated with either prosthetic ePTFE graft versus HUV graft in the below-knee femoropopliteal artery bypass [20]. The study showed that prosthetic graft had a 2.1 times greater incidence of occlusion compared to HUV graft at four years of follow-up. We have previously reported our experience of using cadaveric cryopreserved allograft as a replacement graft conduit in patients with infected prosthetic graft and found remarkable clinical outcomes with low risk of postoperative infection [21]. Our current experience of bovine carotid artery graft included four patients (3%) who had prosthetic graft infection who underwent prosthetic graft excision and bovine artery interposition graft replacement. We found comparable efficacy as a replacement conduit graft in patients with infectious complications.

Since the initial introduction of bovine carotid artery as a graft conduit more than four decades ago, its utility in lower leg bypass has been reported with remarkable efficacy [15, 22]. However, it has not been widely utilized as a vascular conduit in lower extremity bypass. One potential factor may be related to the graft size. A standard 6-mm-internal-diameter bovine carotid artery graft, coupled by the relative vessel wall thickness encompassing the media and adventitial tissues, may reach an outer graft diameter of 8 mm. In contrast to an autogenous saphenous vein which has a relative thin wall, the BCAG may appear to be bulky for tibial artery reconstruction. However, a smaller caliber Artegraft with 5 mm in diameter has become available in recent years, which expanded its suitability for the below-knee popliteal or tibial arterial reconstruction. In our practice, we routinely create a distal anastomotic patch in infra-geniculate revascularization whereby the Artegraft is connected to the anastomotic patch in an end-to-side fashion (Fig. 5). The benefit of this adjunctive technique, which creates a widened distal anastomotic site to minimize compliance mismatch and thereby reduce neointimal hyperplasia, has been reported in several large clinical series with improved patency [9, 23, 24].

The limb salvage rate in our series at one, three, and five years was 93, 87, and 81%, respectively (Fig. 4), which is remarkable considering the complex comorbidities in many of these patients. These results are comparable with other clinical series of autogenous saphenous vein grafts in lower extremity bypass [2, 17]. We attributed the high limb salvage rate to the remarkable secondary patency rate of BCAG (Fig. 2). In contrast to autogenous vein graft occlusion, thrombosed BCAG is generally amenable to thrombectomy or thrombolytic therapy if catheter-based intervention is performed in a timely fashion. Catheter directed thrombectomy or thrombolytic therapy can be performed with high efficacy in removing underlying graft thrombus, which is a common practice in dialysis access intervention with patients with BCAG dialysis graft [6, 8, 25]. Once thrombus is removed by catheter-based interventions, further endovascular interventions such as balloon angioplasty or stenting at the distal anastomotic stenosis can be performed to restore the graft flow, prolong graft patency, and salvage the ischemic limb.

Univariate analysis in our study showed that prior failed bypass graft, active tobacco use, and poor runoff vessels were associated with decreased patency rate. Further examination with multivariate analysis showed poor runoff score as an independent predictor of graft occlusion. These findings were consistent with other reports of the bypass graft series, including autogenous vein graft and prosthetic

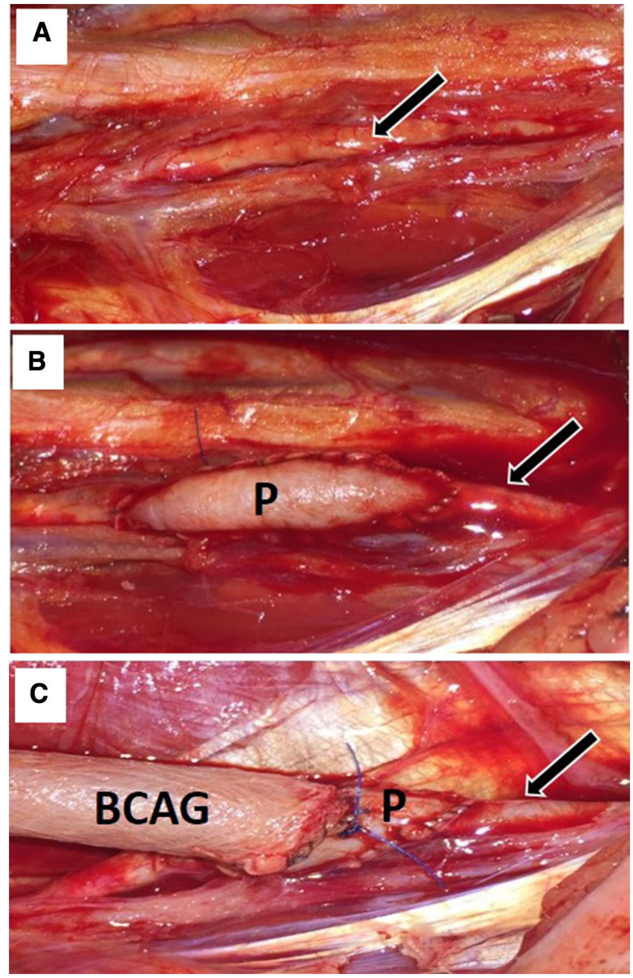

Fig. 5 **a** Tibial artery (*arrow*) is isolated using a sterile tourniquet technique. **b** A tibial anastomotic patch (*P*) is created to widen the anastomotic area of the tibial artery (*arrow*). **c** BCAG is connected to the tibial anastomotic patch (*P*) in an end-to-side fashion to complete the anastomotic reconstruction of the tibial artery (*arrow*)

graft, in predictive factor analysis of graft failure [2, 9, 10, 17].

Several limitations undoubtedly exist in the present study, which were related to the retrospective nature of the study and their potential patient selection and treatment bias. The complexity of medical comorbidities in our patients may have created added challenge in estimating the graft patency and limb salvage rates. Moreover, there was no treatment randomization as each patient who underwent bovine artery graft for leg bypass was largely based on the surgeon's preference as well as in accordance with the patient's individual anatomy and disease etiology. Collecting data in this manner may be of limited value, especially in light of a relatively small patient sample size. Keeping these study limitations in mind, we believe the findings in our study remain valuable because it underscores the important role of bovine carotid artery graft in lower leg revascularization particularly in a challenging group of patients as seen in our series.

In conclusion, the current study demonstrates that the BCAG has proven beneficial in lower extremity bypass. The remarkable long-term patency rate with relative graft-related complication renders this an invaluable graft alternative, particularly when appropriate autogenous vein graft is not available. Further prospective study will be beneficial to evaluate the utility of this bypass conduit in comparison with the autogenous vein graft.

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