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High-pressure, noncompliant balloon angioplasty for long and calcified infrapopliteal and inframalleolar lesions is feasible.

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Abstract

Background: To evaluate the safety, feasibility and effectiveness of high-pressure, noncompliant balloon angioplasty in the management of long infrapopliteal calcified lesions.

Methods: Consecutive patients, presenting with chronic limb-threatening ischemia (CLTI) and long (>100 mm) calcified infrapopliteal lesions who were treated with a high pressure, noncompliant balloon (JADE, OrbusNeich, Hong Kong) between January 2016 and July 2016 were retrospectively analyzed. Angioplasty was performed by inflating the balloon to a pressure of 22 to 24 atm for 90 seconds. Primary outcome was technical success. Secondary outcomes were procedure-related complications, limb salvage, amputation-free survival (AFS), wound healing, overall survival, freedom from clinically driven target lesion reintervention (CD-TLR), and resolution of CLTI at 2 and 3 years.

Results: In total, 23 lesions in 21 limbs of 20 patients were treated. All patients had tissue loss (Rutherford 5 or 6). The mean lesion length was 374.8 mm. Of all lesions, 56.5% were occlusions, 91.3% were classified as TransAtlantic Inter-Society Consensus (TASC) C and D lesions, and 78.3% had severe calcification classification. Of all lesions, 52.2% extended into the below-the-ankle arteries. Technical success was achieved in 22 lesions (95.7%). There were no procedure-related complications. No bailout stenting was required. At 2 and 3 years, limb salvage was 84.7% and 78.7%, AFS was 71.4% and 56.1%, wound healing was 81.0% and 85.7%, overall survival was 75.0% and 64.3% and freedom from CD-TLR was 77.6% and 63.5%, respectively. Resolution of CLTI without TLR was 81.0% at 2 and 3 years.

Conclusions: This study is the first to analyze safety and feasibility of a high-pressure, noncompliant balloon for long, calcified infrapopliteal and inframalleolar lesions.

Keywords: Critical limb ischemia, peripheral arterial disease, calcified lesions, high pressure noncompliant balloon, angioplasty, endovascular therapy, infrapopliteal.

Introduction

Revascularization is essential in treating chronic limb-threatening ischemia (CLTI) patients and can be performed surgically or with an endovascular procedure. In infrapopliteal arteries, endovascular therapy is the initial choice for revascularization with plain old balloon angioplasty (POBA) as the primary choice to perform the procedure with.

However, PTA using POBA is not always successful in treating infrapopliteal lesions in CLTI patients.[1] Technical failure rates of 13.3% are not uncommon and increase when applied for TransAtlantic Inter-Society Consensus (TASC) type D lesions, due to recoil, residual stenosis or failure of balloon expansion.[1–4]

Another limitation of the treatment of POBA in infrapopliteal arteries, is the recurrent need for interventions. A recent meta-analysis found a target lesion reintervention rate of 27.8% at 1 year of follow-up.[5] The high reintervention rate could possibly be due to clinically relevant restenosis from inadequate balloon expansion or recoil at the time of index procedure which occurs more commonly than expected.[6]

Atherectomy devices and plaque modifying balloons were developed to deal with the atherosclerotic plaque when POBA fails. However, there is no evidence to support the superiority of these devices over POBA.[7,8] Other treatment modalities are drug eluting stents (DES) for consideration when POBA fails. A meta-analysis by Varcoe et al.[9] reported improved primary patency and freedom from reintervention rates of DES compared to POBA in infrapopliteal arteries at 1 year. Despite that, long-term studies reported lack these improved rates at 3 years of follow-up,[10,11] resulting DES to be left as a bail-out option.

A potential treatment option for long and severely calcified infrapopliteal lesions may be the JADE (OrbusNeich, Hong Kong) balloon. This is a non-compliant balloon with a rated burst pressure of 22 atm and designed for controlled opening of resistant lesions in the peripheral arteries. Similar high-pressure balloons have previously been applied in coronary studies, which showed high pressure balloons to be safe with a procedural success percentage of 96.6% in heavily resistant coronary lesions.[12,13]

This study evaluated the safety, feasibility and mid-term effectiveness of a high-pressure, noncompliant balloon for the treatment of long, infrapopliteal and inframalleolar lesions in CLTI patients.

Patients and methods

This study was conducted according to the principles of the Declaration of Helsinki and approved by the Institutional Review Board of the Changi General Hospital (IRB number: 2019/2448). The requirement for informed consent was waived by the committee.

Patient selection

All consecutive CLTI patients who were treated with the JADE balloon for long calcified lesions in the Changi General Hospital in Singapore between January 2016 and July 2016 were included in this study. CLTI was defined as the presence of peripheral arterial disease (PAD) in combination with gangrene, a lower limb ulceration >2 weeks duration or rest pain with affirmative hemodynamic studies.[7] Three dedicated vascular surgeons with broad experience in endovascular techniques performed the procedures. The decision to use the high-pressure, noncompliant balloon was at the operator's discretion and primarily based on anticipation of suboptimal results with a conventional balloon due to calcification and length of lesion.

Patient with lesions less than 100 mm in length were excluded. Lesions were considered separate if the plaques were more than 5 cm apart. In total, 20 patients with 21 critically ischemic limbs were retrospectively analyzed.

Endovascular procedure and wound treatment

Before the procedure, patients were evaluated with a high-resolution duplex ultrasound (SonoSite Edge II, FUJIFILM SonoSite, Bothell, United States) by a trained ultrasound technician. Computer Tomography angiography (CTA) was performed if aortoiliac lesions were suspected or if duplex findings were discordant with clinical findings. All patients were pretreated with aspirin (100 mg) and underwent preparation for angioplasty according to the institutional protocol. Prior to the procedure an anesthesiologist administered monitored intravenous sedation and a popliteal nerve block[14] under ultrasound guidance (SonoSite Edge II). This was done primarily to allow surgical debridement of the wounds which was routinely done in the same setting after endovascular intervention. The nerve block had a secondary benefit of allowing high-pressure angioplasty without excessive pain.

Antegrade access to the femoral artery was created using a 18G needle using the Seldinger technique under ultrasound guidance (SonoSite Edge II).[15] A 5 or 6F antegrade 45 cm sheath (BRITE TIP, Cordis, Santa Clara, California, United States) was placed in case of isolated BTK lesions. In case of inflow lesions, a shorter antegrade sheath (BRITE TIP) or a crossover sheath (Flexor, Cook Medical, Bloomington, Indiana, United States) was placed. Inflow lesions were treated by balloon angioplasty using POBA. Systematic anticoagulation was performed with intra-arterial administration of 3000 units unfractionated heparin, followed by 1000 units per subsequent hour of intervention according to institutional protocol.

PTA was performed as follows. Lesions were crossed with a 0.014-inch moderate-support 300 cm long guidewire (PT^2 moderate support, Boston Scientific, Marlborough, United States). A 2 mm balloon (Amphirion Deep, Medtronic, Dublin, Ireland) was inserted to cross and predilate the lesion if necessary. Final balloon angioplasty was performed with the JADE balloon. The balloon was inflated (Encore™, Boston Scientific, Marlborough, Massachusetts, United States) for 90 seconds with a pressure of 22 to 24 atm. The diameter of the balloon was based on the visual diameter of the vessel diameter on a 1:1 basis. The length of the balloon was chosen according to the length of the lesion. No adjunctive scoring balloons, atherectomy, DCBs or stents were used. The result was assessed on completion angiography. In case of non-flow limiting residual stenosis of 30%, this was accepted without placement of a stent. After the procedure, patients were prescribed aspirin at 100 mg/day orally.

Wound debridement, drainage of an infected phlegmon or minor amputation was performed simultaneously in all patients when necessary.

Follow-up

Patients were monitored in a multidisciplinary team lead by the attending vascular surgeon. Simultaneous wound care and clinical assessment of perfusion was performed weekly at least for 1 month, followed by at least fortnightly until the wound healed. Wound care was done in the hospital by a dedicated nurse or podiatric nurse. Reintervention was only performed if the wound healing was deemed to be poor as seen by poor granulation or failure in wound size reduction and if clinical assessment revealed a weak or absent pulse. Reintervention was performed by balloon angioplasty with or without stenting.

Data collection, end points, and definitions

Patient demographics, baseline risk factors, and laboratory, angiographic, and procedural data were retrospectively collected. Data were derived from electronic medical records, clinical records, imaging reports, and laboratory reports. Angiographic data were derived by analyzing the procedural angiographic images, which were independently assessed by 2 experienced interventionalists (GA and RF) who were not involved in the intervention.

The primary end point was technical success. Secondary outcomes were procedure-related complications, limb salvage rate, amputation-free survival (AFS), wound healing, overall survival, resolution of CLTI without TLR, and freedom from clinically driven target lesion reintervention (CD-TLR) at 2 years.

Technical success was defined as ability to cross the lesion and fully efface the balloon, leaving no residual stenosis (<30%) seen on angiography. Lesions were considered separate if more than 5 cm apart. Limb salvage was defined as avoidance of major amputation (above the ankle). AFS was defined as avoidance of major amputation or death. Freedom of CD-TLR was defined as avoidance of any clinically driven repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion. Resolution of CLTI without CD-TLR was defined as absence of rest pain and complete wound healing without the need for CD-TLR. Wounds were considered healed if the wound was fully epithelized, with or without a skin graft. In patients who underwent major amputation, the time to wound healing was considered to be infinite.

Statistical analysis

Quantile-quantile (Q-Q) plots were analyzed to determine whether continuous variables followed a normal distribution. If the points in the Q-Q plot lie on a straight diagonal line, the data is defined as normally distributed. Normally distributed continuous variables are expressed as mean ± standard deviation (SD) and were compared using the paired-samples *t* test. Statistical significance was defined as $P < 0.05$. Nonnormally distributed data are presented as median and the interquartile range. Categorical variables are expressed as number with percentage (%). Limb salvage rate, AFS rate, wound healing rate, overall survival rate, freedom from TLR, and resolution of CLTI without TLR were calculated by Kaplan-Meier analysis. Statistical analysis was performed using SPSS 23 software (IBM, Armonk, NY, United States).

Results

Patient characteristics

The high-pressure, noncompliant balloon was used to treat 23 lesions in 21 limbs of 20 patients (70% male). Patients were a mean age of 65 ± 11 years. Comorbidities included diabetes in 95%, chronic kidney disease in 50%, and dialysis in 20%. All patients had Rutherford 5 and 6 CLTI. Patient demographics and baseline characteristics are reported in Table 1.

Lesion details

All lesions were de novo and were recanalized intraluminally. The mean lesion length was 374 ± 140 mm, with 21 (91.3%) classified as TASC C or D lesions. Of all treated lesions, 11 (47.8%) were confined in the above-the-ankle arteries and 12 (52.2%) lesions extended to below-the-ankle arteries. Of these lesions, 6 (26.1%) extended from the anterior tibial artery to the dorsalis pedis, 5 (21.8%) from the anterior tibial artery to the plantar arch and 1 (4.3%) from the posterior tibial artery to the plantar lateral artery.. These 23 lesions treated spanned 40 arteries as the lesion was contiguous across more than 1 vessel.

Thirteen (56.5%) of the treated lesions were occlusions. Calcification was noted to be severe according to the Peripheral Academic Research Consortium (PARC) classification[16] for 18 lesions (78.3%). In 6 limbs (28.6%), concomitant inflow lesions were treated in the same procedure.

Procedure

The mean balloon diameter used was 3.0 ± 0.07 mm, and the mean balloon length used was 106 ± 22.9 mm. Angiographic details are summarized in Table 2, and the mean preprocedural and postprocedural runoff vessels are reported in Table 3.

30-day outcome

Technical success was achieved in 22 lesions (95.7%). One patient had residual recoil of 30% that was deemed non-flow limiting. No stents were inserted. No perforation, dissection, distal embolization, groin hematoma, or stroke occurred periprocedurally. One patient died of cardiac arrest (pulseless electrical activity) 2 days after the procedure. No other complications occurred within 30 days post procedure.

Subsequent follow-up

Beyond 30-days, a total of 6 other deaths occurred due to myocardial infarction (n=1), ulcerative colitis (n=1), ischemic bowel (n=1) and an unknown cause (n=3). During follow-up, a total of 4 major amputations deemed necessary because of severe infection (n=3) and unsolvable gangrene (n=1).

Reintervention deemed necessary in 6 limbs. In all limbs, lesions were treated by angioplasty using the JADE balloon (n=5) or a drug coated balloon (n=1). In 1 patient, additional stent

placement (XIENCE prime, Abbott, Abbott Park, Illinois, United States) was required. No patient underwent a surgical bypass.

At 2 and 3 years, limb salvage was 84.7% and 78.7% and AFS was 71.4% and 56.1%, respectively. Wound healing rate was 81.0% and 85.7%, with a median time to wound healing of 104 days (range, 48–907 days). Overall survival was 75.0% and 64.3%, freedom from CD-TLR was 77.6% and 63.5% at 2 and 3 years, respectively. Resolution of CLTI without TLR was 81.0% at 2 and 3 years. Kaplan-Meier analyses are shown in Figures 1-6. The median time to follow-up was 31 months (range, 0 – 45 months).

Discussion

This study shows that angioplasty with a high-pressure, noncompliant balloon is safe and feasible for the treatment of severely calcified infrapopliteal lesions. Although endovascular treatment options are expanding and technical success rates of treatment with POBA are increasing, it still often fails. Failure occurs mainly in the more complex lesions, in TASC C and D lesions.[1–3] In this study a technical success rate of 95.2% was achieved in a population with 91% TASC C and D lesions and therefore it suggests that high-pressure, noncompliant balloon angioplasty can be used as an endovascular treatment option for complex lesions.

Even though the combination of high-pressure and noncompliance could be effective in treating complex lesions, it may also lead to an increased risk of vessel damage, including dissections and artery rupture. These complications were not seen in any of the patients in the present study, but artery rupture has been described in coronary studies.[12] The ruptures occurred when an inflation pressures of 30-40 atm were applied. Furthermore, the balloon size was based on angiographic estimation without using intravascular imaging. When applying pressures of 30-

40 atm, special attention should be paid to the size of the balloon to reduce the risk of artery rupture. By inflating the high-pressure, noncompliant balloon to 22-24 atm for 90 seconds in the present study, no immediate procedurally related angiographic complications occurred.

One patient died of cardiac arrest within 30 days after the procedure. This patient was 85 years old, had a left ventricular ejection fraction of 30%, was known to have segmental wall-motion abnormalities of the left ventricle and was diagnosed with chronic kidney disease. The death occurred despite prior optimization with medical therapy and periprocedural monitoring by an anesthetic team. There was no record of severe pain experienced that may have exacerbated a coronary condition. This event highlights the fragile status of CLTI patients. A study of the Poor-Risk Patients With and Without Revascularization Therapy for Critical Limb Ischemia (PRIORITY) registry[17] also observed that patients with heart failure who underwent revascularization were at a higher risk of death. In addition, the study by Martinez et al.[18] reported increasing age and below-the-knee intervention as risk factors for major amputation or death. In selecting patients for endovascular procedures, attention should be paid to the patients' comorbidities and the periprocedural risks.

There are several other treatment modalities designed for complex lesions, such as cutting balloons and atherectomy devices. Cutting balloons have shown to be technically successful in 96-100% of the cases,[19,20] but with a complication rate of 8.9%[20] including dissections and vessel leakage. Studies that investigated atherectomy devices report also high technical success rates (99%), but with complication rates ranging from 3.4% to 27.5%.[21–23] Complications included perforation, distal embolization and dissections among others. Therefore, treatment with these devices should be performed with caution in infrapopliteal arteries.

Compared to POBA, the freedom from CD-TLR rate found in the present study is higher (89.2%) at 1-year follow-up. A recent meta-analysis[5] reported a freedom from TLR rate of 71.6% after POBA in infrapopliteal arteries. The explanation for the higher freedom from CD-TLR rate found in this study compared with the recent meta-analysis remains unclear. A possible explanation could lie with the good angiographic results seen on completion angiogram after a combination of high-pressure, noncompliant balloon and prolonged inflation time of 90 seconds. In the study by Baumann et al.[6] occurrence of early elastic recoil, defined as lumen compromise >10%, was assessed by comparing minimal lumen diameter at baseline, immediately after PTA and 15 minutes after PTA. Interestingly, elastic recoil was found in 97% of the patients with a mean luminal compromise of 29% 15 minutes post PTA. However, the assessment of elastic recoil 15 minutes after angioplasty was not assessed in this study. Therefore, the true effect of a high-pressure, noncompliant balloon and the effect of prolonged inflation time on elastic recoil are undefined and could be further explored in the future.

The pathophysiology of restenosis is poorly understood, but early elastic recoil, arterial injury and residual dissection could be contributory factors to the high restenosis rates.[6,24–26] The high-pressure, noncompliant balloon may possibly deal with elastic recoil and reducing the risk of arterial injury because of the combination of the high pressure and the noncompliance. Disrupting the fibro-calcific plaque reduces the risk of recoil[27] which is sometimes difficult to achieve with POBA. A high pressure may be required in these calcified lesions to disrupt the plaque. In addition, the risk of vessel damage may be reduced by the noncompliancy of the balloon that allows the balloon to explant uniformly and thereby prevents over-expansion of the balloon in the more compliant segment.[12,13] However, this study did not include assessment arterial plaque disruption or vessel damage thus no hard conclusions can be drawn. More research is necessary to support these hypotheses.

Limitations

This retrospective study has limitations due to its design. There was no comparative group and it includes a small sample size. A completion angiogram was performed, but no further angiograms or duplex ultrasounds were performed to assess recoil and target vessel patency. Hence no meaningful conclusions could be drawn on the effect of high pressure and noncompliant angioplasty on vessel patency. However, data on clinically driven reinterventions served as a surrogate indication of clinically patency. No routine hemodynamic measurement was performed as per institution practice in view of the calcified nature of the vessels in a predominantly diabetic population. However, this study is the first to analyze the safety and feasibility of the high-pressure, noncompliant balloon in long, severely calcified infrapopliteal lesions.

Conclusions

This study shows that a high-pressure, noncompliant balloon is feasible for the treatment of infrapopliteal and inframalleolar calcified lesions. The outcome of this study can be used as a stepping stone for further research to fully investigate the safety and effectiveness of high-pressure, noncompliant balloons in comparison with POBA

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Table 1. Baseline characteristics

Variable	Number (%)
Patients	20
Limbs	21
Men	14 (70.0)
Age, years	65.90 ± 10.9
Left limb	12 (57.1)
Comorbidities	
Hypertension	18 (90.0)
Diabetes	19 (95.0)
Hyperlipidemia	16 (80.0)
Hemodialysis	4 (20.0)
Cerebrovascular accident	4 (20.0)
Chronic kidney disease	10 (50.0)
Laboratory results	
Serum creatinine (μmol/L)	117 (85-211)
GFR <30 (mL/min/1.73m^2)	6 (30.0)
Rutherford	
5	18 (85.7)
6	3 (14.3)
Mobility	
ADL assisted	3 (15.0)
Community ambulation	16 (80.0)

GFR = glomerular filtration rate,

ADL = activities of daily living.

Continuous data are presented as mean ± standard deviation or median (interquartile range).

Categorical data are presented as number (%).

Table 2. Angiographic findings at baseline

Variable	Total
Vessels treated	40
Anterior tibial artery	19 (47.5)
Dorsalis pedis	11 (27.5)
Plantar arch	5 (12.5)
Posterior tibial artery	3 (7.5)
Peroneal artery	1 (2.5)
Plantar lateral artery	1 (2.5)
Lesions	23
Occlusions	13 (56.5)
Lesion length, mm	374.8 ± 140.03
Vessel diameter treated, mm	3.0 ± 0.15
PARC classification	
Focal	1 (4.8)
Moderate	4 (19.0)
Severe	18 (78.3)
TASC classification	
A	1 (4.8)
B	1 (4.8)
C	10 (43.5)
D	11 (47.8)

PARC = Peripheral Academic Research Consortium,
TASC = Trans-Atlantic Inter-Society Consensus Document
Continuous data are presented as mean ± SD.
Categorical data are presented as number (%).

Table 3. Runoff vessels pre- and postprocedural

Variable	Preprocedure	Postprocedure	*P* value
Runoff vessels	0.62 ± 0.67	1.57 ± 0.60	<0.001
Runoff vessels to the foot	0.19 ± 0 .40	1.14 ± 0.36	<0.001

Data are presented as mean ± SD.

Titles of figures:

Figure 1. Limb salvage

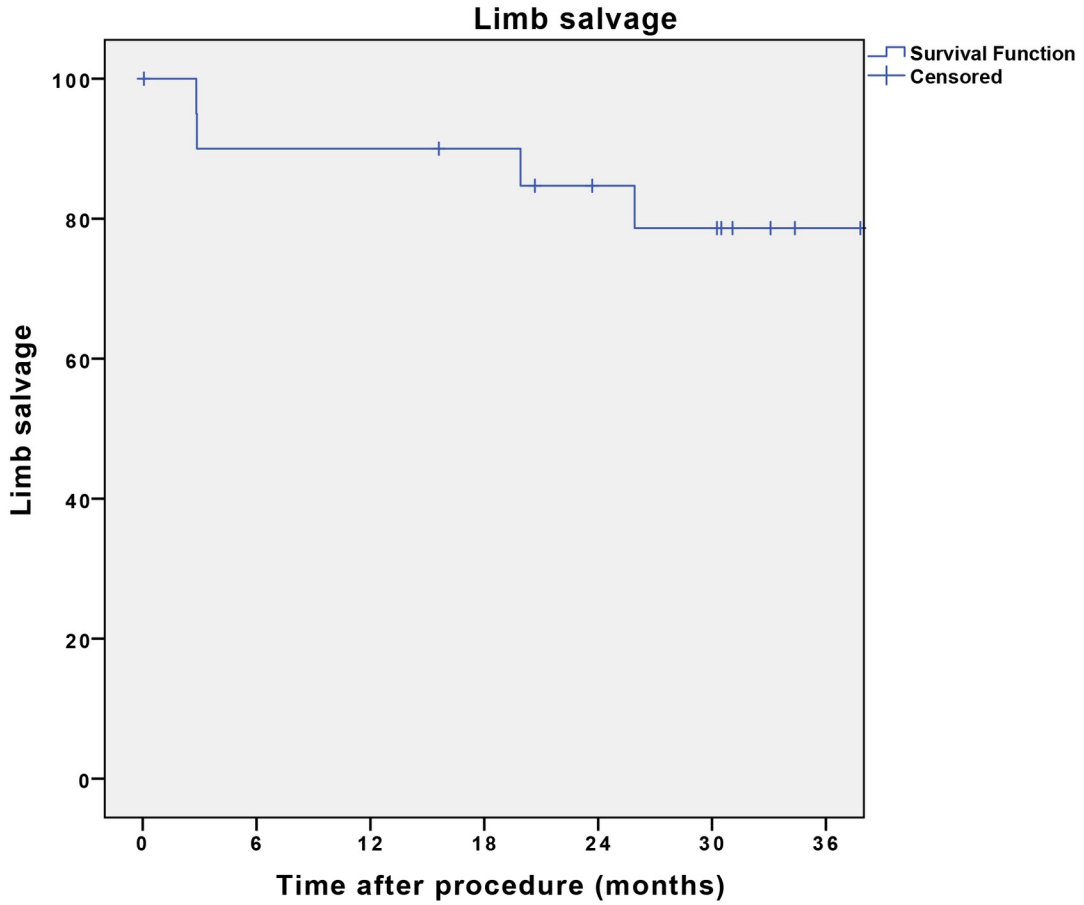
Figure 2. Amputation-free survival

Figure 3. Wound healing

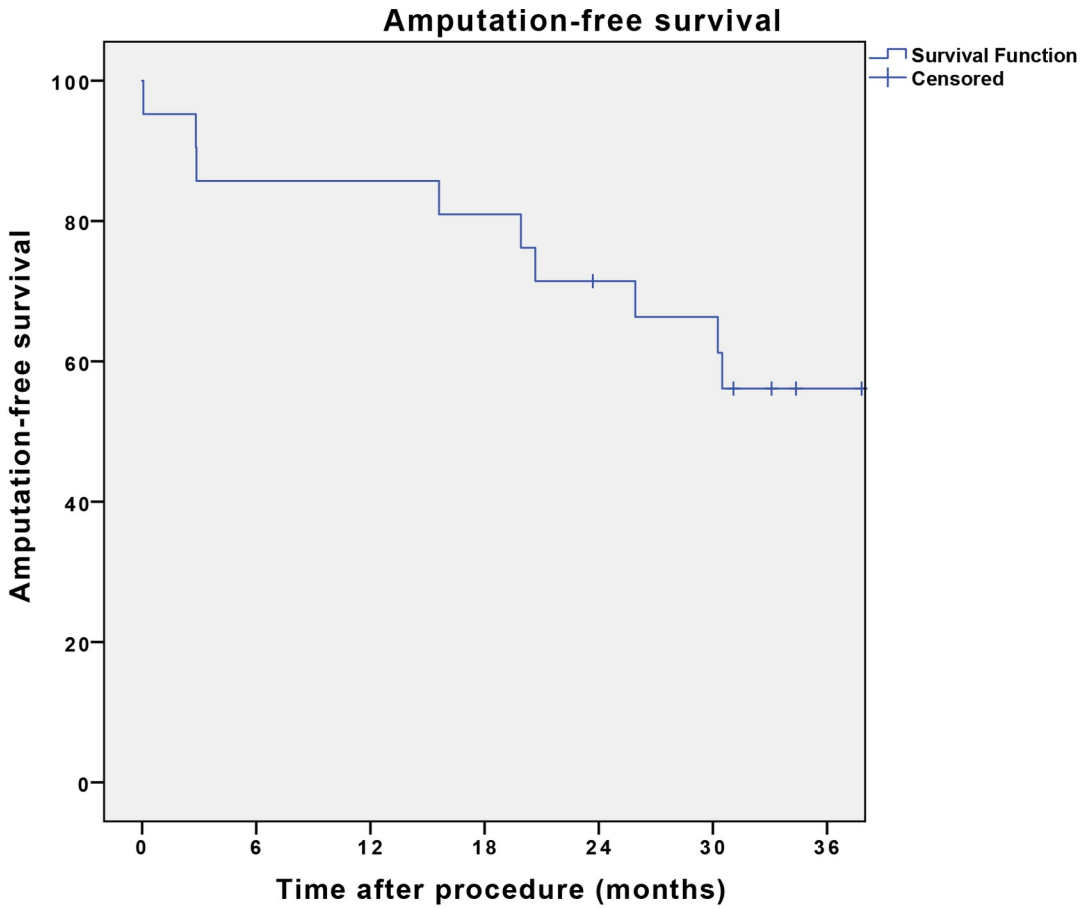
Figure 4. Overall survival

Figure 5. Freedom from CD-TLR

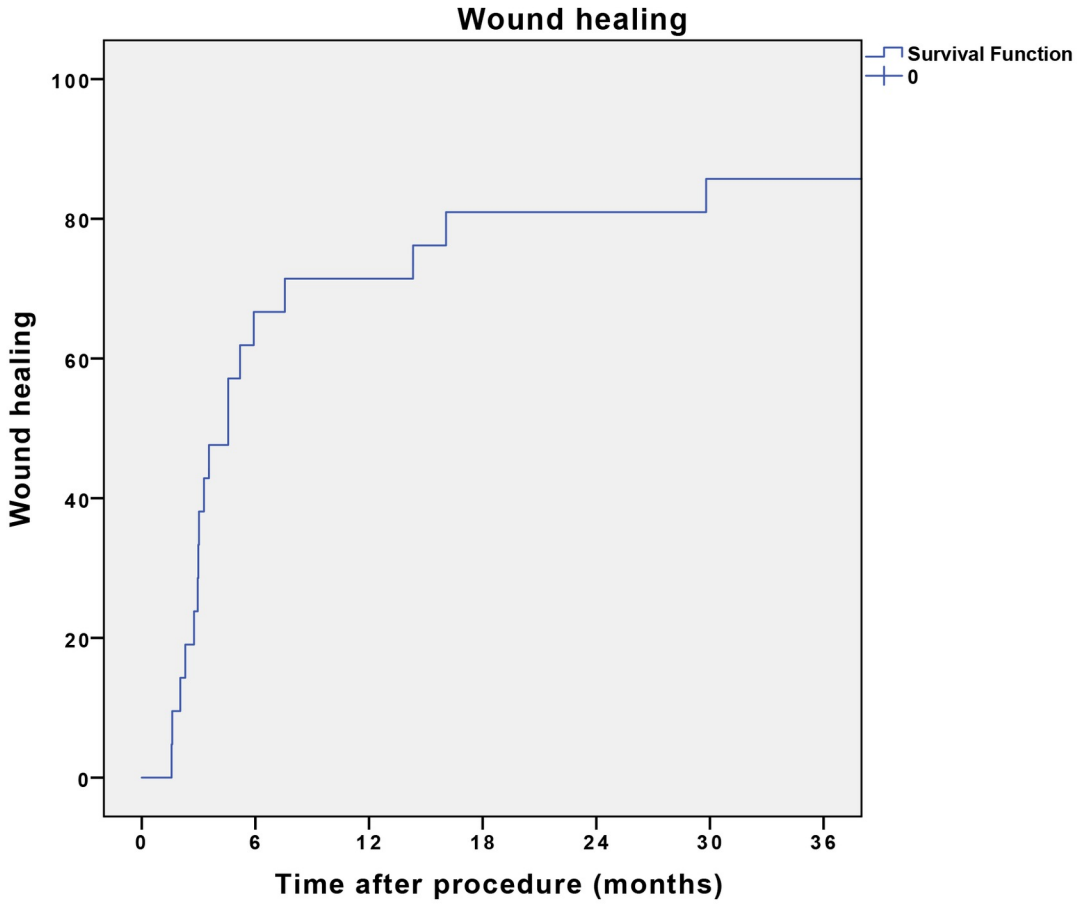
Figure 6. Resolution of CLTI without CD-TLR



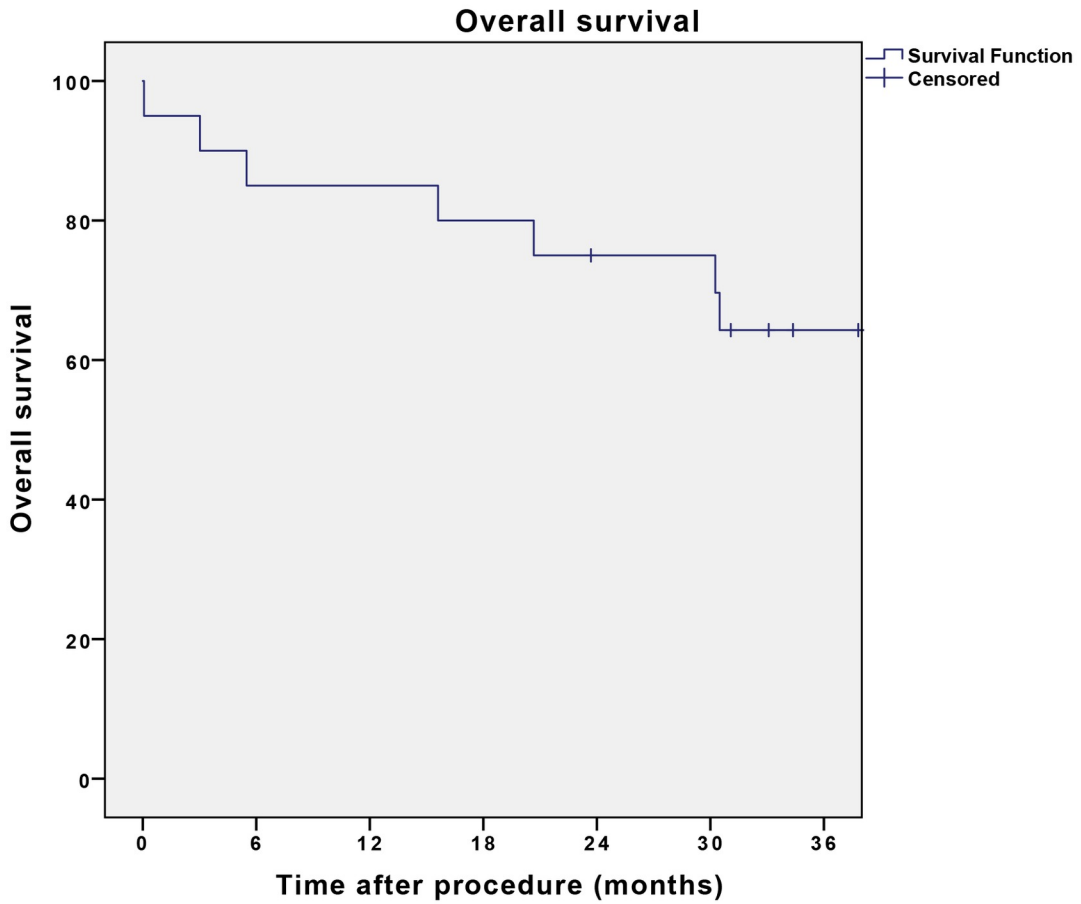
Months	0	6	12	18	24	30	36
No. at risk	21	18	18	17	14	13	8
%	100	90.0	90.0	90.0	84.7	78.7	78.7



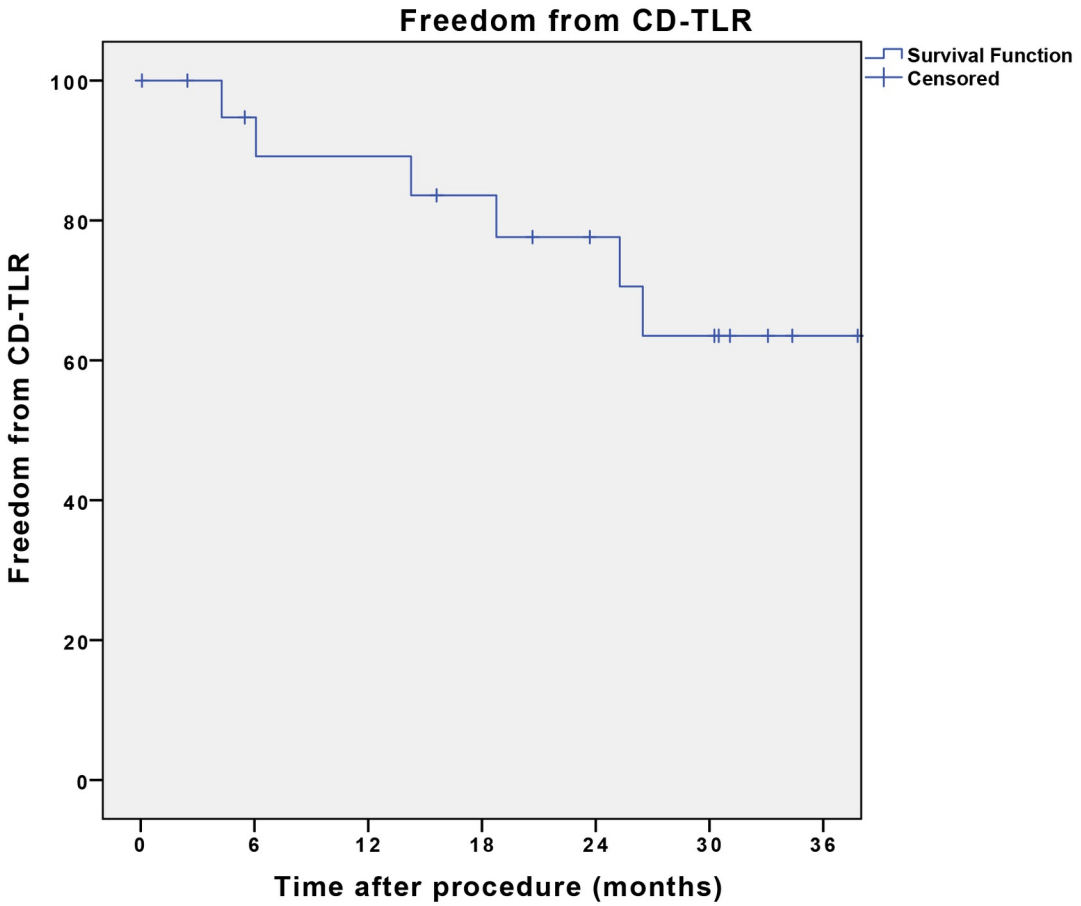
Months	0	6	12	18	24	30	36
No. at risk	21	18	18	17	14	13	8
%	100	85.7	85.7	81.0	71.4	66.3	56.1



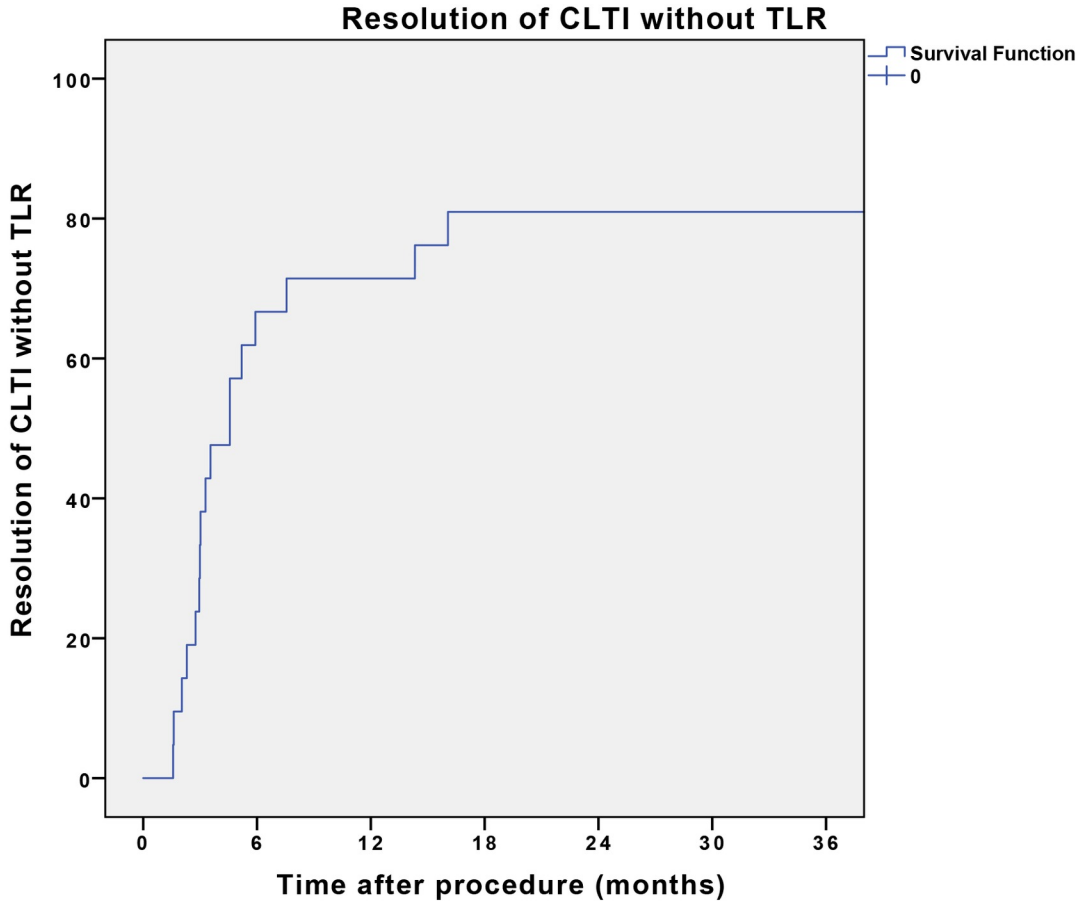
Months	0	6	12	18	24	30	36
No. healed	0	14	15	17	17	18	18
%	0	66.7	71.4	81.0	81.0	85.7	85.7



Months	0	6	12	18	24	30	36
No. at risk	20	17	17	16	14	14	9
%	100	85.0	85.0	80.0	75.0	75.0	64.3



Months	0	6	12	18	24	30	36
No. at risk	21	17	16	14	11	9	4
%	100	94.7	89.2	83.6	77.6	63.5	63.5



Months	0	6	12	18	24	30	36
No.	0	7	6	17	17	17	17
%	0	66.7	71.4	81.0	81.0	81.0	81.0