



Research Article

Kissing Balloons Angioplasty for Infra-genicular Lower Limb Critical Ischemia

M Ayman Fakhry^{1*}, Sohiel Nagib² and A Elabd³

¹Professor of Vascular Surgery, Egyptian Medical Military Academy, Egypt

²Vascular surgeon, Royal Vascular Centre, Alexandria, Egypt

³Professor of Radiology, Alexandria University, Egypt

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***Corresponding author:** M Ayman Fakhry, MD, PhD, Professor of Vascular Surgery, Egyptian Medical Military Academy, Egypt, E-mail: ayman_vasc@live.com

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Abstract

Background: This study aimed to analyze the technical aspects and follow-up findings regarding patients with critical limb ischemia who underwent the Kissing Balloon Technique (KBT).

Methods: 20 patients (22 bifurcations) were enrolled in this retrospective analysis between September 2020 and February 2022. All patients were submitted to infrapopliteal intervention for critical limb ischemia. The KBT is the primary treatment in 3 situations: for cases with > 70% stenosis of the main artery located less than 1 cm of the bifurcation, occlusion of one branch with greater than 50% stenosis of the contralateral branch, or greater than 50% bilateral stenosis.

Results: Primary patency at 30 days, 1 year, and 2 years was 100%, 68.1%, and 68.1%, respectively. Limb salvage rates at 30 days, 1 year, and 2 years were 100%, 86.6%, and 65.0%, respectively. Wound healing rates at 30 days, 6 months, 1 year, and 2 years were 7.1%, 34.4%, 44.5%, and 68.7%, respectively. The bifurcations of the V-shape and T-shape groups were compared in terms of wound healing, primary patency, and limb salvage. No differences were observed in wound healing (P = 0.268), primary patency (P = 0.394), and limb salvage (P = 0.755).

Conclusion: The KBT is a feasible bifurcation approach for infrapopliteal angioplasties to maintain the patency of both branches after ballooning. The comparison between the anterior tibial artery and tibioperoneal trunk bifurcation and the peroneal artery and posterior tibial artery bifurcation revealed no difference in wound healing, primary patency, and limb salvage.

Introduction

The percutaneous treatment of arterial disease has crossed the boundaries of many Specialties with the treatment of Peripheral Vascular Disease (PVD) now being performed by cardiologists, radiologists, and vascular surgeons. This has a positive impact on the treatment of PVD with the diffusion of techniques and devices Used in one arterial bed being applied in others [1]. Endovascular treatment has been the primary approach for revascularization of the Infrapopliteal (IP) arteries in the majority of cases [2]. Treatment of more than one artery has been demonstrated to be an option to accelerate wound healing [3]. In tibial multi-vessel disease with involvement of the popliteal or tibial-peroneal trunk bifurcation, a single

balloon angioplasty can dislocate the plaque in adjacent untreated arteries, causing thrombosis, dissection, and embolism. These complications could be avoided using the kissing balloon technique [4]. The term kissing balloon was first used by Grüntzig and Hopff to describe the percutaneous treatment of iliac bifurcation stenosis [5]. In 1980, Velasquez, et al. published the first report on this technique for distal aorta angioplasty in a patient with Leriche syndrome. Later, several studies have successfully used the kissing balloon technique for treating peripheral artery disease and have taken their place in the literature [6]. We report the treatment of eight limbs with diseased infrapopliteal artery bifurcation by kissing balloon technique, with two low-profile catheters (KBT) [3]. The kissing-balloon technique, also termed the two-

balloon technique, is a procedure designed for percutaneous transluminal angioplasty of arterial bifurcations. It was initially described for percutaneous transluminal angioplasty of the aortic bifurcation, which used simultaneous inflation of two balloons, one introduced through each common femoral artery, to avoid occlusion or embolization of the opposite common iliac artery. For angioplasty of more than one vessel, the endovascular approach of bifurcation of the IP arteries with 2 balloons at the same time is often required (the kissing balloon technique [KBT]) to avoid plaque or carina shift, dissection of the branched artery [7]. Limited literature on the KBT has ostium, and residual stenosis of the side branch been described for the treatment of bifurcations in the IP arteries; in 2 cohort studies of 7 and 8 patients and 2 case reports [7,8]. Percutaneous transluminal angioplasty of such bifurcation lesions with a single angioplasty catheter is contraindicated inflation of the balloon may displace the plaque laterally and occlude the contralateral iliac artery or result in distal embolization. Tegtmeier described the use of the technique for angioplasty of the popliteal artery trifurcation after a single ante-grade puncture of the ipsilateral common femoral artery [7].

Objective

This study aimed to present our mid-term experience in the endovascular treatment of the infra genicular arterial disease using the kissing balloon technique as a safe and effective procedure for revascularization.

Patients & Methods

The study comprised 20 patients (22 bifurcations) who presented with critical-threatening limb ischemia and were enrolled in this retrospective analysis between September 2020 and February 2022. All patients were scheduled for infrapopliteal intervention for critical limb ischemia at Royal Vascular Centre, Alexandria - Egypt. Each patient was subjected to:

1. Sign Enforced medical consent.
2. Careful history taking and clinical examination.
3. ABI and duplex assessment
4. CT Angiogram of the abdominal Aorta and the arterial tree of both lower limbs
5. All patients were submitted to infrapopliteal intervention for critical limb ischemia. The Kissing Balloon Technique (KBT) (by inserting two wires (0.01800 and/or 0.01400) were pushed down separately to the 2 tibial arteries below the bifurcation being treated, Non-compliant balloons were positioned with half the length in the branch artery and half in the main artery. We inflated them twice simultaneously at 12e 15 atm. for 1 min. [4]) is the primary treatment in 3 situations:
 - a. for cases with > 70% stenosis of the main artery located less than 1 cm of the bifurcation
 - b. occlusion of one branch with greater than 50% stenosis of the contralateral branch,

- c. Or greater than 50% bilateral stenosis [4].
 - Technical success was defined as PTA resulting in less than 30% residual stenosis with sufficient ante-grade flow; a suboptimal result was defined as sluggish flow and/or residual stenosis of 30% to 50% after repeated dilatation. Primary clinical success was defined as an improvement of at least one clinical category in the Rutherford-Becker classification) Primary patency was defined as persistent patency without any re-intervention including angioplasty, surgical procedures performed on or at the margins of the treated lesion, or amputation. Limb salvage was defined as the prevention of major amputation. Major amputation was defined as limb loss below or above the knee level, while minor amputation was defined as a trans metatarsal or more distal level amputation of the lower extremity [5].
6. In all cases, ante-grade access to the Common Femoral Artery (CFA) was preferred, 7 French sheaths were used was inserted through CFA, 0.018-inch hydrophilic guidewire (Terumo; Terumo Corporation, Tokyo, Japan) through a vertebral 4-French catheter was used. The guidewire was kept in each artery until balloon positioning.
7. The balloon diameter was ranged from 2 mm to 3.5 mm and selected based on the diameter of the target artery, while the length of the balloon was selected to cover the entire stenotic/occluded site and to proximally cover at least 2 cm of the popliteal artery (in cases of the AT and TPT) or the TPT (in cases of the PA and PT).
8. The balloon was inflated according to a lower pressure sufficient to expand completely the center of the stenotic/ occluded site. Balloons were inflated for 3 min, and the pressure was continuously corrected to the previous pressure value when a decrease was identified in the inflator. Both balloons were inflated and deflated at the same time.
9. In cases of recoil or dissection, 0.5 mg of nitroglycerin was administered, and the balloons were inflated a second time and held for 5 min.
10. Data from the institution's database and the angiographic images and videos of the procedures were analyzed. A specific protocol was used to collect the data. Patency and limb salvage were analyzed based on their definitions according to the Society of Vascular Surgery. (Stoner MC, Calligaro KD, Chaer RA, et al. Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease *Vasc Surg* 2016;64:e1e21.)
11. Follow-up examinations at an outpatient clinic within 10 days of the procedure and between 7 and 30 days, depending on the wound and clinical status.
12. The Ankle-brachial Index (ABI) was calculated, and duplex scanning was performed in all patients at 1, 3, 6, and 12 months and then annually.

Results

Between September 2020 and February 2022, 22 limbs with Threatened Critical Limb Ischemia (TCLI), defined according to TASC recommendations, and short tibial obstructive disease obstruction < 4 cm single or multiple stenosis) underwent endovascular therapy using the kissing balloon technique. This technique was planned only in patients in whom tibial arteries below the diseased bifurcation provided in-flow to the foot. Patient's ages ranged from 57-72 years with a mean age of 66.4 +1.07 years and male to female ratio was 13:7. All limbs were studied by ultrasonography & CT Angiogram from the external iliac artery to the pedal arteries. 2 Patients had bilateral tibial disease, 11 patients had 50% sided affection, and 7 patients had 32% with right-side Tibial vessel problems. Five limbs (23%) with ischemic ulcers or gangrene were evaluated for KBT treatment of infrapopliteal bifurcations (Figure 1).

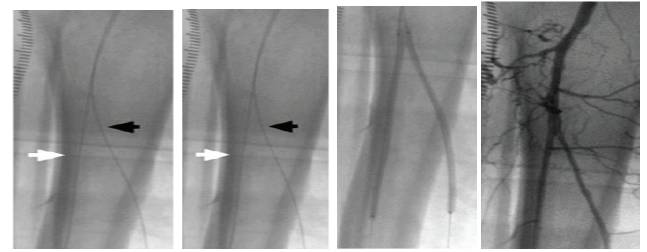
All angioplasty procedures were technically successful. No tibial branch was sacrificed. The degree of residual stenosis at bifurcation was below 30% in 6 limbs 30%, and a sub-optimal result in the peroneal artery ostium required reinflation of the 205 F. balloon for 2 minutes. The procedure time ranged between 40: and 65 minutes, with about 90-110 ML of contrast. Navigation time to insert the guidewire through the branch vessel depended mostly on the nature of the bifurcation B angle, which was defined as V- or T-type according to angle B being below 70° or above 70°, respectively. In the present study, 16 limbs 72% were of V type angle and 6 limbs 28% were of type T angle (Figure 2).

Three patients 13.5% had ischemic wounds with tibial vessel disease at the Bifurcation level had healed completely following angioplasty after 6 weeks, while 6 limbs 27% with foot gangrenous changes underwent minor amputation with good amputation stump healing after 8 weeks. The total healing time of the ulcers and gangrene varied from 2 to 6 months. Results in terms of disappearance of rest pain were achieved in 7 patients with 32% vessel patency and limb salvage was reported in 6 limbs 27% (Table 1).

During the follow-up using Duplex ultrasonography, showed 2 cases 9% showed thrombosis after 5 months requiring redo-KBT and then restenosis 7 months later, again treated with KBT. 4 cases developed asymptomatic restenosis (20% -30%) after 9 months, but without clinical indications for further treatment. No major complication was elicited during the procedure or at the early follow-up period.

Discussion

This study comprised 22 limbs of bifurcated infra popliteal atherosclerotic lesions and all of them were treated by the kissing balloons technique, while previous studies of the popliteal artery and tibio-peroneal trunk bifurcation that was treated by the kissing balloon technique were limited to a case report⁴ and a technique description [6]. In contrast to the coronary arteries, the use of stents in IP vessels has no consensus. In a meta-analysis by Jens, angioplasty with



(Before treatment)

(3 months after angioplasty)

Figure 1: Clinical result.

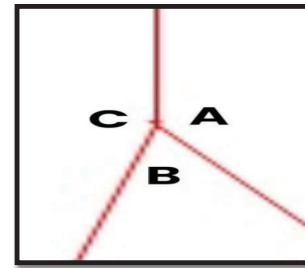


Figure 2: The Complexity of Bifurcation Lesions.

Table 1: Clinical patient outcome.

Clinical patient outcome	No of limbs
Spontaneous wound healing	3 limbs
Wound healing with minor amputation	6 limbs
Rest pain disappearance	6 limbs
Limb salvage & improvement of claudicating distance	5 limbs

bailout stenting was the recommendation.1 DES with sirolimus or everolimus coating (DES) was studied in Infra popliteal lesions and demonstrated better primary patency than plain angioplasty [1]. The mean age in this study was 66.4 +1.07 years and patients' ages ranged from 57-72 years which was similar to that age reported by M. Gargiulo, et al. The male-to-female ratio was 13:7with a high predominance of this type of pathology in male gender, which agreed with M. Gargiulo, et al. who reported male/female as 5/3 in his series [4]. For the infra popliteal and tibial region, kissing balloon angioplasty may be performed using a single catheter with a double short balloon 5 or two balloon catheters [4]. In the present study, we considered two long shaft balloons with different diameters to be more effective in extensive infrapopliteal stenotic and obstructive lesions, even if they need a larger diameter sheath and two inflators. It is possible to choose the proper balloon length and diameter according to the extent of the lesion and vessel morphology. Single access of ipsilateral transfemoral puncture with a 7 F sheath was done for all cases, while Biaggio



RB, et al. reported that in most of the cases, two access sites with 4 or 5- French sheaths, rather than 1 access site with a 6 or 7-F sheath, were used based on the team's experience with SFA access [4]. The use of 2 smaller access sites helped avoid the misplacement of the guidewire during manipulation. The procedure time ranged between 40: and 65 minutes, with about 90-110 ML of contrast. Navigation time to insert the guidewire through the branch vessel depended mostly on the nature of the bifurcation B angle, which was defined as V- or T-type according to angle B being below 70° or above 70°, respectively. In the present study, 16 limbs 72% were of V type angle, and 6 limbs 28% were of type T angle, and there was no significant difference in navigation time in both types. In the coronaries, the V-shape is easier to cannulate, but the carinal shift often occurs. Cannulation of the lateral branch is more difficult with the T-shape, but the carinal shift occurs less frequently [6,9] All limbs had 100% clinical success and 100% primary patency rate with residual occlusion below 30%, and no tibial vessel was sacrificed in all procedure, this was in agreement with Kacrinishi, et al. who made their study for limb salvage procedure in infrapopliteal lesions using the kissing balloon technique [10]. In this study all limbs had been successfully dilated without the need to use a peripheral arterial stent, while Guardiola had to use a peroneal artery stent to overcome persistent stenosis at its ostium [4]. Clinical and Duplex Follow-up results showed Primary 30-day patency was achieved in all cases with no early restenosis and without kissing stent. As we reported primary patency at 30 days, 1 year, and 2 years was 100%, 73%, and 63.5%, respectively in our study and no data are available on effective treatment strategies for the infrapopliteal region, these results were to those results obtained by Sameh Elimam, et al. when they analyzed their outcome after angioplasty with duplex assessment [11]. No major complications were reported in this study, although serious complications were observed by Arash, et al. who got balloon entrapment while they were performing below-the-knee angioplasty and succeeded in withdrawing it endovascularly [12,13].

The limitations of the study are the retrospective analysis of the data and selective sampling with the possibility of more advanced disease in Infrapopliteal (IP) arteries among our patients.

Recommendations and future directions

Arterial bifurcation usually needs special care while dealing with ostial stenosis, and in these situations, using the 2 wires technique is essential to maintain patency of the two arteries either by inflation of one artery or both arteries. As arterial stent was rarely used in the infra popliteal region, the kissing balloons technique could be the promising one to maintain patency of bifurcated lesions, providing a quick and safe technique. Developing one shaft with two balloons dedicated to peripheral arterial angioplasty and running multicentre randomized studies is needed to increase the learning curve for infra popliteal interventions.

Conclusion

The kissing balloon technique is a feasible bifurcation approach for infrapopliteal angioplasties to maintain the patency of both branches after ballooning. The results regarding wound healing, limb salvage, and primary patency are comparable to those in the usual infrapopliteal approach. The comparison between the anterior tibial artery and tibioperoneal trunk bifurcation and the peroneal artery and posterior tibial artery bifurcation revealed no difference in wound healing, primary patency, and limb salvage. In patients with popliteal and tibioperoneal trunk bifurcation lesions, the Kissing Balloon Technique using retrograde pedal access in conjunction with the conventional antegrade CFA access could be the treatment of choice as it appeared to be a successful, safe, and effective technique with lower access site complications and shorter procedure time.

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