

PERCUTANEOUS BALLOON ANGIOPLASTY FOR ISOLATED BELOW-THE-KNEE LESIONS ORIGINATING CRITICAL LIMB ISCHEMIA. ONE CENTER EXPERIENCE.

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INTRODUCTION:

Major amputation is of great concern in patients with critical limb ischemia (CLI). These patients are typically elderly, with multiple co-morbidities and limited life expectancy. There is not consensus for this illness yet; however, most reports remark that endovascular techniques, such as percutaneous balloon angioplasty (PTA), should be the first choice of treatment. Long-term patency remains an issue, though, the most important thing to take into consideration should be injury healing or rest-pain relief; as these may lead to limb salvage.

PURPOSE:

To show our experience in endovascular treatment with simple PTA for patients with CLI and isolated below-the-knee lesions (BTK). We describe limb salvage rate as a primary end-point. As secondary end-points we remark technical success, primary clinical success at 6 months, 1 and 2 years, need of minor amputation, mortality and hospital stay.

METHODS:

We present an observational study from a retrospectively collected. We include all patients with CLI and isolated BTK, that were treated in our centre with simple PTA, from 2005 to 2015. Patients who underwent concurrent treatment for above the knee disease were excluded from the study. Diagnosis was done with preoperative Doppler ultrasonography mapping and intraoperative angiography.

Procedure details: Most procedures were performed under regional anaesthesia or under sedation combined with local anaesthesia. Cases were performed using 4Fr and 5Fr sheaths, usually via femoral ante-grade approach.

All patients received 5000 heparin-bolus during the procedure. To cross the lesions, 0,014' or 0,018 guide-wires were used. PTA was performed with low-profile balloons with different inflating pressures depending on the manufacturer. Ballooning time was 3 minutes. Balloon size and length depended on vessel characteristics (stenosis or occlusions) and on the surgeon preference. Following sheath removal, manual compression for 15-20 minutes was done.

Dual antiplatelet treatment was assigned after PTA for a period of 6 months with combination of statin therapy.

Statistical analysis: STATA Statistic/Data Analysis, Version12.0. Continuous variables expressed as mean +/- SD or Median. Categorical variables presented as absolute numbers and percentages. Comparison of subjects: student-t / Chi-Square test, as appropriate. Kaplan-Meier for survival analysis. Statistical significance: $p < 0,05$.

DEFINITIONS:

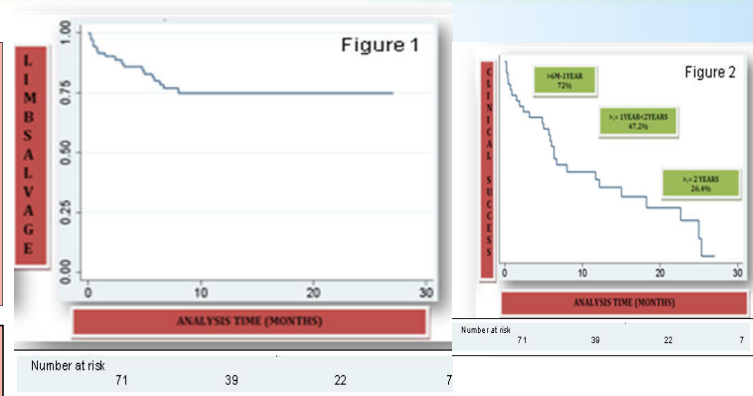
- Technical success: performing PTA in at least one injured vessel.
- Primary clinical success: evaluated as clinical outcome with ulcers healing or free of rest pain. In 25% of cases, follow up included Doppler ultrasonography and ankle-brachial index.
- Minor amputations: digital and trans-metatarsal amputations.

RESULTS:

We included in our study a total 72 limbs treated with PTA for isolated BTK disease. Demographics: Table 1. In 59,8% of cases, one vessel PTA was done, and in 40,2% two or more tibial PTA were performed. Procedural data: Table 2. All mayor amputations were performed in the first year (median 83,5 days, ranged from 6 to 240). Limb salvage rate was 75% (Figure 1). Mayor limb amputation was done in 17 cases (25%). The univariate analysis showed that failed attempt of one vessel angioplasty was the only statistically significant predictor of limb amputation ($p=0,014$). Technical success rate was 97%. Primary clinical success is represented in Figure 2. Table 3 summarizes the strenght of association between different risk factors and absence of clinical success. Minor amputation was needed in 64% of cases. There was no perioperative mortality. For patients who died during the follow-up, the median survival time was 56 days (range: 52-1095). Survival rate was 75%.

VARIABLE	NUMBER OR MEDIAN	% OR RANGE
Age (years)	75	49-94
Male	53	74%
CO-MORBIDITIES		
HYPERTENSION	55	75%
DIABETES	58	80,5%
HYPERLIPIDEMIA	39	54%
CURRENT SMOKER	10	14%
RENAL IMPAIRMENT	16	22%
ISCHEMIC HEART DISEASE	26	33%
RUTHERFORD STAGE		
RUTHERFORD 4	9	12,5%
RUTHERFORD 5-6	63	87,5%

VARIABLE	NUMBER OR MEDIAN	% OR RANGE
VESSEL LESIONS		
STENOSIS	35	49%
OCCLUSION	36	51%
VESSEL TREATED		
ANTERIOR TIBIAL	22	31%
POSTERIOR TIBIAL	8	11%
PERONEAL	13	18%
2 OR MORE VESSEL PTA	29	40%
FAILED PTA ATTEMPTED	21	30%
STENOSIS	10	48%
OCCLUSIONS	11	52%
ANTERIOR TIBIAL	9	43%
POSTERIOR TIBIAL	4	19%
PERONEAL	2	9%
PEDIA	4	19%
MORE THAN 1 FAILED ATTEMPTED	2	10%
Antegrade APPROACH	69	97%
Retrograde APPROACH	0	
Combined APPROACH	2	3%
NEED OF MINOR AMPUTATION	46	64%
DIGITAL AMPUTATION	24	52%
TRANSMETATARSAL	22	48%
TECHNICAL SUCCESS	69	97%
COMPLICATIONS	7	10%
PSEUDOANEURYSM	1	14%
MAYOR AMPUTATION <30 DAYS	6	86%
HOSPITAL STAY (DAYS)	18	3-45
FOLLOW UP (DAYS)	365	6-2555



VARIABLE		ABSCENSE OF CLINICAL SUCCESS >,=6 m <1year	ABSCENSE OF CLINICAL SUCCESS >,=1year <2 years	ABSCENSE OF CLINICAL SUCCESS >,=2years
HYPERTENSION	O.R.	8	4,791	9,09
	C.I. 95%	0,981-65,199	0,946-24,269	1,564-49,965
DIABETES	P-value	0,025	0,435	0,005
	C.I. 95%	0,514-12,641	0,439-8,227	0,590-13,813
DYSLIPIDEMIA	P-value	0,239	0,384	0,18
	O.R.	2,006	1,888	2,638
RENAL IMPAIRMENT	C.I. 95%	0,661-6,086	0,643-5,442	0,777-8,956
	P-value	0,214	0,244	0,115
IHD (ischemic heart disease)	O.R.	0,888	0,522	0,758
	C.I. 95%	0,852-7,333	0,962-9,538	1,002-16,793
RUTHERFORD 5-6	P-value	0,090	0,053	0,041
	O.R.	1,322	0,709	0,941
FAILED PTA ATTEMPT	C.I. 95%	0,249-7,006	0,130-3,849	0,141-6,254
	P-value	0,742	0,69	0,95
RUTHERFORD 4	O.R.	2,160	2,455	3,437
	C.I. 95%	0,731-6,382	0,800-7,535	0,799-14,772
RUTHERFORD 5-6	P-value	0,159	0,112	0,087

CONCLUSIONS: Endovascular treatment with PTA in patients with CLI and isolated BTK is a safe treatment, moreover representing a high-risk group. It shows a low rate of perioperative morbidity and mortality. We demonstrate an acceptable rate of limb salvage at one year of follow up, as some previous series report.