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 endpoint. 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 Doppler ultrasonography 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-pressure balloons with different inflating pressures depending on the lesion characteristics. Ballooning time was 3 minutes. Balloon size and length depended on vessel characteristics (stenosis or occlusions) 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 aspirin and clopidogrel, as absolute numbers and percentages. Comparaison 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 major amputations were performed in the first year (median 83.5 days, ranged from 6 to 240). Limb salvage rate was 75% (Figure 1). Major 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 strength 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%.

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.