

BACKGROUND

- **Autologous cell therapy (ACT)** is a new therapeutic approach for patients with **critical limb ischemia (CLI)** who are not eligible for standard revascularization (**no-option CLI**)
- Data about **long-term clinical outcomes of ACT** in these patients are lacking

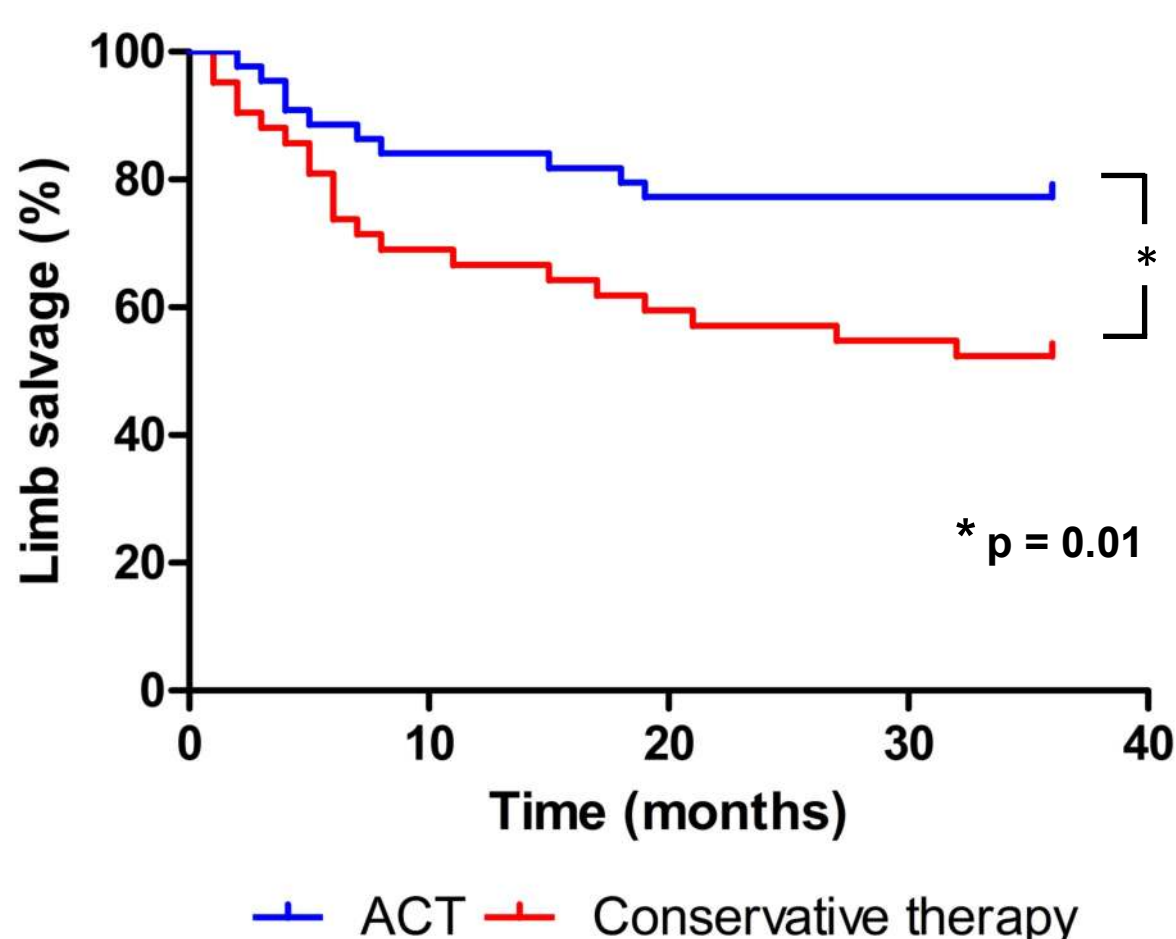
AIM

The aim of our study was to compare the mortality and amputation rates of patients with diabetic foot (DF) and CLI treated by ACT with patients treated conservatively

Table 1. Basic characteristics of patients

	ACT group n = 45	Control group n = 42	p
Age (years)	64.4 ± 14	67.5 ± 9	NS
Gender (% of men)	80	71.4	NS
Type of diabetes (% DM2T)	82.2	90.5	NS
Diabetes duration (years)	24.2 ± 14	20.9 ± 10.8	NS
Glycated hemoglobin (mmol/mol)	59.6 ± 14	62 ± 15.2	NS
Ischemic heart disease (%)	64.4	45.2	0.07
Hypertension (%)	91.1	92.9	NS
Renal failure - dialysis (%)	20	11.9	NS
Immunosuppressive therapy (%)	17.8	7.1	NS
Angiographic finding - Graziani (mean ± SD)	5.0 ± 0.9	5.1 ± 0.8	NS
Baseline TcPO ₂ values (mmHg)	17.7 ± 10.4	16.5 ± 9.8	NS

Figure 1. The rate of major amputation in patients treated by ACT compared to conservative therapy over 3 years



METHOD

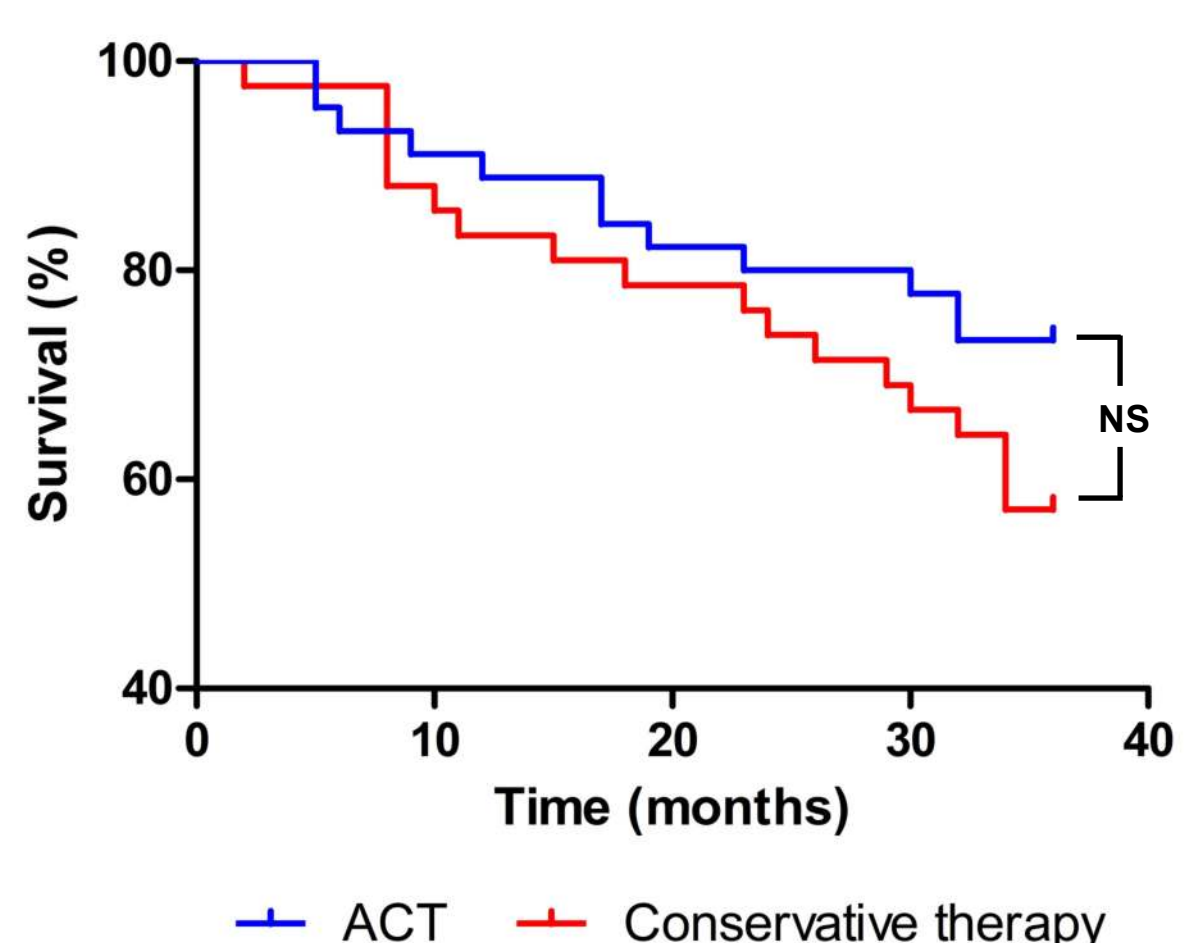
- **Eighty-seven patients** with DF and no-option CLI treated in our foot clinic over 5 years were enrolled into the study (Table 1.)
- **No-option CLI** was defined as **TcPO₂* < 30 mmHg** with ulcers after **unsuccessful standard revascularization**
- **Forty-five patients** were treated by **ACT**
- **Forty-two patients** were treated **conservatively** and formed the control group
- **Mortality and rate of major amputation** were assessed over **3 years** follow-up period

*TcPO₂ - transcutaneous oxygen pressure

RESULTS

- The **rate of major amputation** after 3 years was **significantly lower in ACT group** in comparison with control group (22.2 % vs. 47.6 %, p = 0.01), Figure 1.
- There was a **trend to lower mortality** (24.4 % vs. 42.9 %, p = 0.07) and slightly higher frequency of ischemic heart disease (64.4 % vs. 45.2 %, p = 0.07) **in ACT group** in comparison with control group, Figure 2.
- **Causes of major amputation after ACT:** progression of infection (70%), progression of ischemia (20%), pain or others (10%)

Figure 2. Mortality rate in patients treated by ACT compared to conservative therapy over 3 years



CONCLUSION

- Our study showed **significantly lower long-term amputation rate** in patients treated by ACT in contrast to patients treated conservatively

- Our results suggest that **ACT has the potential to be a promising treatment** of diabetic patients with no-option CLI and DF