

BIONETIC-I

The BIONETIC-I¹ study evaluates the safety and effectiveness of Dynetic[™]-35 stent in treating atherosclerotic iliac artery lesions..

Conclusions

- The 24-month BIONETIC-I study results support the long-term safety and effectiveness of the Dynetic[™]-35 Cobalt Chromium Balloon-Expandable Stent System in the treatment of iliac artery disease:
 - 6.1 % Major Adverse Events (MAE)
 - 95.4 % Freedom from clinically-driven Target Lesion Revascularization (Fcd-TLR)
 - 82.6 % Primary Patency (PP)
 - 99.0 % Freedom from Major Target-Limb Amputation
 - 91.2 % Survival Rate
- Clinically relevant improvement in Rutherford Classification: 94.7 % improved at least 1 category

Study design

Prospective, international, multicenter, non-inferiority, single-arm study with up to 60-month follow-up evaluating the safety and efficacy of Dynetic[™]-35 stent in the treatment of peripheral artery disease in the iliac arteries.

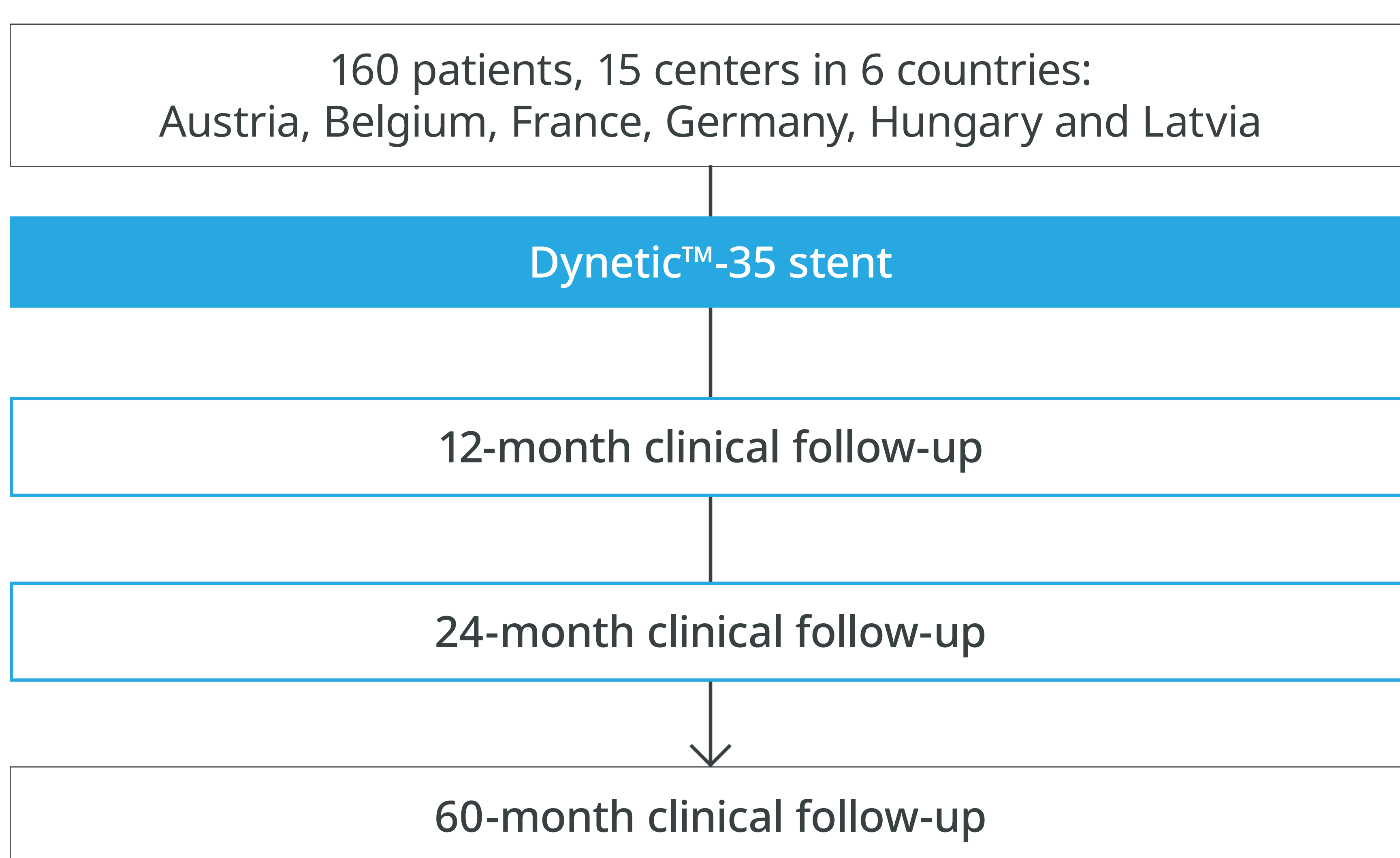
Endpoints

Primary endpoint (composite MAE rate)

- Device or procedure related death within 30 days post index procedure
- Clinically-driven target lesion revascularization (cd-TLR)
- Major index limb amputation up to 12 months post index procedure

Main secondary endpoints*

- Primary patency
- Survival
- Freedom from major target limb amputation
- Freedom from CD-TLR
- Ankle brachial index (ABI)
- Walking impairment questionnaire (WIQ)
- Rutherford classification



Lesion characteristics

	N=212
Lesion location	
Common Iliac Artery (CIA)	79.2 %
External Iliac Artery (EIA)	19.3 %
CIA and EIA	1.4 %
Lesion length**	
Occlusion	10.4 %
Length of occluded section** (mm)	47.2±21.8
Stenosis pre-procedure** (%)	85.5±9.3
RVD** (mm)	8.0±1.0
Calcification	
None/Mild	9.9 % / 27.8 %
Moderate/Severe	31.6 % / 30.7 %
TASC classification	
Type A/B	60.8 % / 34.4 %
Type C/D	3.8 % / 0.9 %

Baseline characteristics

	N=160
Male	61.9 %
Age**	64.6±8.8
BMI**	26.0±4.4
Smoker (current)	51.9 %
Hypertension	77.5 %
Hyperlipidemia	74.4 %
Previous peripheral intervention/surgery (PVI)	33.1 %
Diabetes	21.9 %
Coronary artery disease	31.9 %
Renal disease	5.6 %
Cancer	14.4 %

Procedure characteristics

Pre-dilatation lesions	38.7 %
Number of Dynetic [™] -35 stent implanted per lesion	
1/2/3	92.5 % / 7.1 % / 0.5 %
RS [§] after Dynetic [™] -35 stent implantation** (%)	3.7±9.5
Procedure duration** (min)	41.2±26.4
Technical success of Dynetic [™] -35 stent ³	98.1 %
Procedural success based only on Dynetic [™] -35 stent ⁴	98.1 %

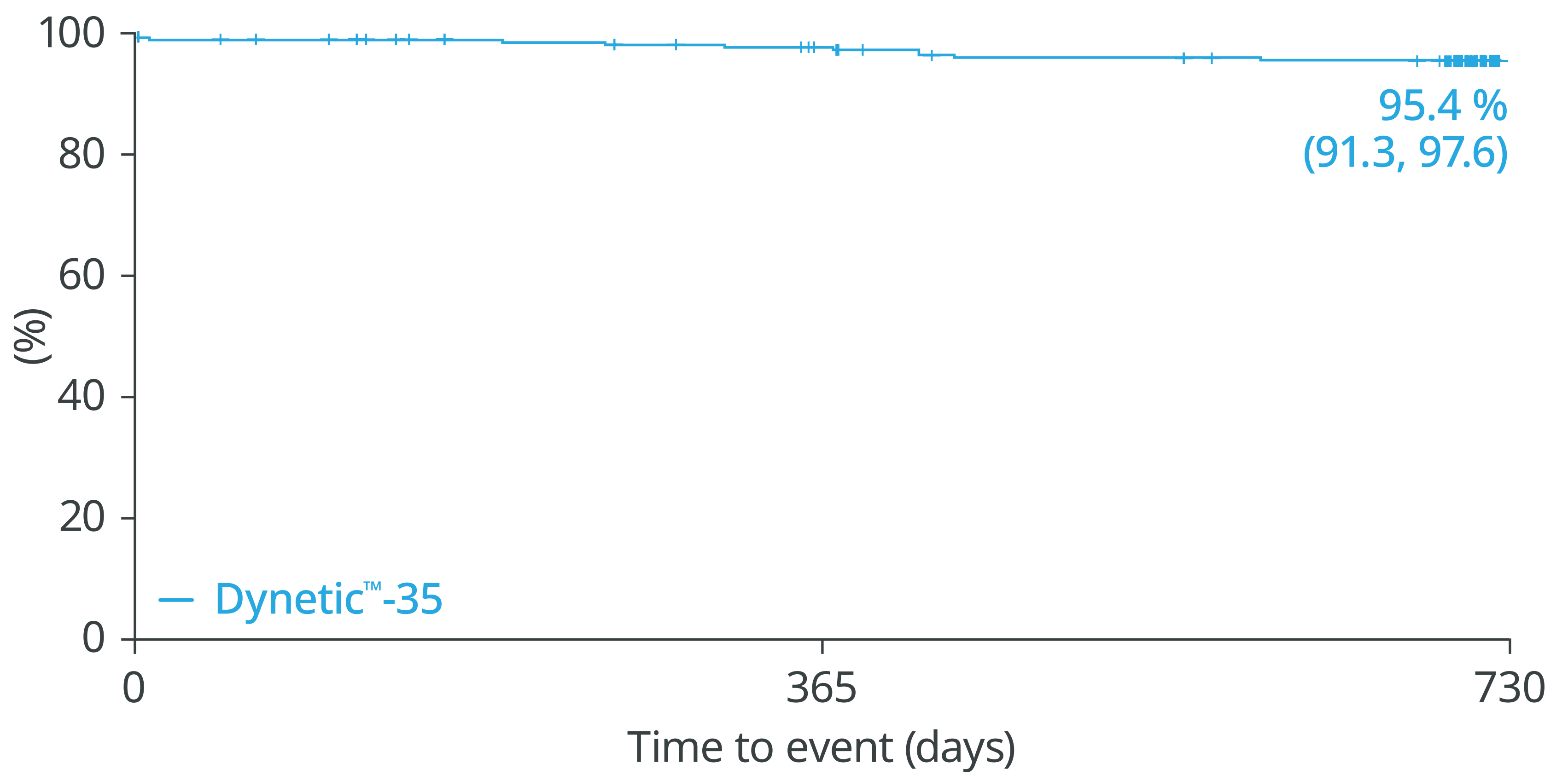
* 12-, 24- and 60-month

** Data shown as mean±SD (range)

[§] Residual Stenosis

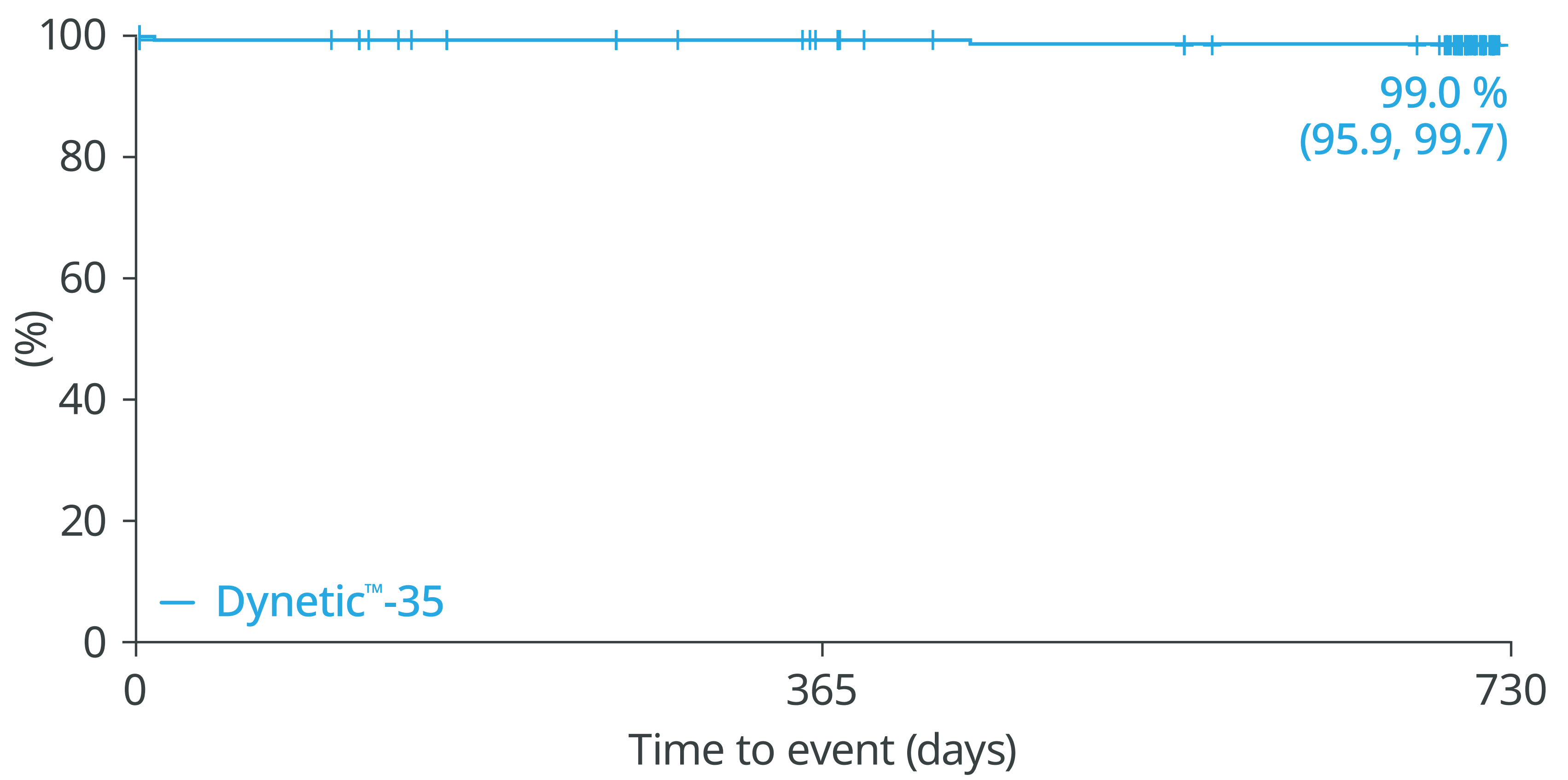


Freedom from clinically-driven TLR



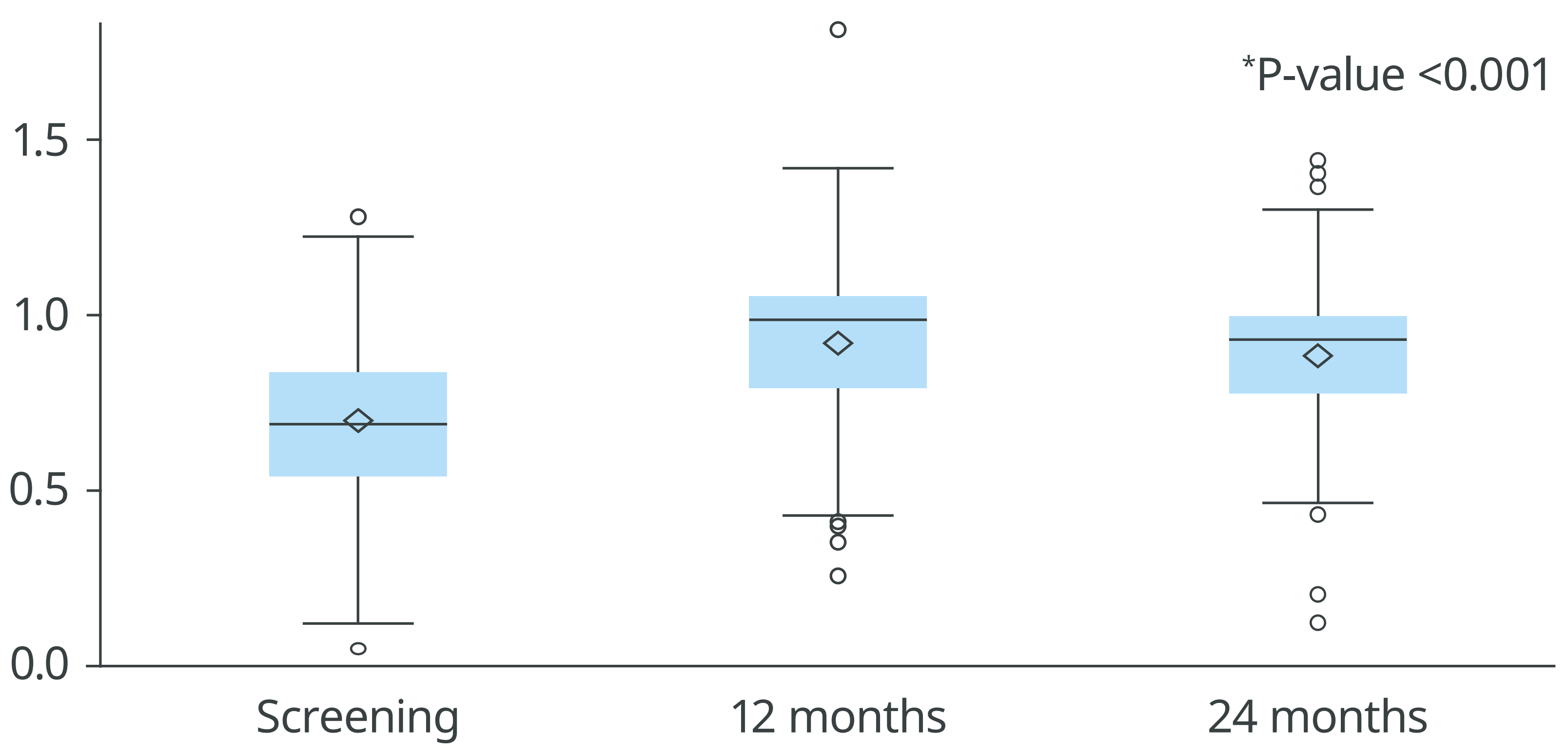
Number at risk	212	190	104
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Freedom from Major Target-Limb Amputation

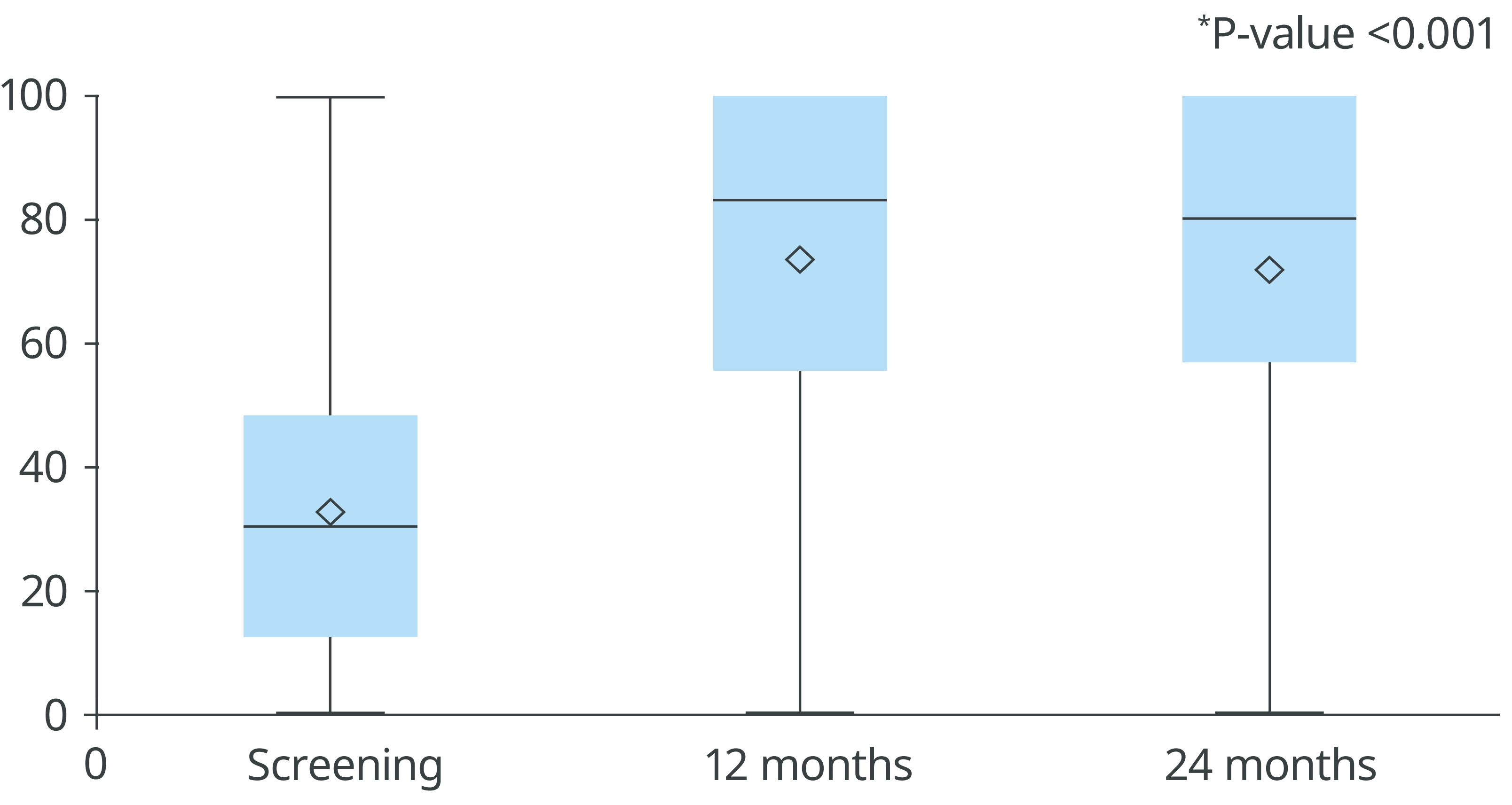


Number at risk	205	186	104
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Change in ankle brachial index (ABI)

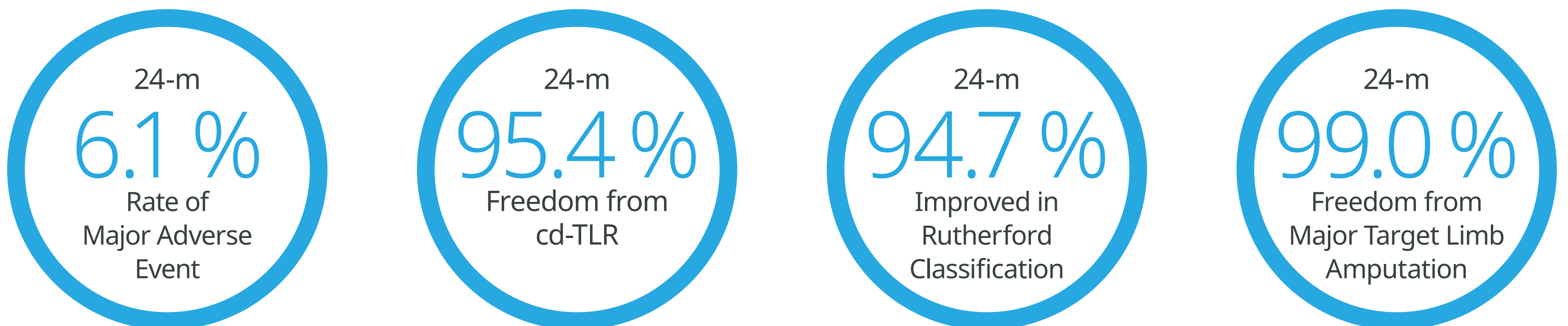


Walking impairment questionnaire (WIQ) overall score



*for difference from screening

BIONETIC-I 24-month key outcomes



Principal investigator: Prof. Marianne Brodmann, Graz, Austria

References:

- 1 Brodmann M. Dynetic-35 Cobalt chromium balloon-expandable stent for peripheral iliac lesions: 24-month results of the BIONETIC-I Multi-Center study. Presented at: CIRSE, September 16, Barcelona, Spain.
- 2 Technical Success: successful delivery of the investigational stent at the lesion site and deployment to cover the adequate length of the lesion with residual stenosis of <30 % (for all treated lesions during index procedure determined by angiography immediately after stent placement).
- 3 Procedural success: rate of technical success and no MAEs from time of enrollment through discharge (or if moved to a different ward).

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