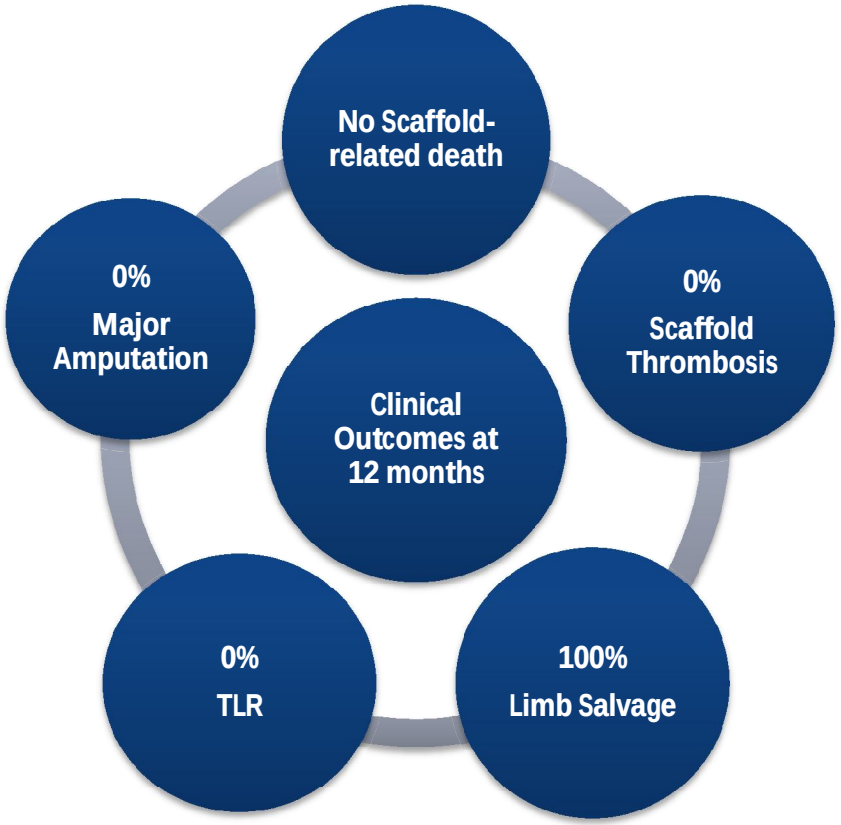
CREDENCE BRS-1 study

Study Highlights

- Principal Investigator: Dr. Vimal Someshwar
- Credence BRS-1 is a prospective, open-label and multicentre clinical study to evaluate the safety and performance of Credence BRS Sirolimus-Eluting BioResorbable Peripheral Scaffold System in subjects with *de novo* native peripheral artery lesions
- The present study demonstrated favourable safety and performance of Credence BRS Sirolimus-Eluting BioResorbable Peripheral Scaffold in *de novo* native peripheral artery lesion



❖ Study Design

A prospective, multicentre, single-arm, open-label study

Till date a total of 26 patients are enrolled

8 investigational sites across India

Clinically follow up at 30 days, 6 months, 1 year

Telephonic follow up at 2 years, 3 years, 4 years and 5 years

Angiographic follow-up at 6 months

Analysed by Independent Core Lab-Stanford University, Stanford, CA, USA

❖ Study Results

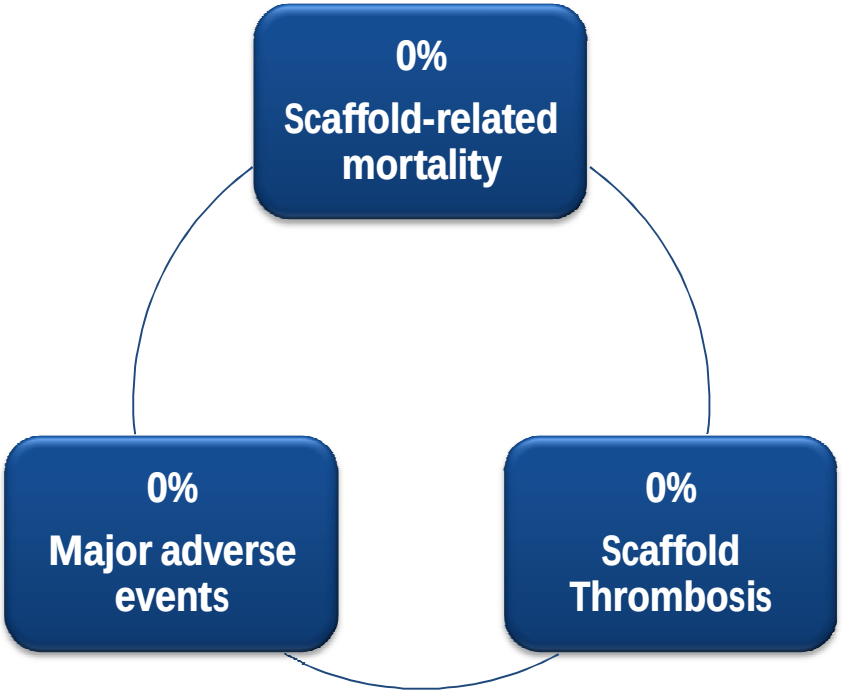


Figure 1: Cumulative clinical events till 12 months follow-up

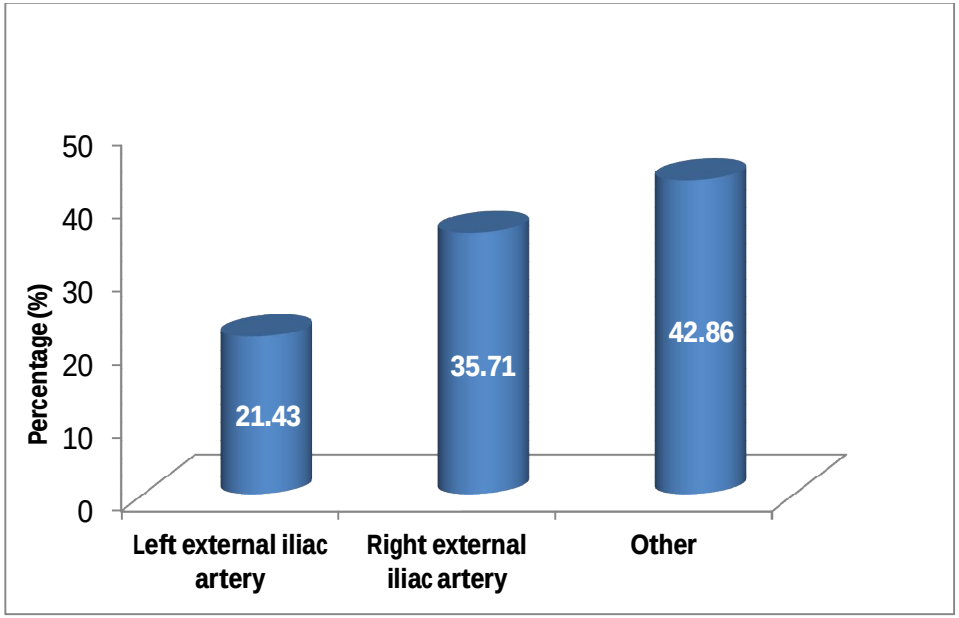


Figure 2: Baseline lesion characteristics of study population

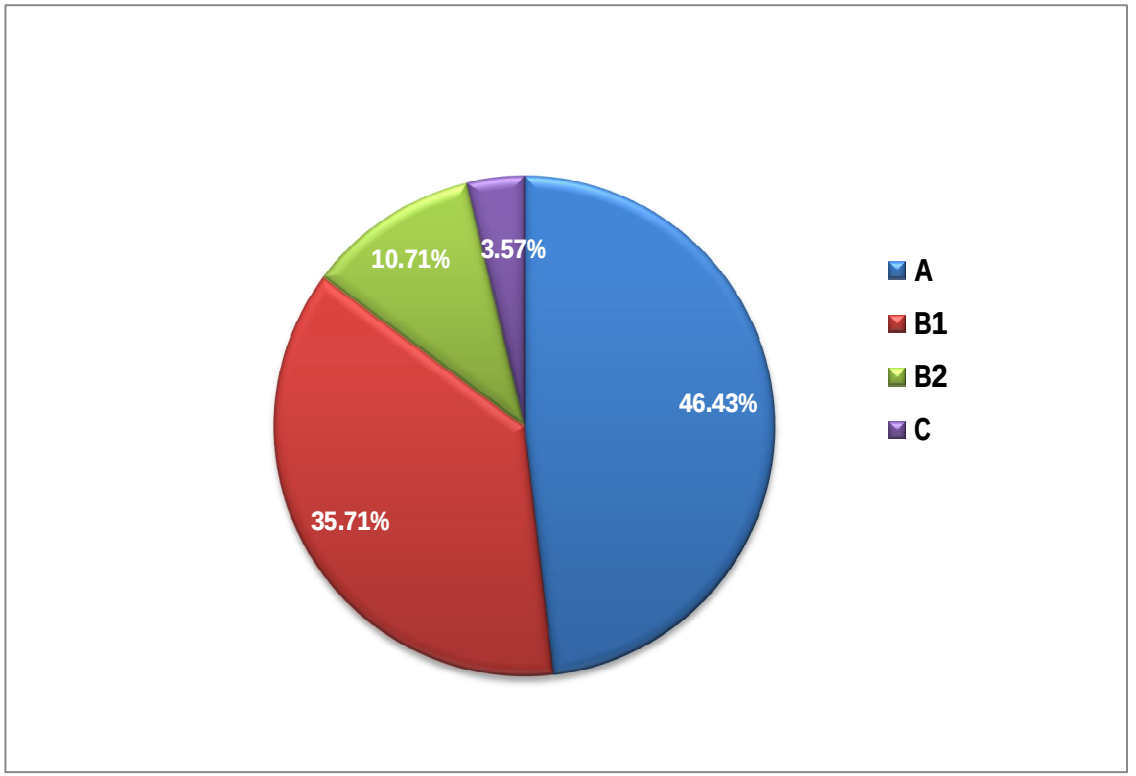


Figure 3: ACC/AHA Lesion type, (%)

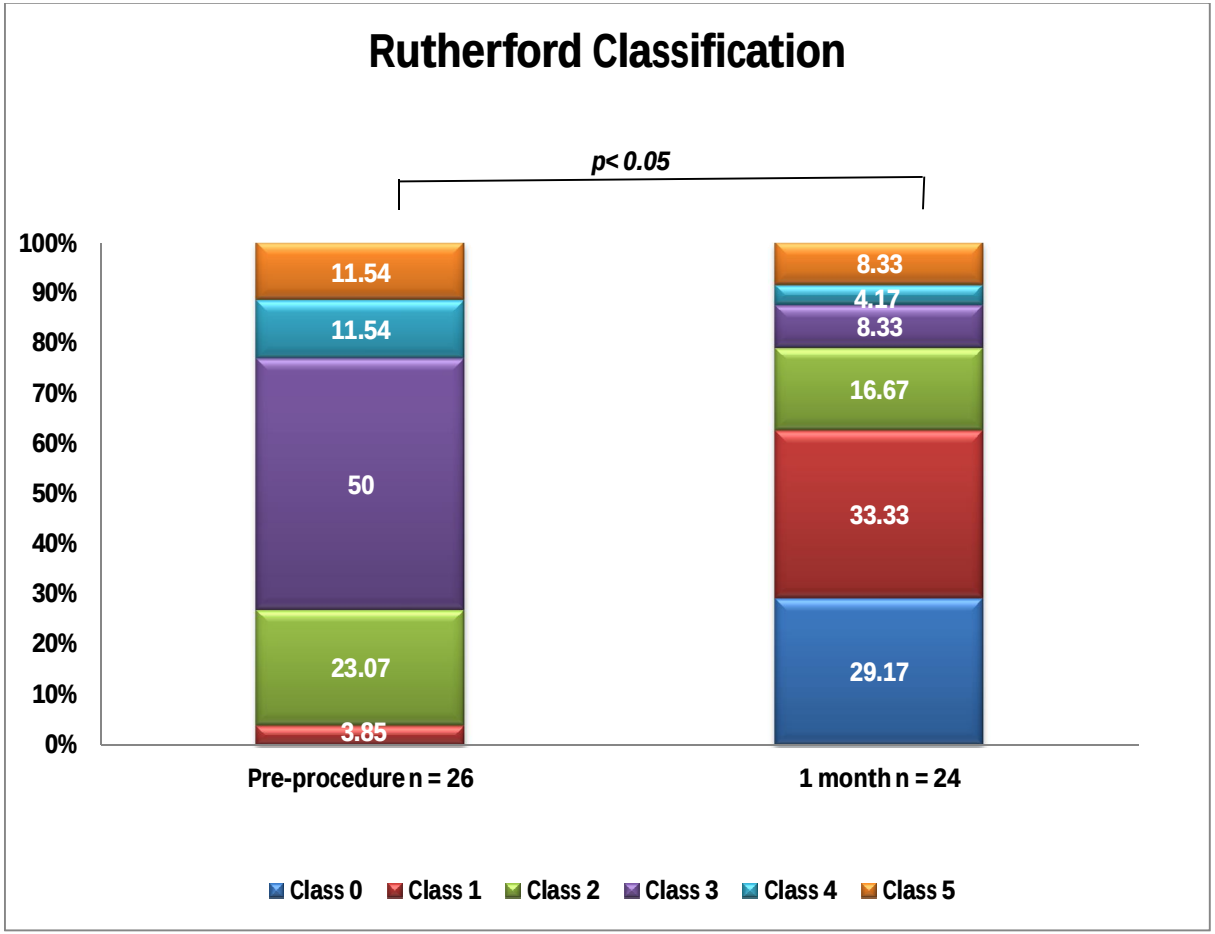


Figure 4: Distribution of Rutherford Classification at pre-procedure and 1-month follow-up

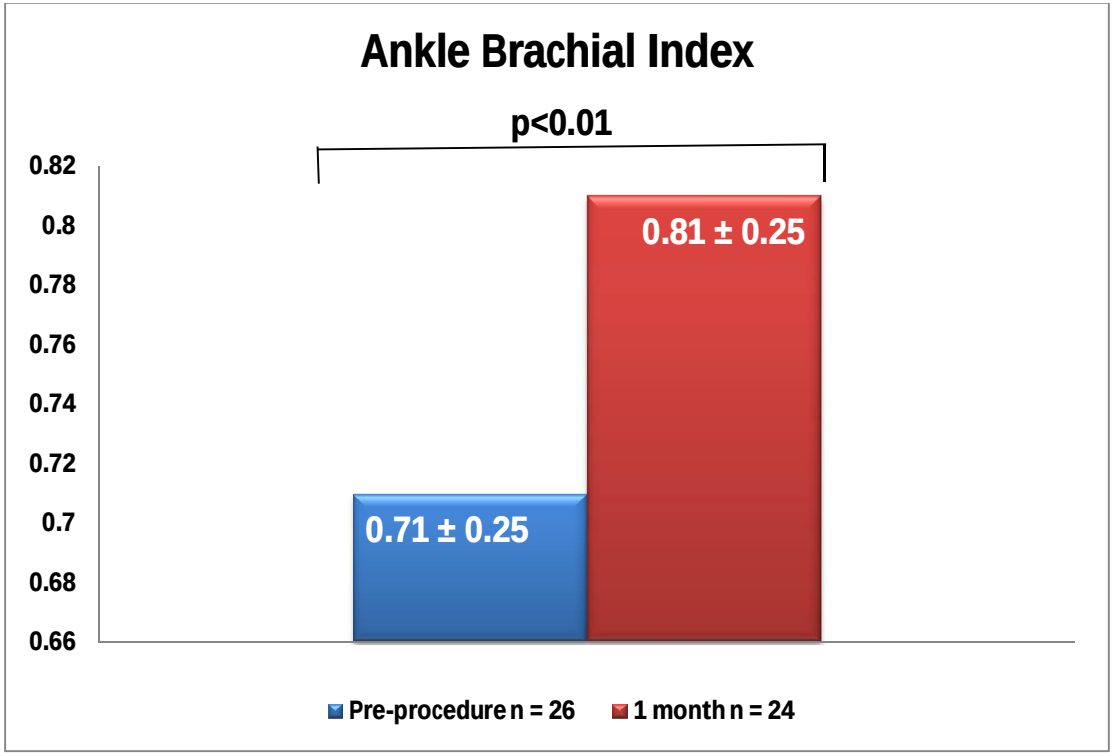


Figure 5: Rate of hemodynamic improvement as assessed by changes in Ankle-Brachial Index

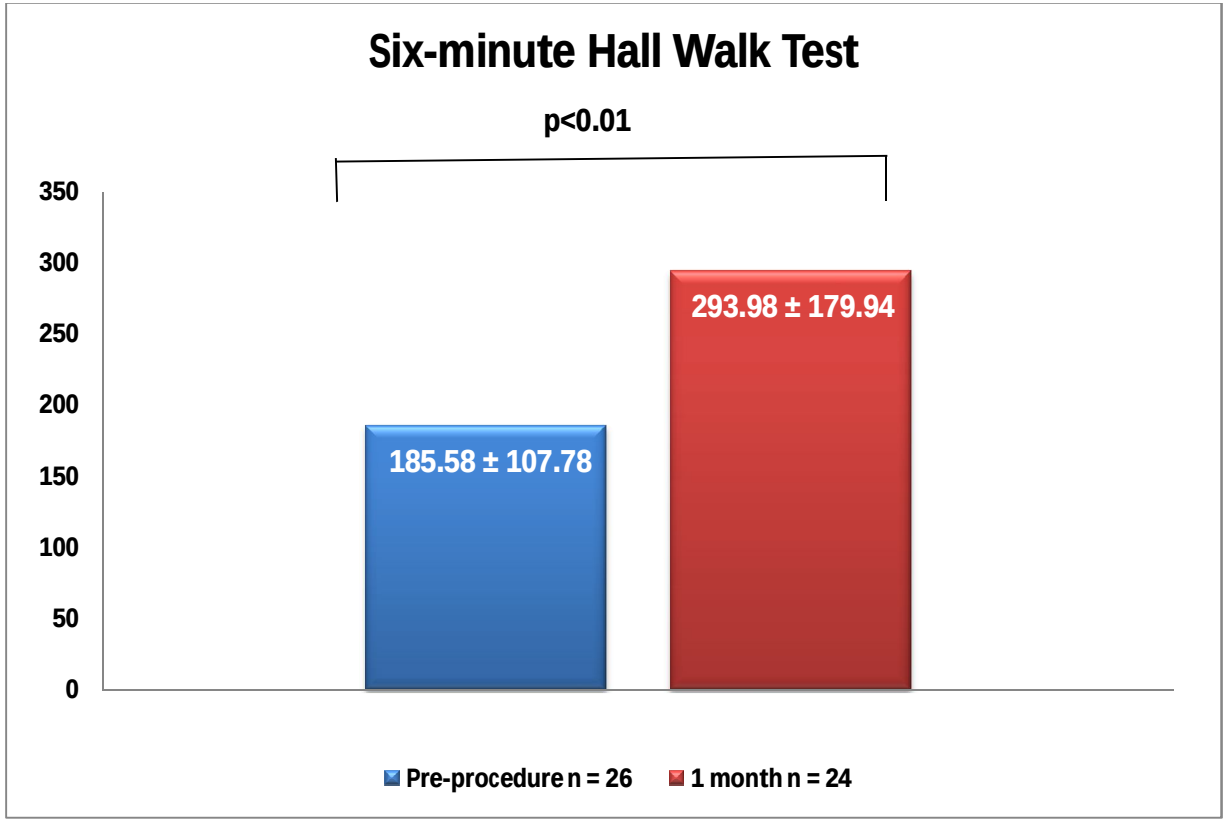


Figure 6: Outcome of Six-minute hall walk test at pre procedure and 1-month follow-up

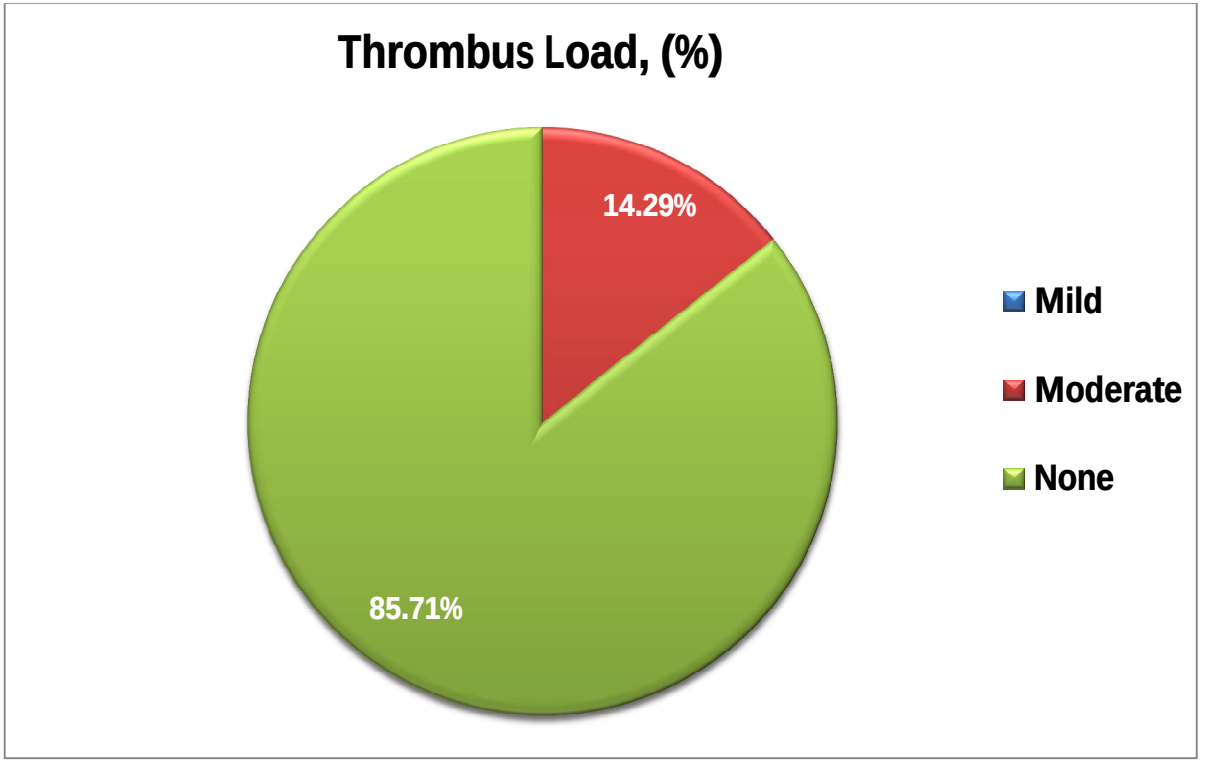


Figure 7: Distribution of Thrombus load in patients treated with Credence BRS

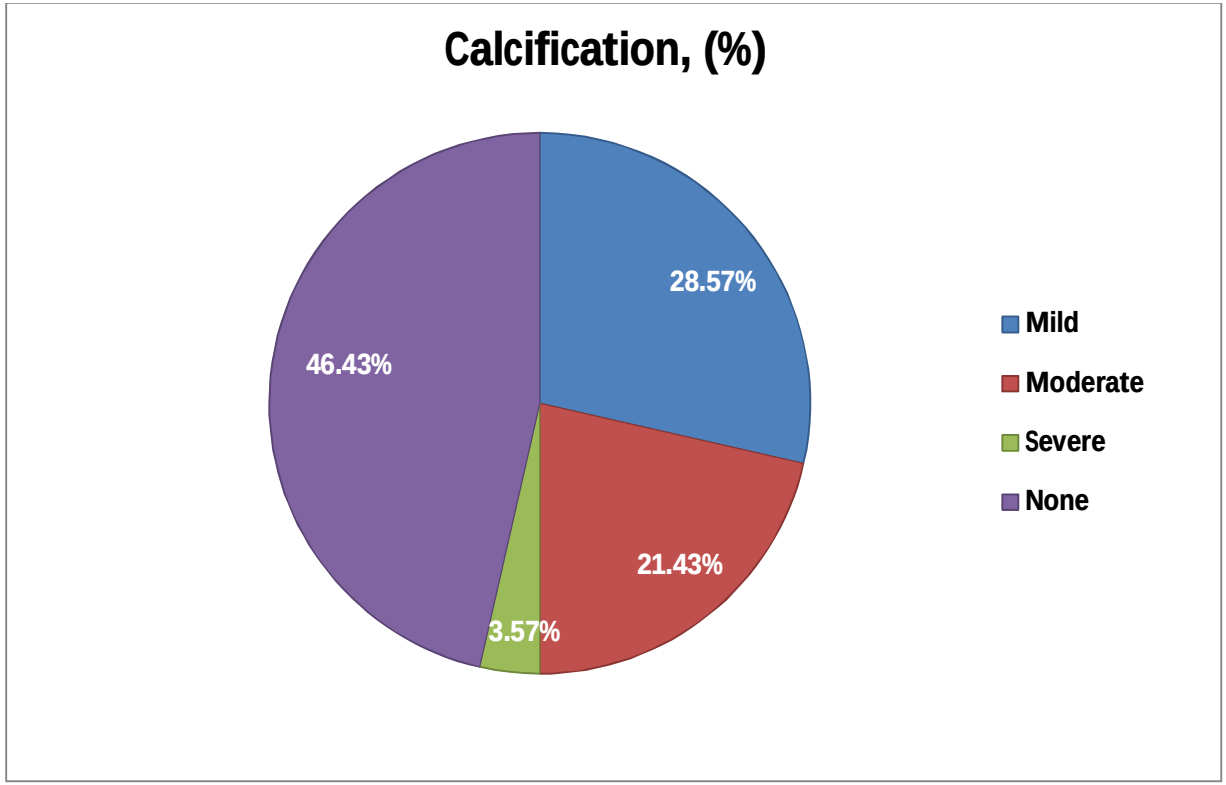


Figure 8: Calcification in patients treated with Credence BRS

❖ Reference

1. CTRI Number: CTRI/2017/01/007638

http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=15326&EncHid=&userName=CTRI/2017/01/007638

2. Gireesh Warawdekar, Initial experience with sirolimus-eluting bioresorbable peripheral scaffold for the treatment of de novo native peripheral artery lesions, The Charing Cross Symposium 2020 (21-24 April)