The Benelux-IVL registry

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HEART LUNG
CENTER LEIDEN

BENELUX-IVL

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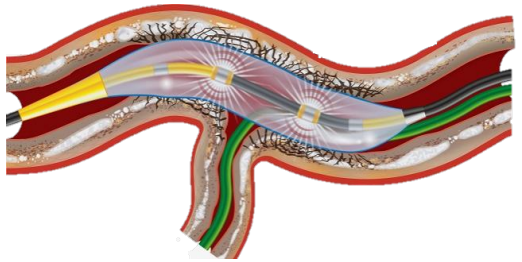
ntroduction

Severe coronary artery calcification

- present in up to 25% of PCI's[1]
- Associated with worse procedural success (stent underexpansion) and risk of future events (in-stent restenosis/TVR)

Intravascular lithotripsy (IVL)

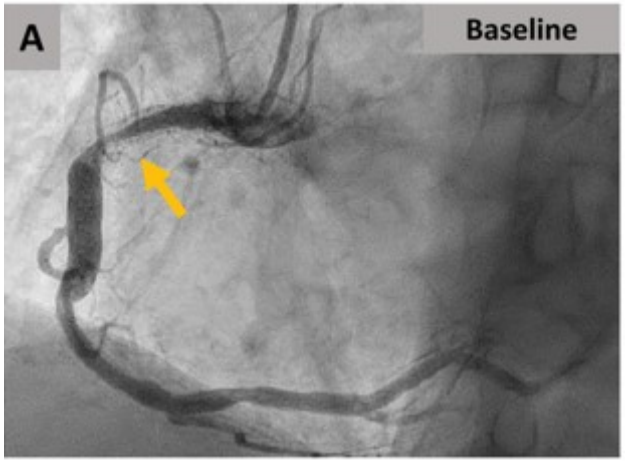
- Balloon-based technique
- Acoustic shockwaves at low pressure → fracture calcium deposits in vessel wall → compliance increase
- Deployment of stents and balloons → luminal gain
- Proven to be safe and effective for treatment of severe CAC in the DISRUPT-CAD studies I – IVL[2]

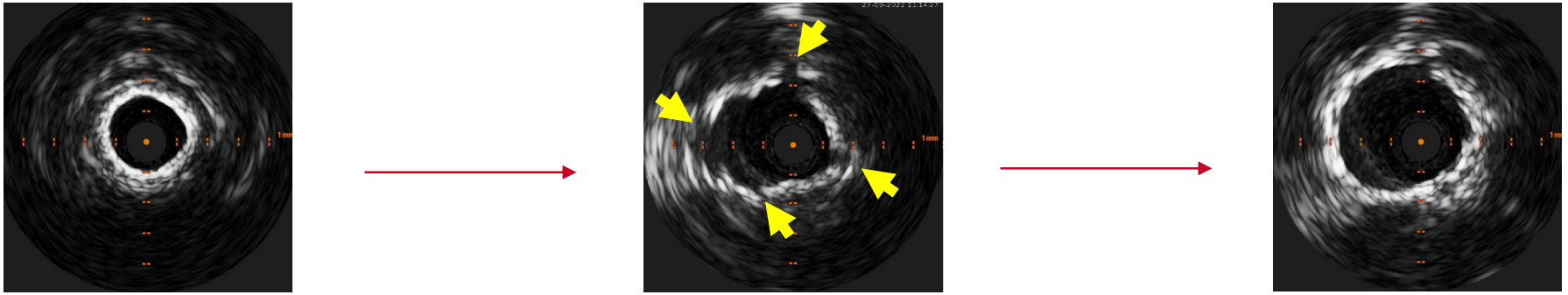


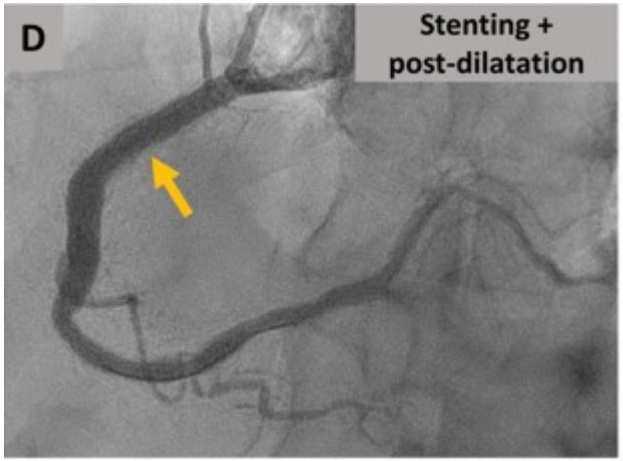
1: Kawashima H, Serruys PW, Hara H, Ono M, Gao C, Wang R, Garg S, Sharif F, de Winter RJ, Mack MJ, Holmes DR, Morice MC, Kappetein AP, Thuijs D, Milojevic M, Noack T, Mohr FW, Davierwala PM, Onuma Y, Investigators SES. 10-Year All-Cause Mortality Following Percutaneous or Surgical Revascularization in Patients With Heavy Calcification. JACC Cardiovasc Interv 2022;15:193-204.

2: Kereiakes DJ, Di Mario C, Riley RF, Fajadet J, Shlofmitz RA, Saito S, Ali ZA, Klein AJ, Price MJ, Hill JM, Stone GW. Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions: Patient-Level Pooled Analysis of the Disrupt CAD Studies. JACC Cardiovasc Interv 2021;14:1337-1348.

Example







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- Acoustic shockwaves at low pressure → fracture calcium deposits in vessel wall → compliance increase
- Deployment of stents and balloons → luminal gain
- Proven to be safe and effective for treatment of severe CAC in the DISRUPT-CAD studies I - IV
  - **Mostly in stable patients in prespecified clinical scenarios**

Rapid expansion of the technique (in combination) with other modification techniques and other anatomical/clinical scenarios

- Scenarios where evidence is lacking
- Longer-term (one-year) effects have not yet been studied

Aim

To assess the longer-term efficacy and safety of IVL in a real-world all-comers registry

Methods

Retrospective, international, observational multicenter, all-comers registry

Patients ≥18 years undergoing PCI for coronary artery calcification with IVL

2018 – now (ongoing)

Demographic, clinical, procedural and follow-up data

Centralized imaging analysis

- Quantitative Coronary Analysis (QCA)
- Intracoronary imaging

Endpoints

- Efficacy (procedural success)
  - Residual stenosis <30% (QCA)
  - No in-hospital events
- Safety
  - IVL-related complications
  - MACE in hospital and up to one-year follow-up

atient + lesion characteristics

- 397 patients included; 415 lesions treated
- 73.2 ± 9.0 years, 76% male
- Acute coronary syndrome in 46%
- High levels of comorbidities
- Diverse target lesions addressed

Diverse (complex) patient population

	Overall (n=415)
Target vessel	
LM, n(%)	44(11)
LAD, n(%)	177(43)
LCx, n(%)	65(16)
RCA, n(%)	152(37)
Bypass, n(%)	4(1)

	Overall (n=415)
Lesion characteristics	
Bifurcation, n(%)	98(24)
Ostial, n(%)	91(22)
Tortuous, n(%)	11(3)
CTO, n(%)	33(8)
Long-segment, n(%)	267(64)
In-stent, n (%)	157(38)

Procedural characteristics

IVL

- 3.5±0.5mm and 70±23 pulses
- 93% after NC-inflation (undilatable)
- 73(18%) were performed Bail-out after stenting

Other debulking techniques before IVL (n=64, 15%)

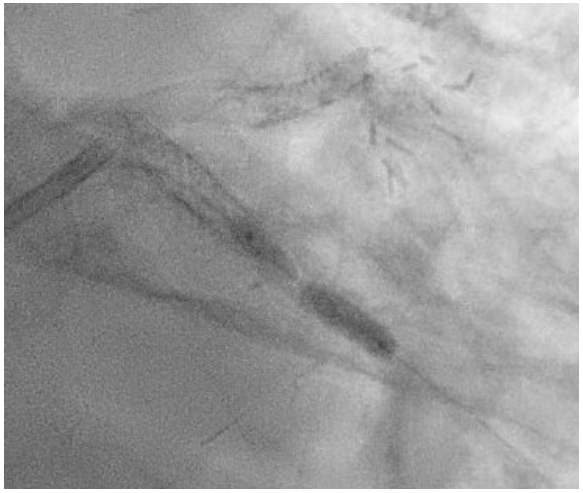
- Rotational atherectomy: 94%

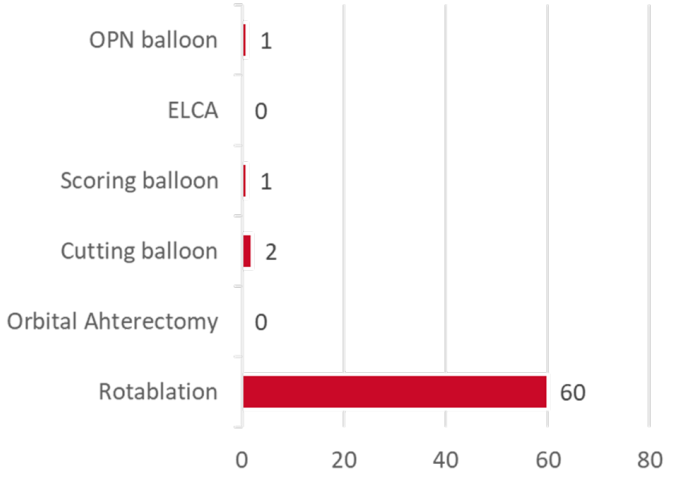
Post-IVL

- Post-dilatation with NC-balloon (93%)
- Stenting (77%)
- Drug eluting balloons (7%)

Intracoronary imaging guiding: in 221 target lesions (53%)

- 168 pre-IVL, 184 post-IVL
  - Pre: Assessment of plaque morphology + strategy
  - Post: treatment success (expansion + apposition)





Other debulking techniques used before IVL

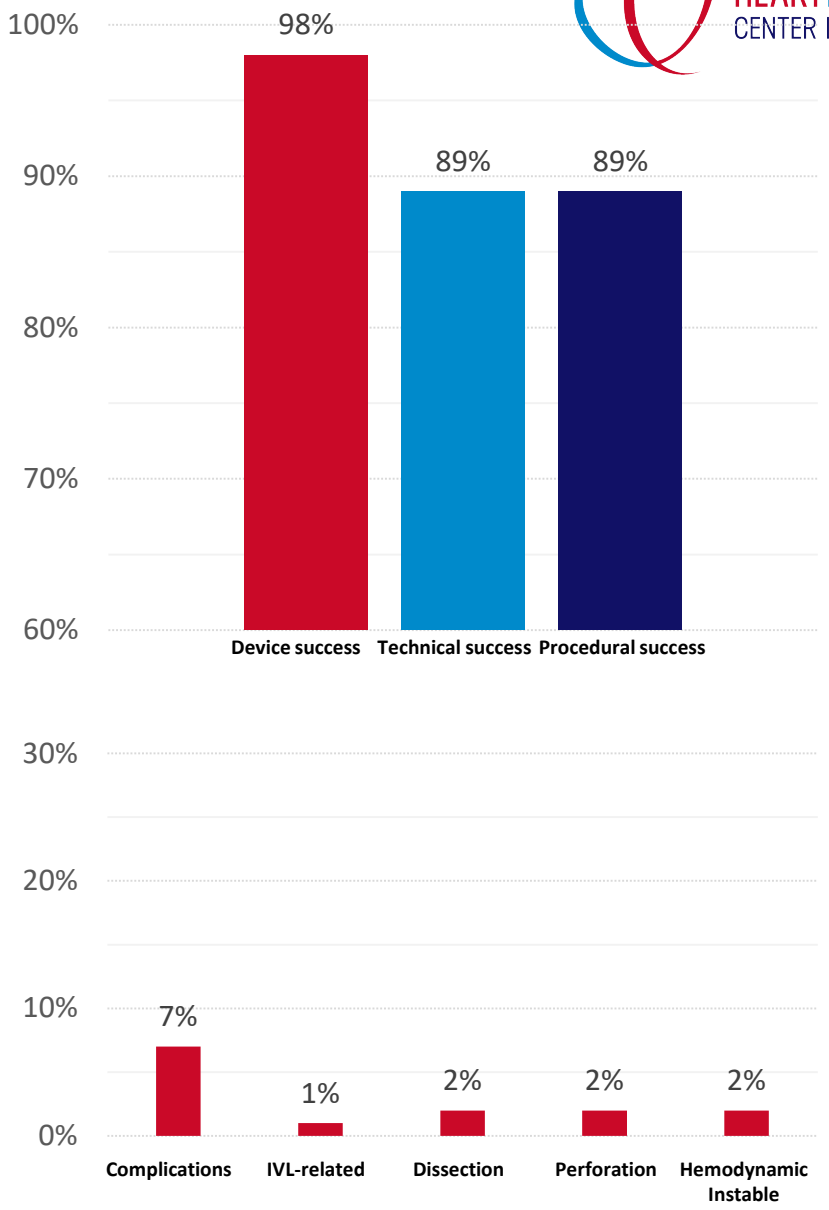
Procedural results

Success rates are high

- Device success: therapy without direct angiographic complications
- Technical success: residual stenosis <30% + TIMI 3 flow
- Procedural success: technical success without in-hospital event

Complications: n=27, 7%

- IVL-related complications are scare: 5(1%)
- Most complications related to NC post-dilatation



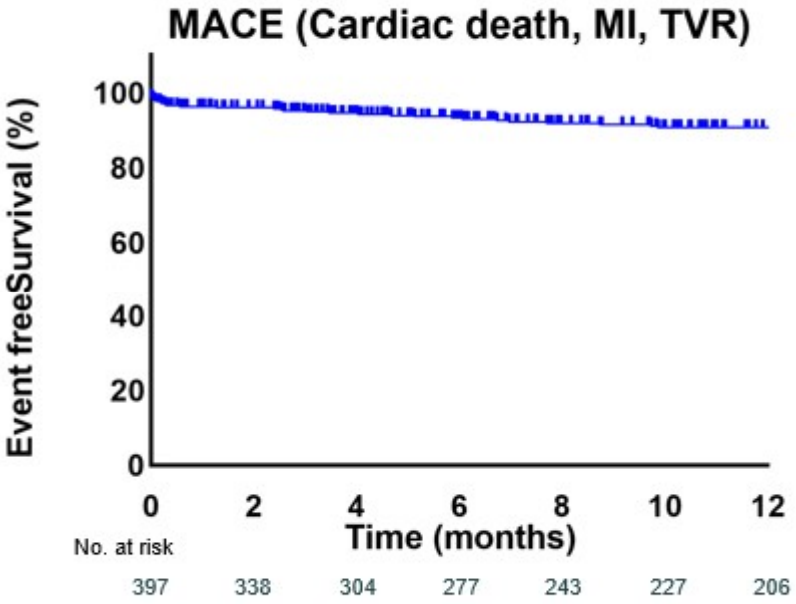
One-year follow-up

One-year follow-up was currently present in 237 (60%)

MACE rates low (n=31, 13%)

- In-hospital: 9 (2%)
  - 8 Cardiac death
  - 1 TVR
- Post discharge: 22 (9%)
  - 17 TVR
  - 7 MI
  - 3 Cardiac death

	Overall (n=397)
MACE	
In-hospital, n(%)(397)	9(2)
30-days, n(%)(371)	15(4)
6-months, n(%)(307)	25(8)
1-year, n(%)(237)	31(13)



Conclusion

In this real-world all-comers registry:

IVL was safe and effective

- IVL achieved high success rates
  - (Even when used in different clinical and anatomical scenarios that are underrepresent in current clinical trials (acute coronary syndrome/in-stent/CTO/bifurcations))
- One-year MACE rate was low (13%), mostly at the expense of TVR

IVL is used occasionally in combination with other plaque modification techniques (mostly rotablation), frequently planned upfront.

Discussion and questions

Thanks to all the contributors

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