



Cardiologia
Federico II



PAD NETWORK

AD INTERIM ANALYSIS

Update to 24th November 2021

Study Principal Investigators

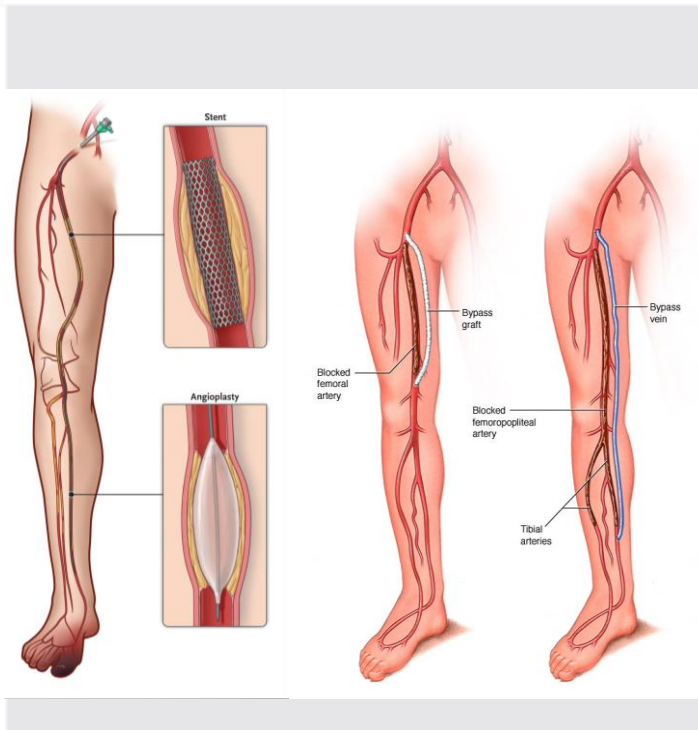
PROF. GIOVANNI ESPOSITO

PROF. EUGENIO STABILE

BACKGROUND I

Patients with established ASCVD

Documented ASCVD, clinical or unequivocal on imaging. Documented clinical ASCVD includes previous AMI, ACS, coronary revascularization and other arterial revascularization procedures, stroke and TIA, aortic aneurysm and PAD. Unequivocally documented ASCVD on imaging includes plaque on coronary angiography or carotid ultrasound or on CTA. It does NOT include some increase in continuous imaging parameters such as intima-media thickness of the carotid artery.



Very high-risk

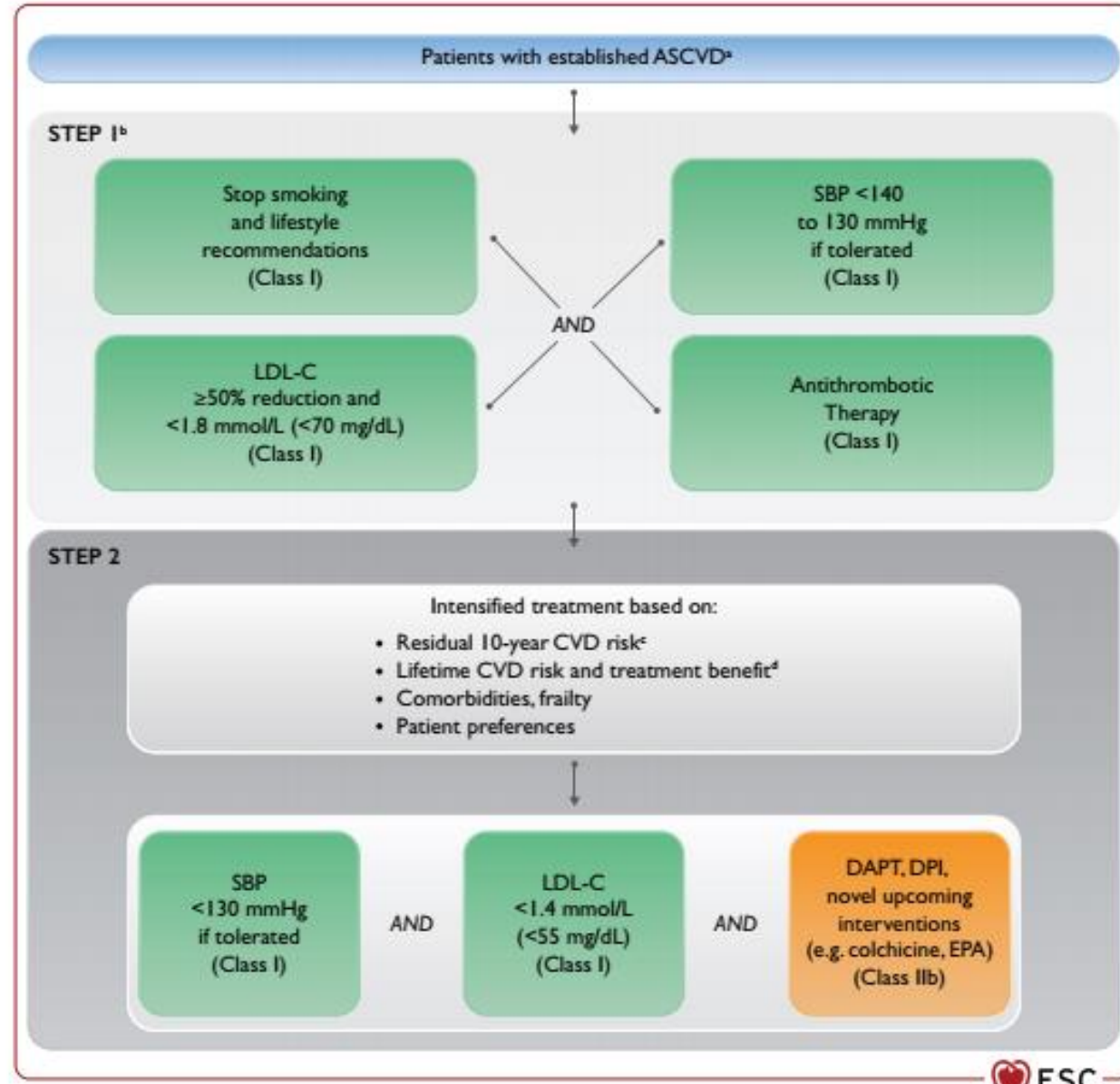
Residual CVD risk estimation after general prevention goals (e.g. 10-year risk with the SMART risk score for patients with established CVD or 1- or 2-year risk with EUROASPIRE risk score for patients with CHD). Consider lifetime CVD risk and benefit estimation of risk factor treatment (e.g. SMART-REACH model; or DIAL model if diabetes).

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BACKGROUND II



BACKGROUND III

- ▶ Despite the elevated cardiovascular risks, claims studies have shown that a large portion of LEAD patients undergoing LER do not receive a medical therapy that properly mirror guidelines recommendations.
- ▶ In our country, the portion of LEAD patients who are prescribed a guideline recommended medical therapy and take the medications as prescribed after LER is unknown.



METHODS

- ▶ **Study design:** Multicentered, prospective, non-interventional study.
- ▶ **Study population:** Patients undergoing Lower Extremity Revascularization (LER) in Campania will be eligible for inclusion in the study. Patients aged < 18 years old will be excluded.
- ▶ **Definitions:**
 - Adherence to recommendations (*Physician adherence*): the process by which physician prescribe medications as recommended by guidelines.
 - Adherence to medications (*Patient Adherence*): is the process by which patients take their medication as prescribed.
- ▶ **Data management:** demographic, clinical, procedural and therapeutic data relating to patients and from all the involved centers in an anonymized digital platform (RedCap®).



ENDPOINTS

- **Primary endpoint**

Evaluate the *Physician and Patients adherence* for antithrombotic agents, lipid lowering agents, angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blocker (ARB) at 1 month, 6 months, 1 and 2 years follow up after LER

- **Secondary endpoints**

Efficacy: Achievement of recommended target of therapy (BP and LDL-c values).

Estimate predictors of *Patient and Physician Adherence*

Safety: Occurrence of Major Adverse Cardiovascular Events (MACE) and Major Adverse Limb Events (MALE)






EXPECTED RESULTS


- ▶ Define adherence to guidelines recommendations of prescribed therapy to LEAD patients who have undergone LER (Physician adherence).
- ▶ Define LEAD patients' adherence to prescribed therapy (Patient Adherence)
- ▶ Design future strategies to improve physician and patient adherence to guidelines recommended medical therapy in these clinical setting



INVOLVED CENTERS



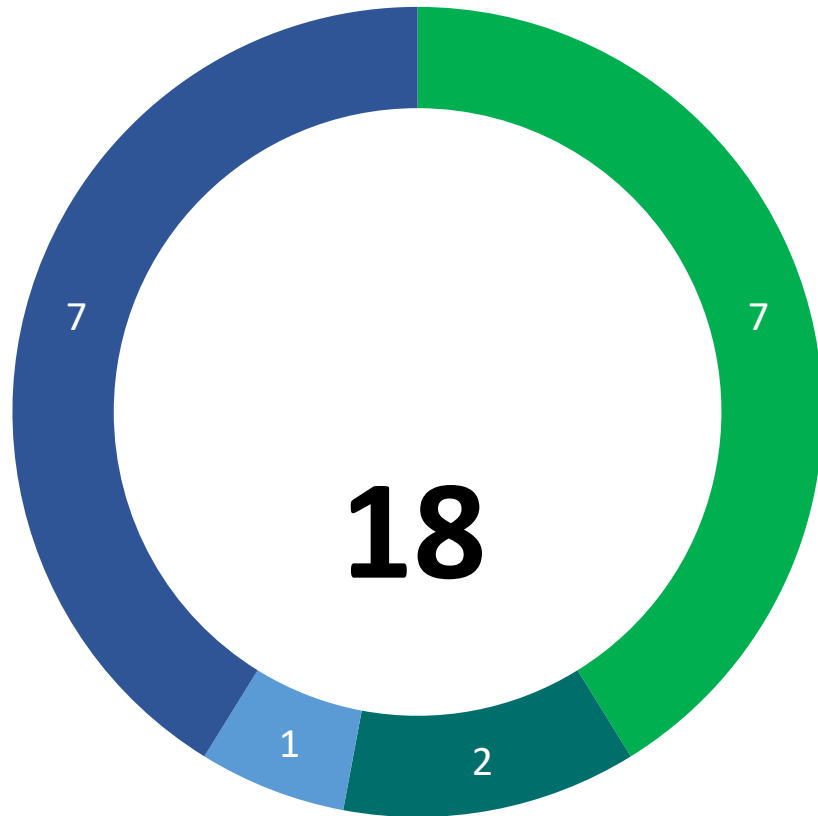
-  CARDIOLOGIA
-  CHIRURGIA VASCOLARE
-  RADIOLOGIA INTERVENTISTICA

-  AOU Federico II di Napoli– UOC Cardiologia, Emodinamica e UTIC
-  Casa di Cura Montevergine di Mercogliano (AV) – Cardiologia
-  AORN San Giuseppe Moscati di Avellino – UO Ch. Vascolare
-  AO San Pio di Benevento – UO Ch. Vascolare
-  AORN dei Colli – Ospedale Monaldi di Napoli – UO Ch. Vascolare
-  Casa di Cura Salus di Battipaglia (SA) – Ch. Vascolare
-  AOU Federico II di Napoli – UOSD Chirurgia Vascolare
-  AORN Cardarelli di Napoli– UOC Radiologia vascolare
-  AORN Sant'Anna e San Sebastiano di Caserta – UOC Ch. Vascolare
-  Ospedale Fatebenefratelli di Benevento – UOC Cardiologia
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-  Clinica Mediterranea di Napoli – UOC Ch. Vascolare
-  Ospedale del Mare di Napoli – UOC Ch. Vascolare
-  Presidio Ospedaliero dei Pellegrini di Napoli– UO Ch. Vascolare
-  Casa di Cura Villa dei Fiori di Acerra (NA) – Ch. Vascolare
-  Casa di Cura San Michele di Maddaloni (CE) - Cardiologia
-  OORR San Giovanni di Dio e Ruggi d'Aragona di Salerno– UO Ch. Vascolare
-  AO San Luca di Vallo Della Lucania (SA) – UOC Ch. Vascolare



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APPROVATION AND ENROLLING STATUS



- AOU Federico II di Napoli– UOC Cardiologia, Emodinamica e UTIC
- Casa di Cura Montevergine di Mercogliano (AV) – Cardiologia
- AORN San Giuseppe Moscati di Avellino – UO Ch. Vascolare
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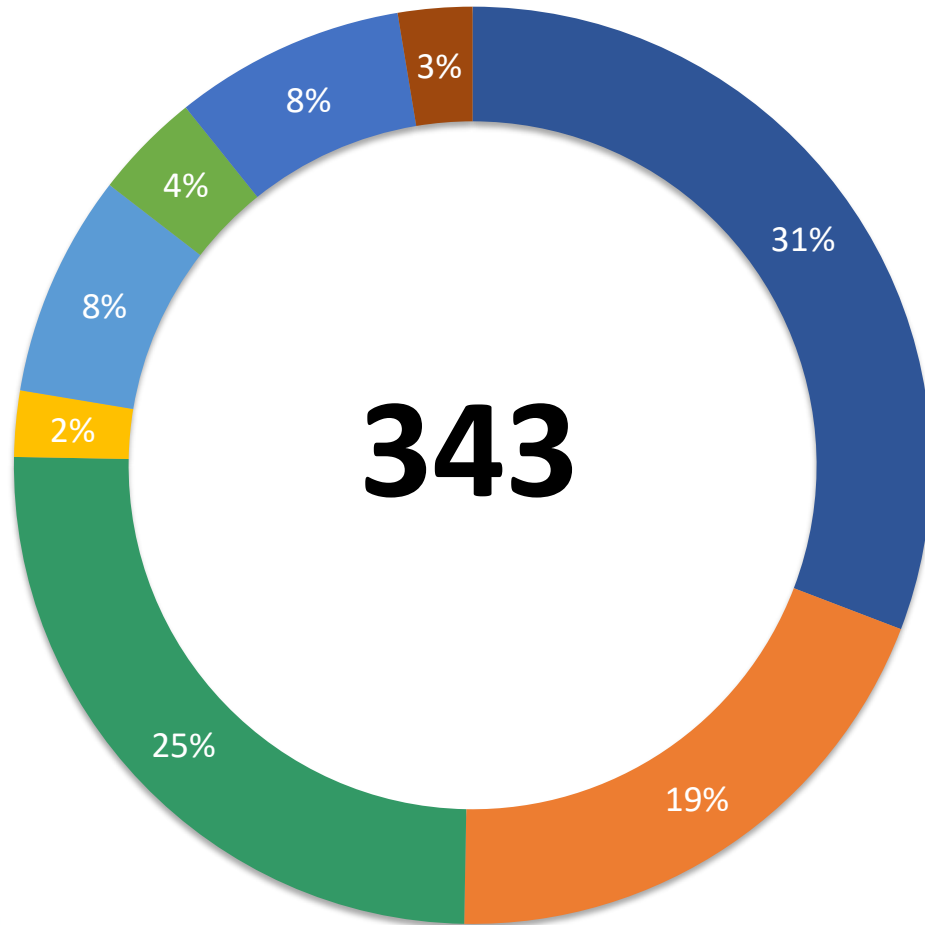
■ Approved and enrolling ■ Approved not enrolling yet ■ Submitted ■ Not approved



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STUDY POPULATION



ENROLLED PATIENTS

- AOU Federico II – UOC Cardiologia, Emodinamica e UTIC
- Casa di Cura Montevergine di Mercogliano (AV)
- AORN San Giuseppe Moscati di Avellino – UO Ch. Vascolare
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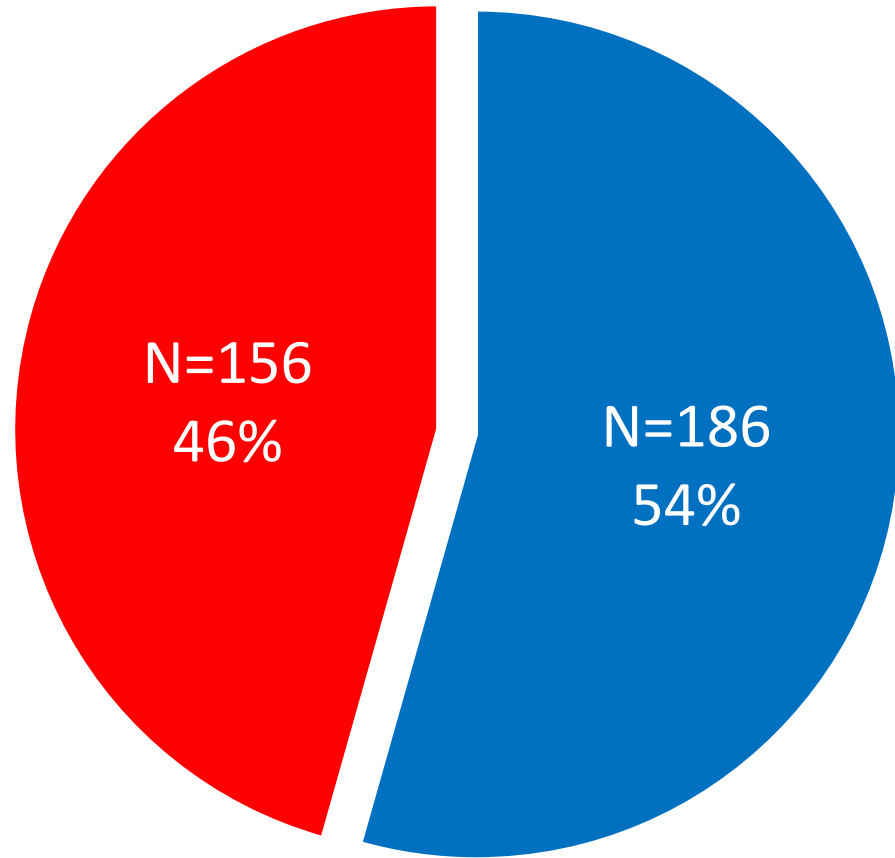
DEMOGRAPHICS

Males, n (%)	260 (75,6)
Age, years	67,81 ± 9,35
Body mass index, kg/m ²	27,24 ± 4,00
Smoker, n (%)	233 (68,1)
Current smoker, n (%)	128 (55,0)
Former smoker, n (%)	105 (45,0)
Arterial hypertension, n (%)	294 (85,7)
Diabetes mellitus, n (%)	179 (52,2)
Insulin dependent, n (%)	106 (59,2)

Dyslipidemia, n (%)	277 (80,8)
Chronic kidney disease, n (%)	78 (22,9)
Dialysis, n (%)	13 (3,8)
Chronic obstructive lung disease, n (%)	69 (20,1)
History of atrial fibrillation/flutter, n (%)	37 (10,8)
Previous PCI, n (%)	115 (33,5)
Previous CABG, n (%)	53 (15,5)
Prior stroke, n (%)	14 (4,1)
Previous peripheral revascularization, n (%)	137 (40,4)



CLINICAL PRESENTATION



■ Fontaine IIb

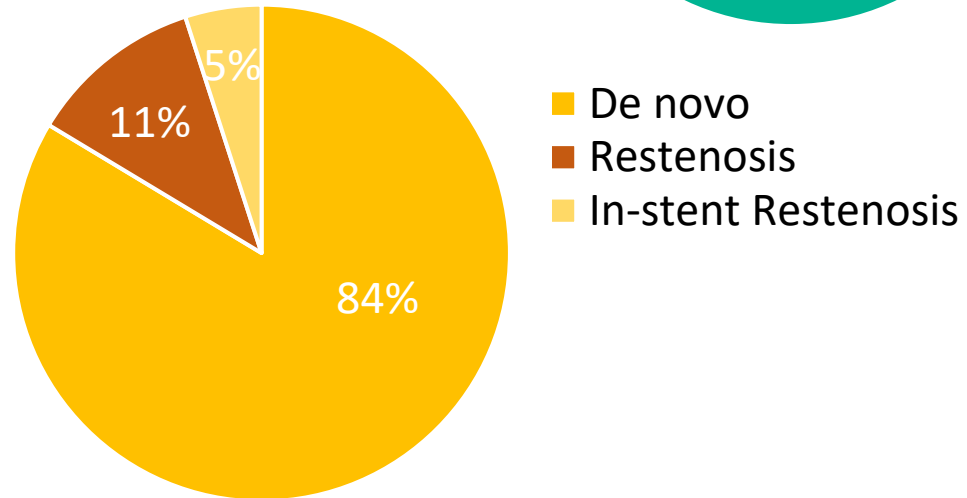
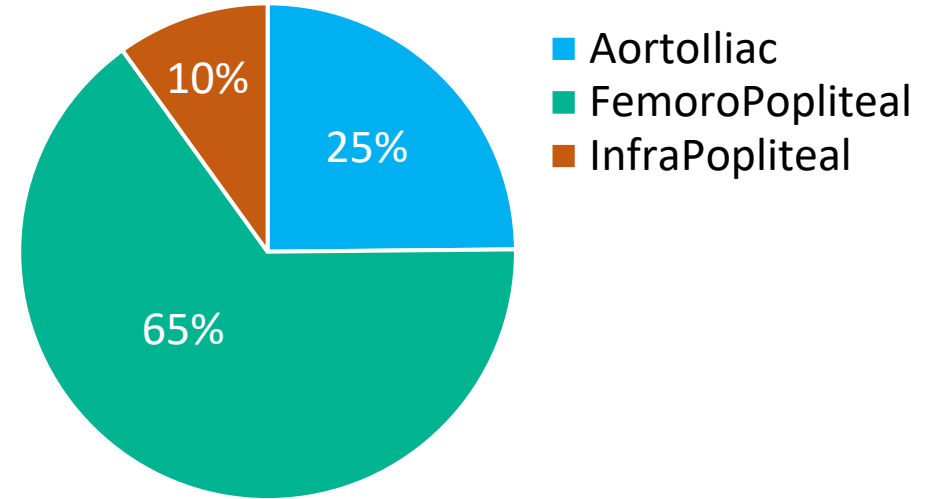
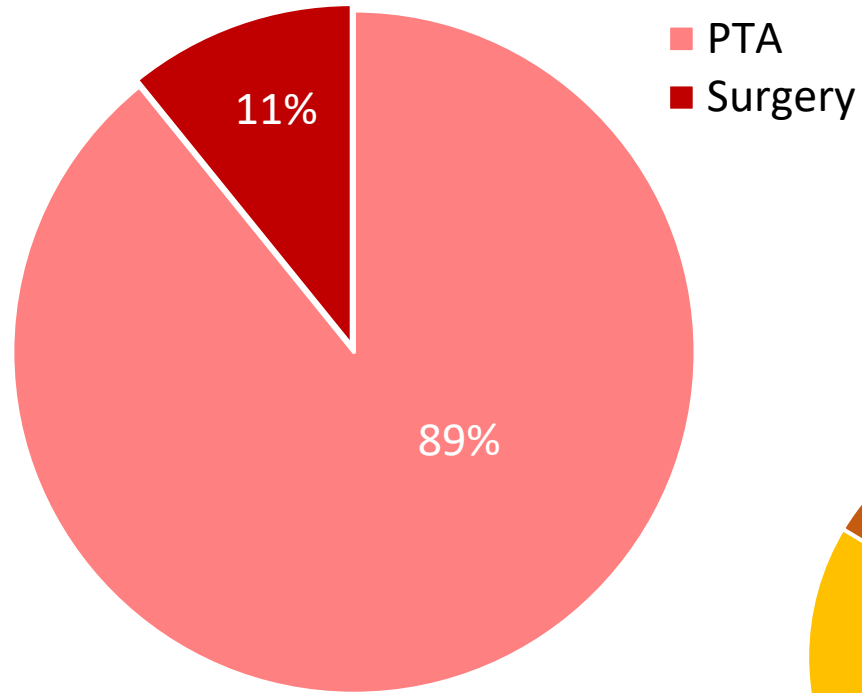
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TARGET LESION REVASCULARIZATION



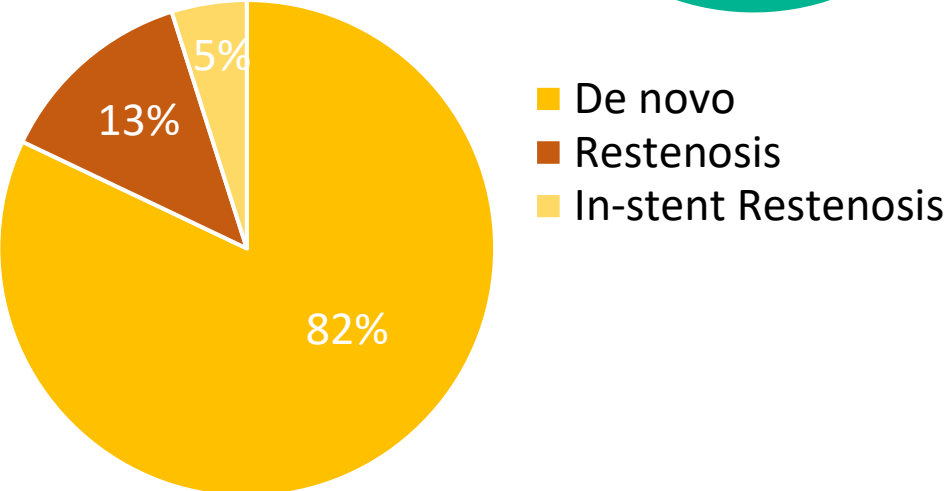
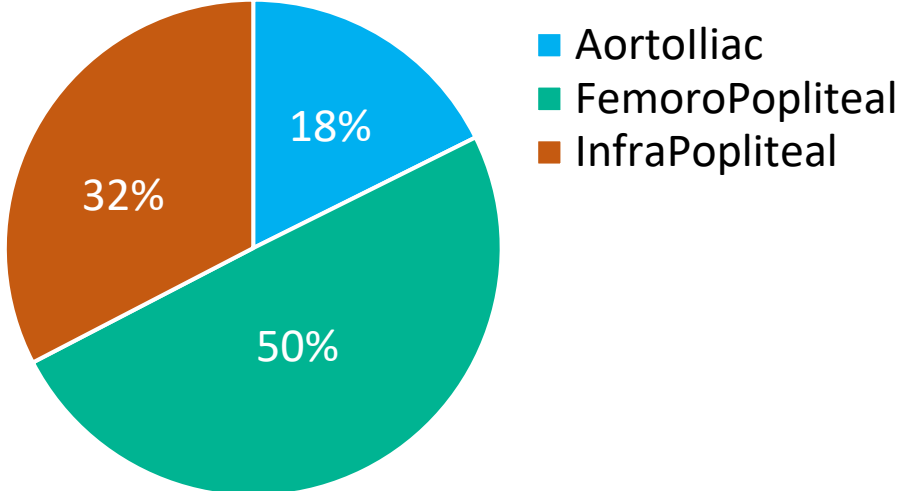
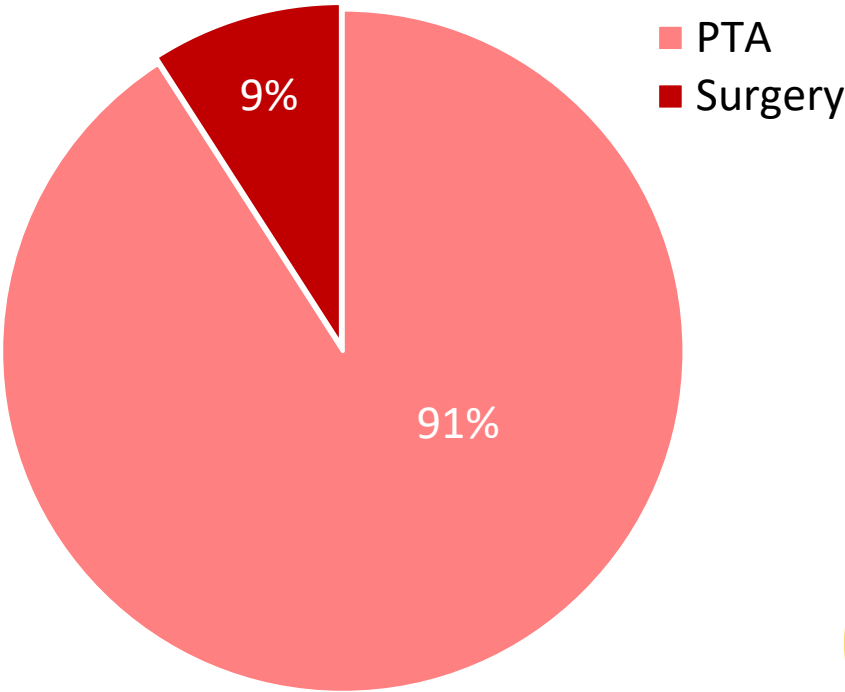
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ADDITIONAL LESION REVASCULARIZATION

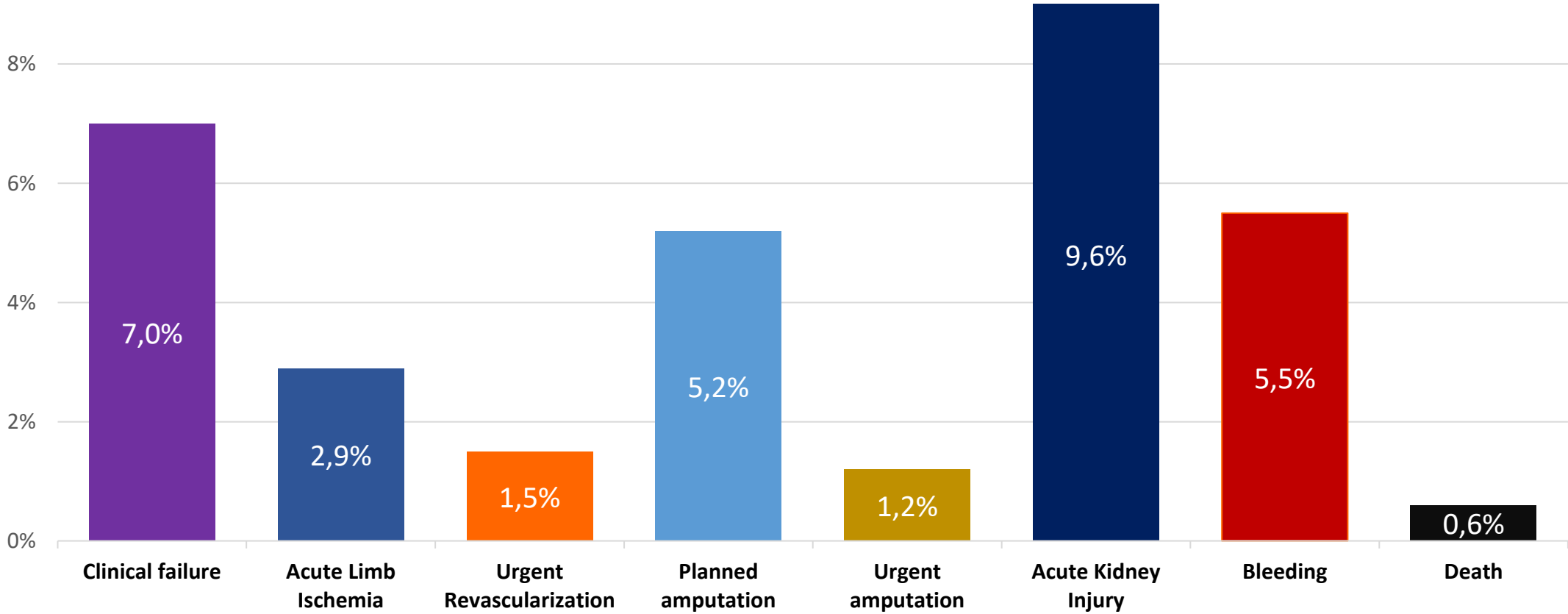


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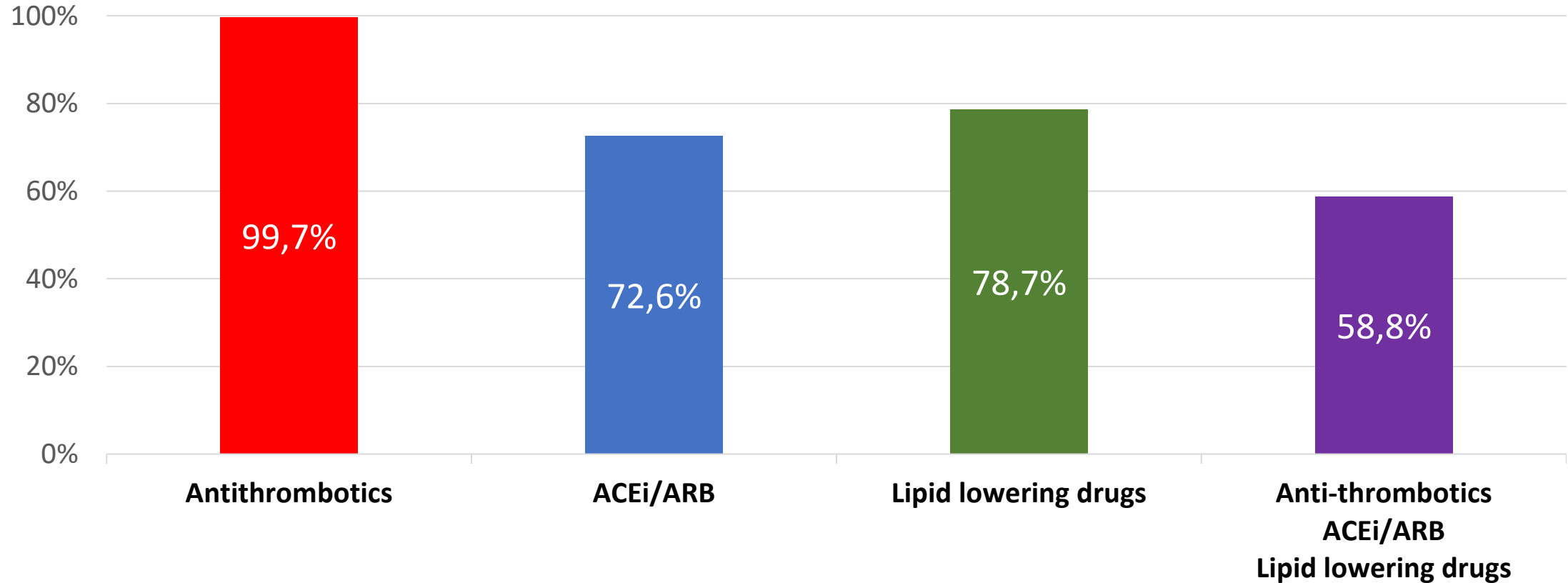


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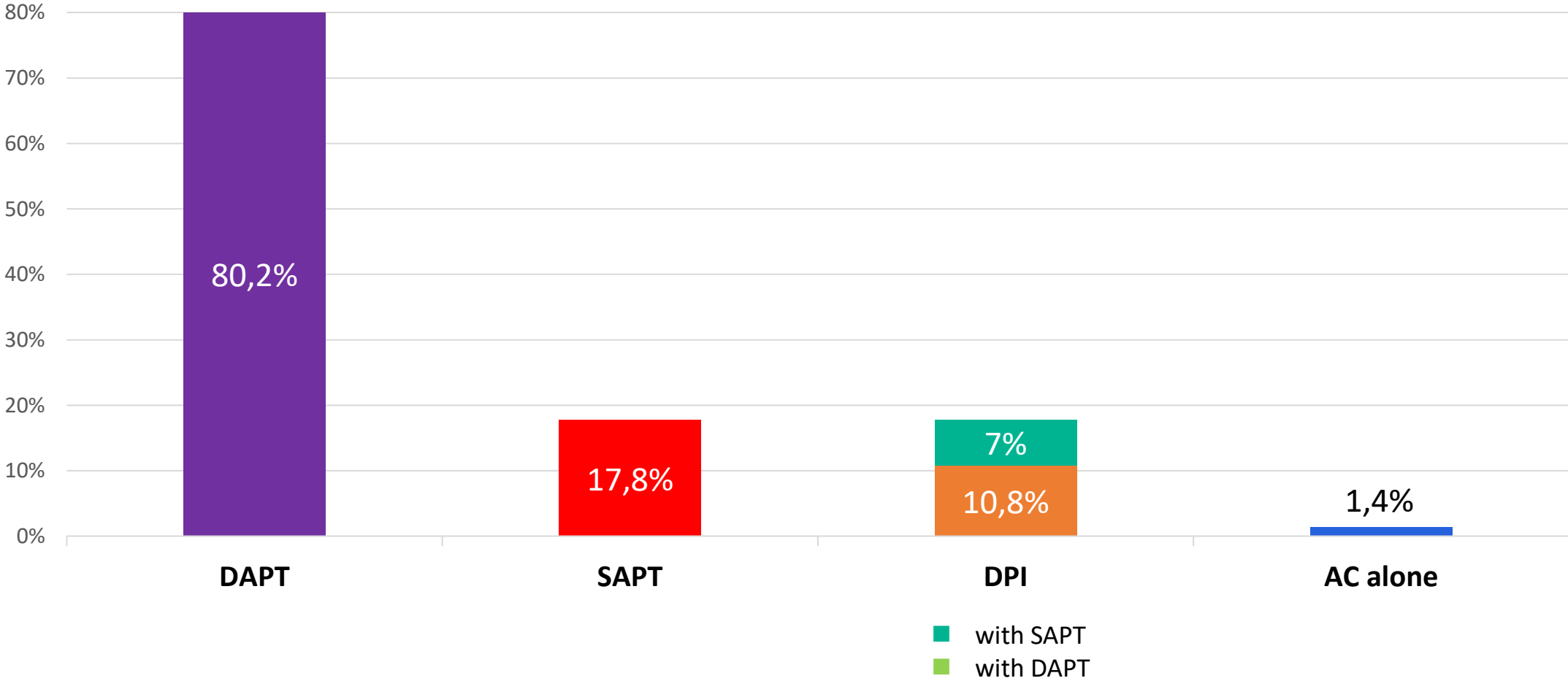
IN-HOSPITAL EVENTS



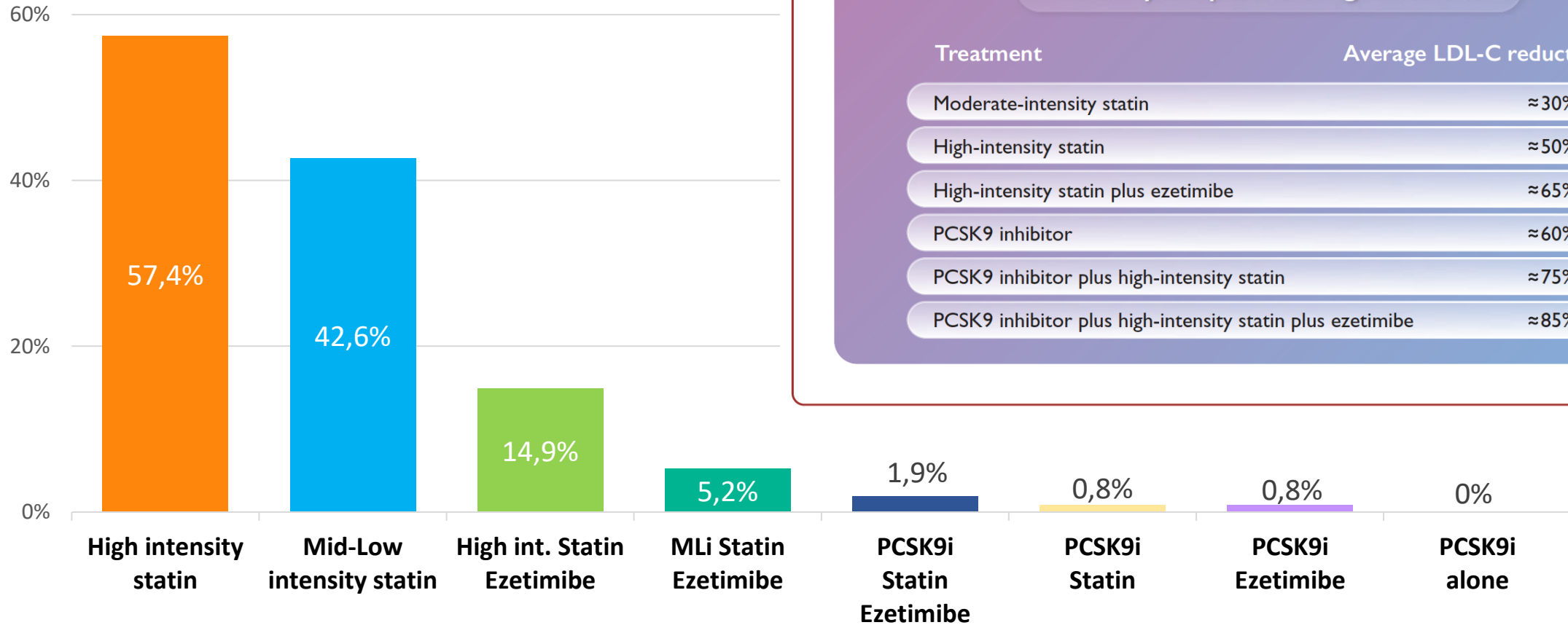
MEDICAL THERAPY AT DISCHARGE



ANTI-THROMBOTICS AT DISCHARGE



LIPID LOWERING DRUGS AT DISCHARGE

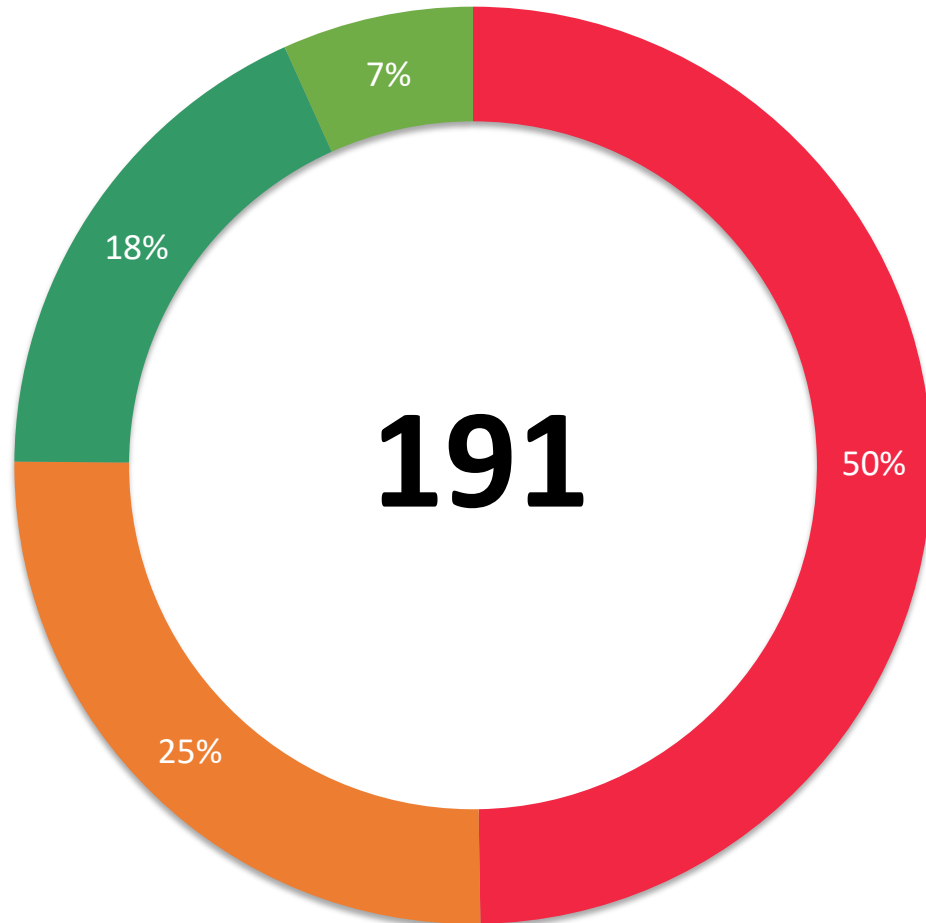


Intensity of lipid-lowering treatment

Treatment	Average LDL-C reduction
Moderate-intensity statin	≈ 30%
High-intensity statin	≈ 50%
High-intensity statin plus ezetimibe	≈ 65%
PCSK9 inhibitor	≈ 60%
PCSK9 inhibitor plus high-intensity statin	≈ 75%
PCSK9 inhibitor plus high-intensity statin plus ezetimibe	≈ 85%



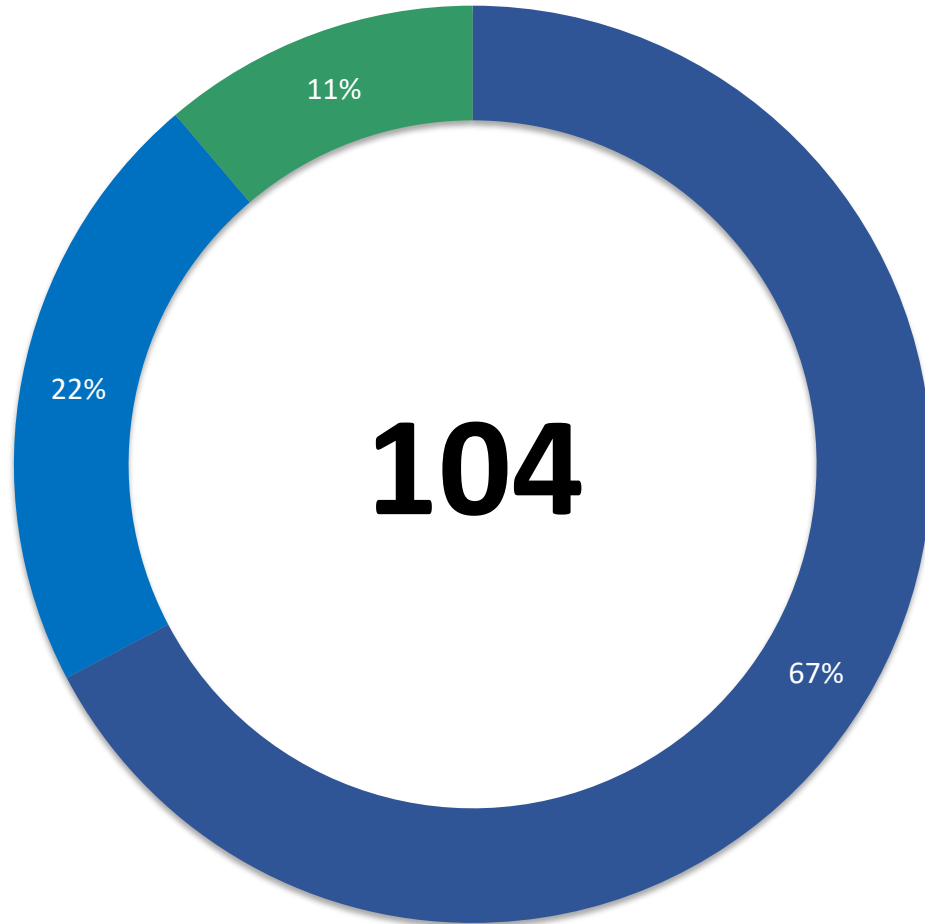
STUDY POPULATION



1 MONTH FOLLOW UP

- AOU Federico II – UOC Cardiologia, Emodinamica e UTIC
- Casa di Cura Montevergine di Mercogliano (AV)- UTIC -Emodinamica
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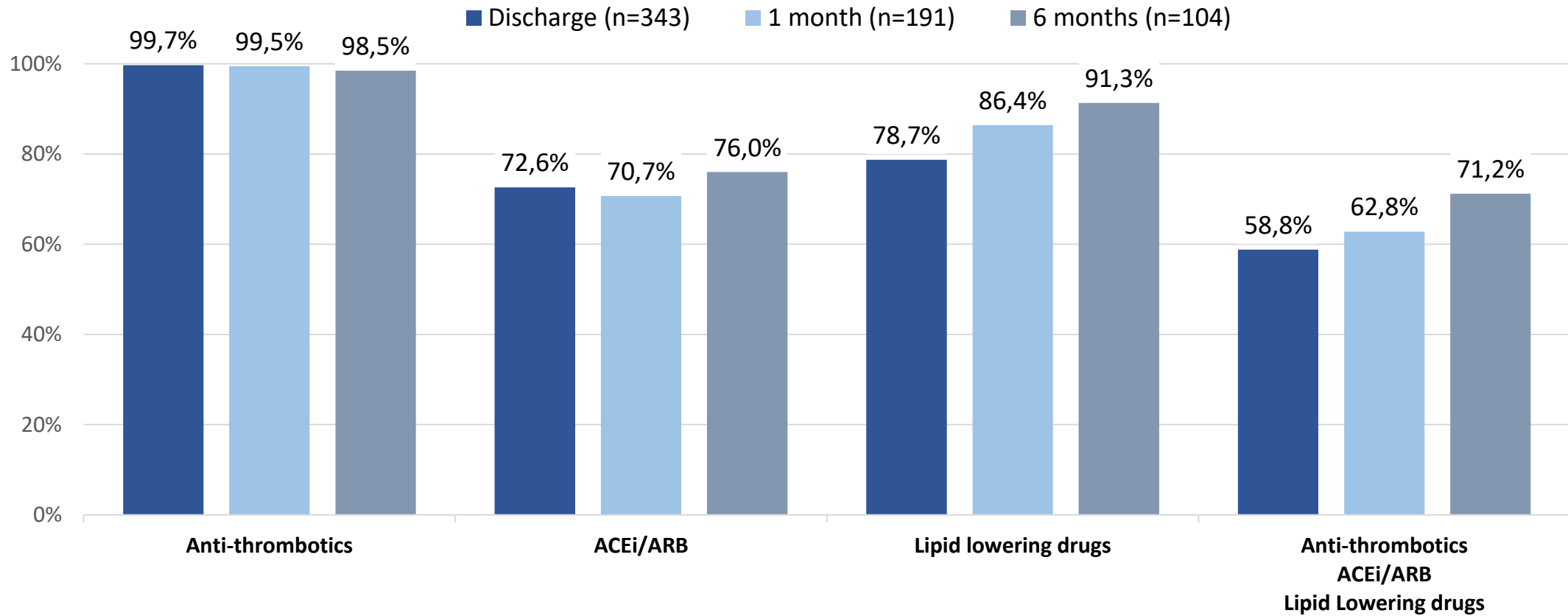
STUDY POPULATION



6 MONTHS FOLLOW UP

- AOU Federico II – UOC Cardiologia, Emodinamica e UTIC
- Casa di Cura Montevergine di Mercogliano (AV) -UTIC- Emodinamica
- AORN San Giuseppe Moscati di Avellino – UO Ch. Vascolare

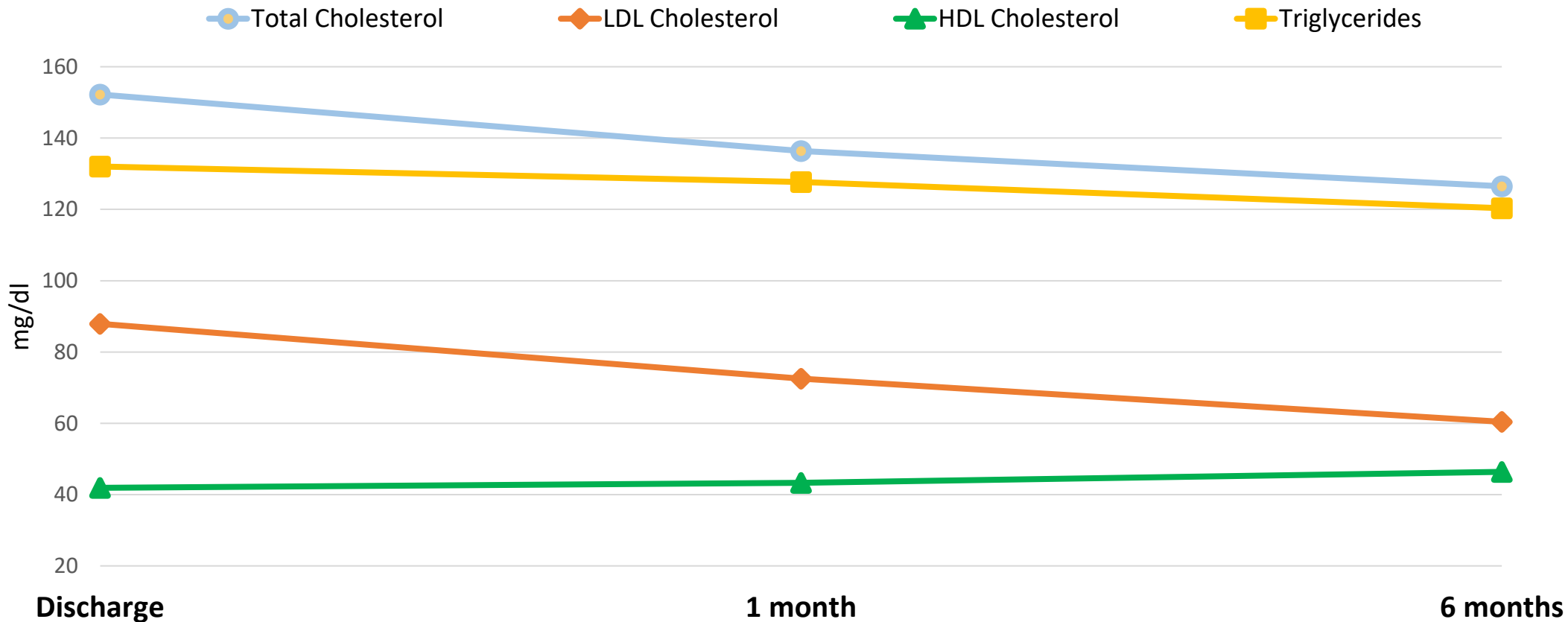
ADHERENCE TO MEDICAL THERAPY



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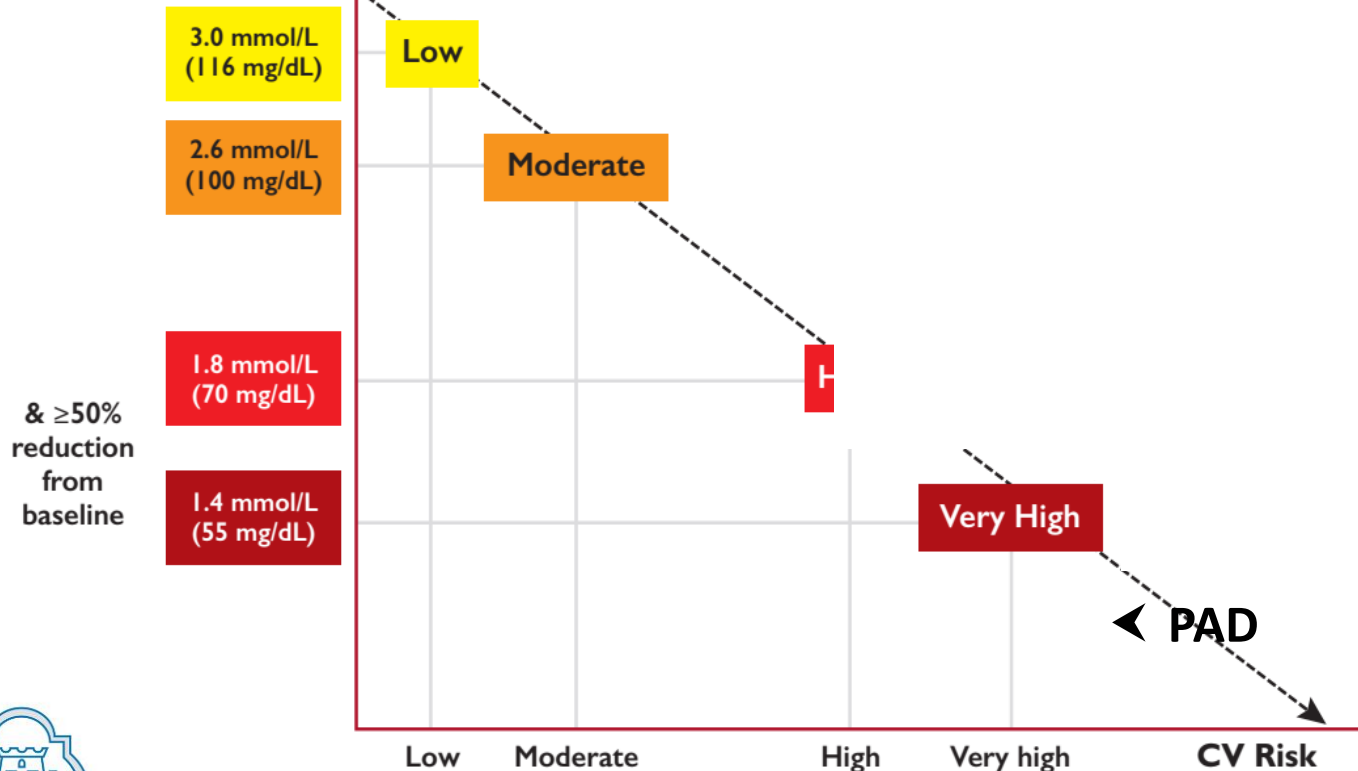


LIPIDS TREND DURING FOLLOW UP

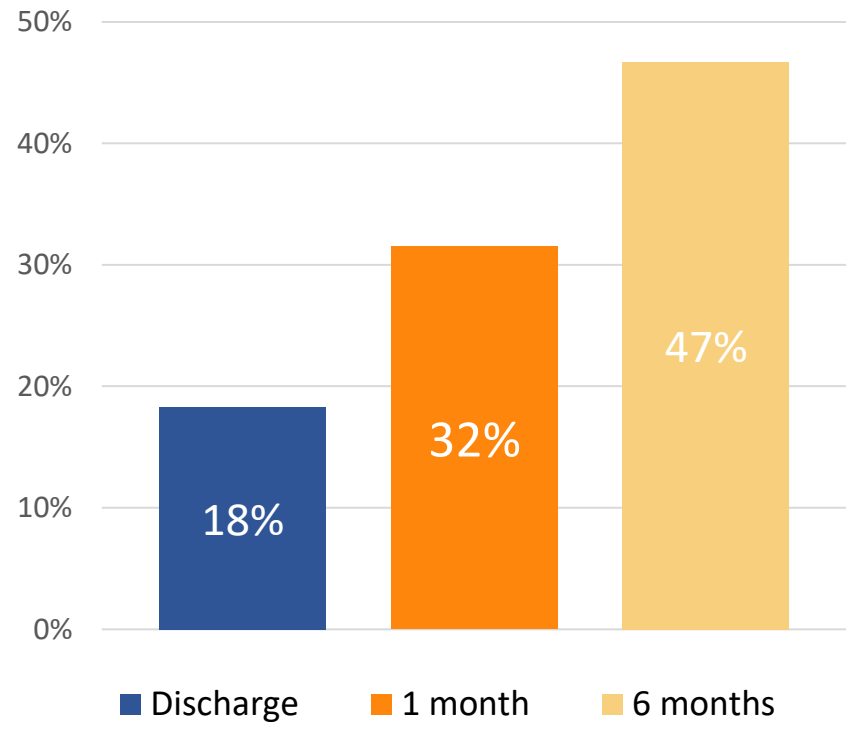


LDL DURING FOLLOW UP

Treatment goal for LDL-C

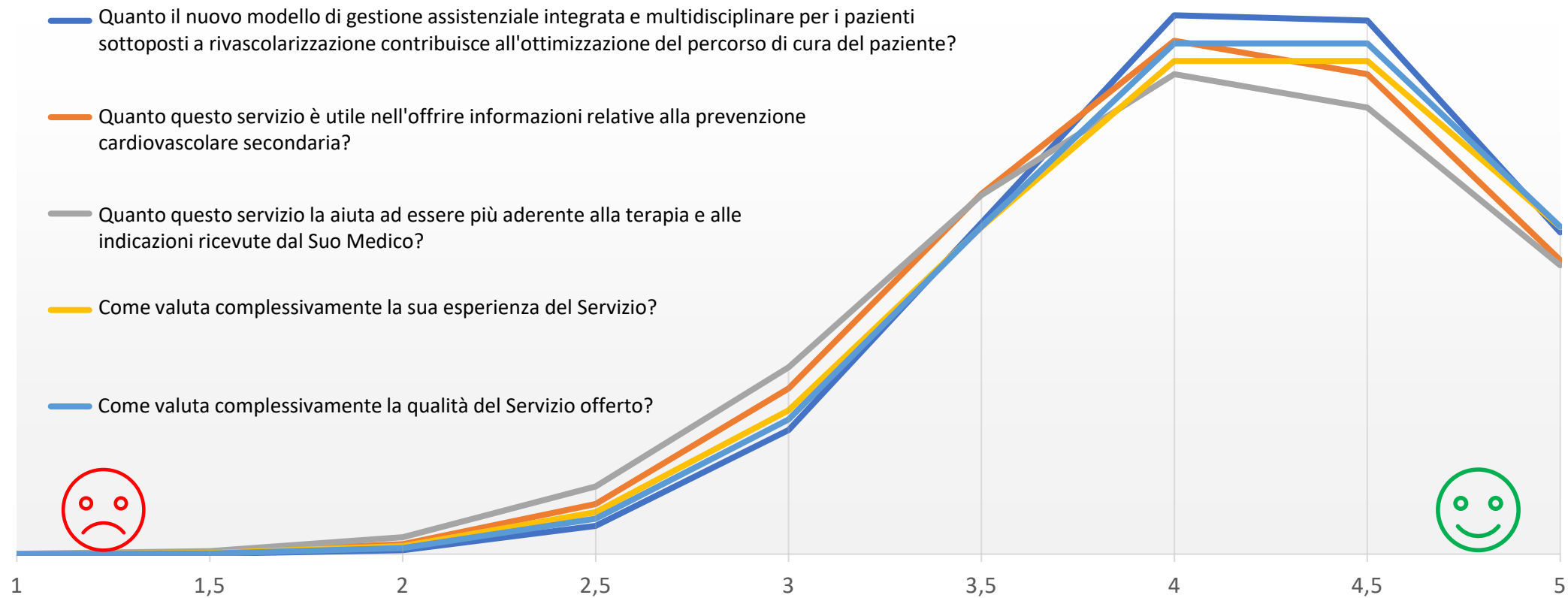


LDL-C < 55 mg/dL (14 mmol/L)



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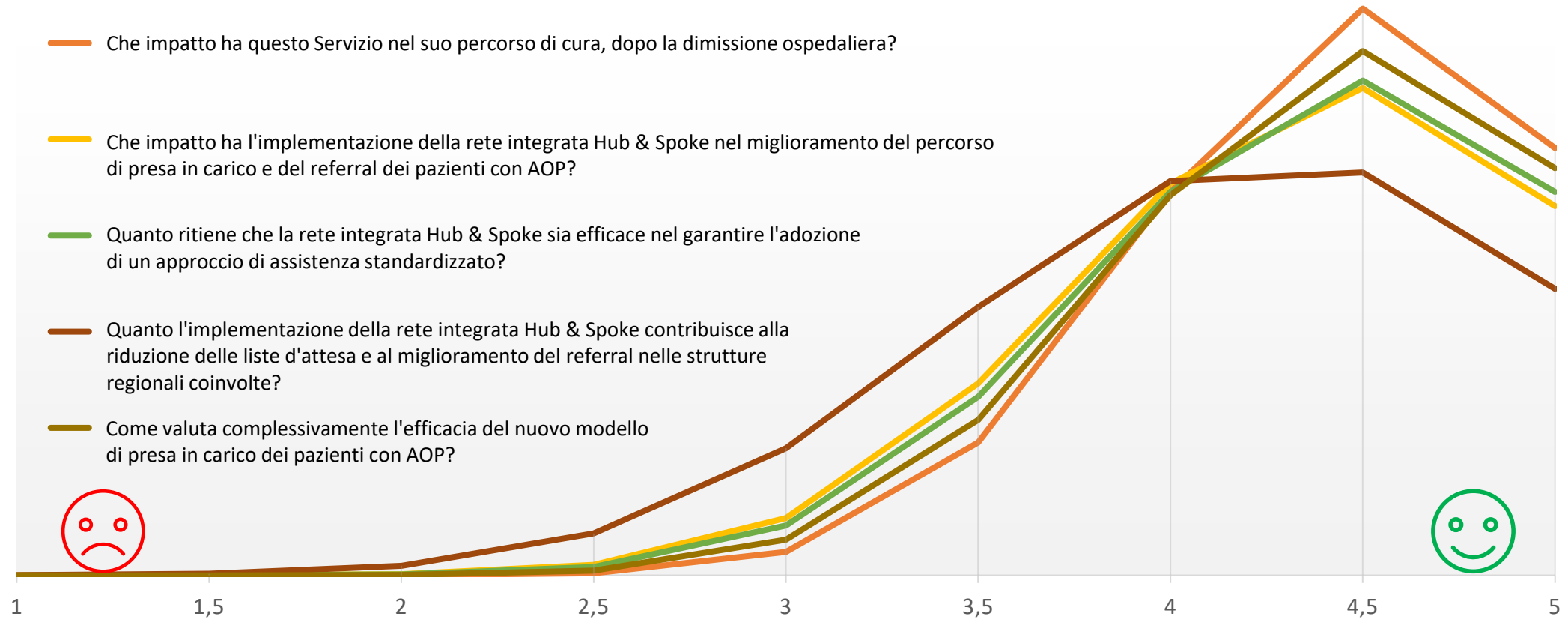
PATIENT SATISFACTION SURVEY



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PHYSICIAN SATISFACTION SURVEY



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CAMPANIA



Eugenio Sta