Bringt die Verwendung zusätzlicher Devices Fortschritte in der Therapie der akuten Koronarsyndrome?

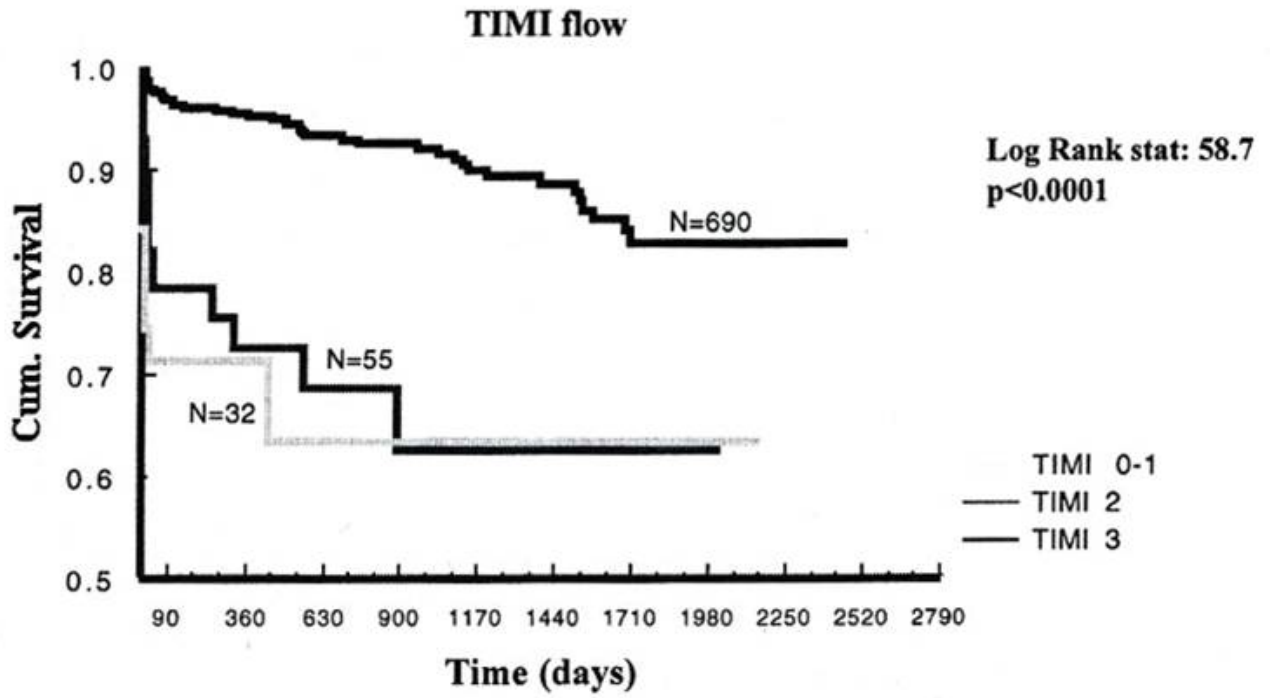
L. Bruch

Unfallkrankenhaus Berlin

Kardiologie heute

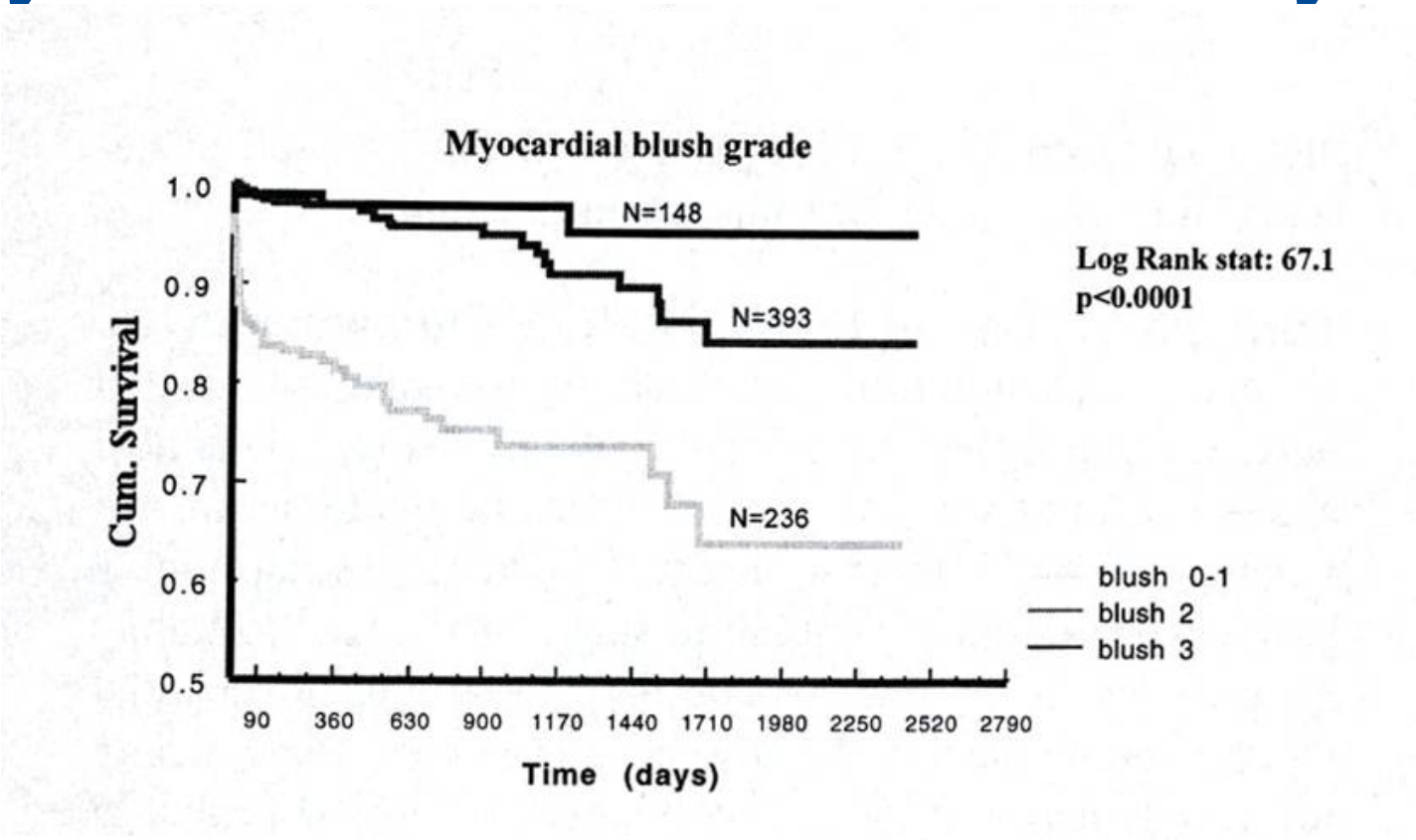
Berlin 20.11.2010

AMI: TIMI flow vs. Mortality



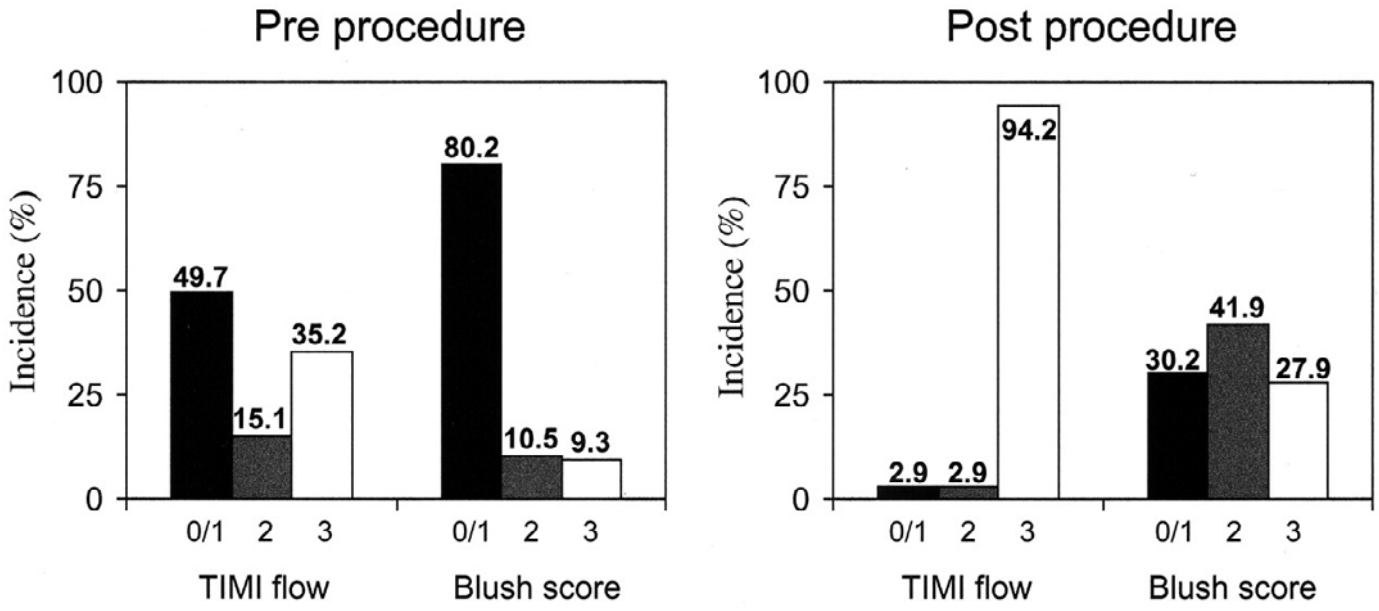
van´t Hof AWC et al., *Circulation.* 1998;97:2302-2306

AMI: Myocardial Blush Grade vs. Mortality



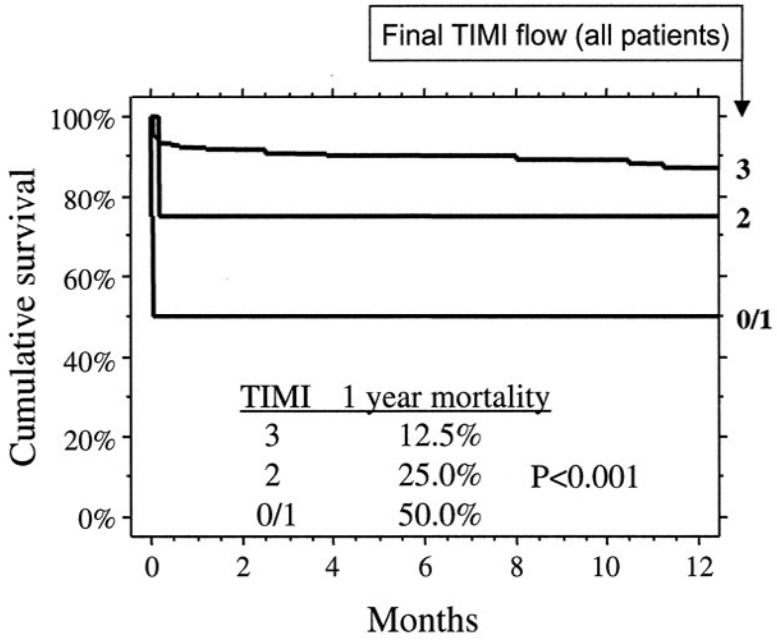
van´t Hof AWC et al., *Circulation.* 1998;97:2302-2306

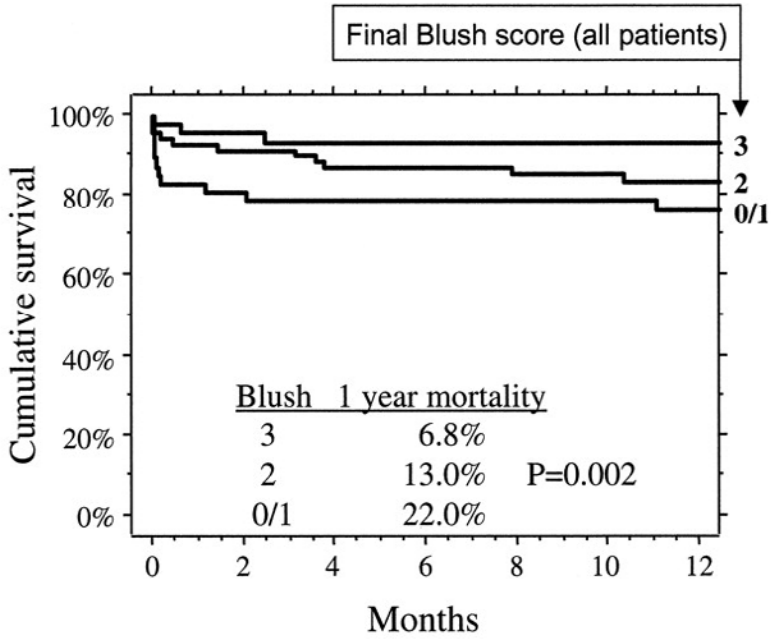
AMI: TIMI flow vs. Myocardial Blush Grade



Stone, G. W. et al. J Am Coll Cardiol 2002;39:591-597

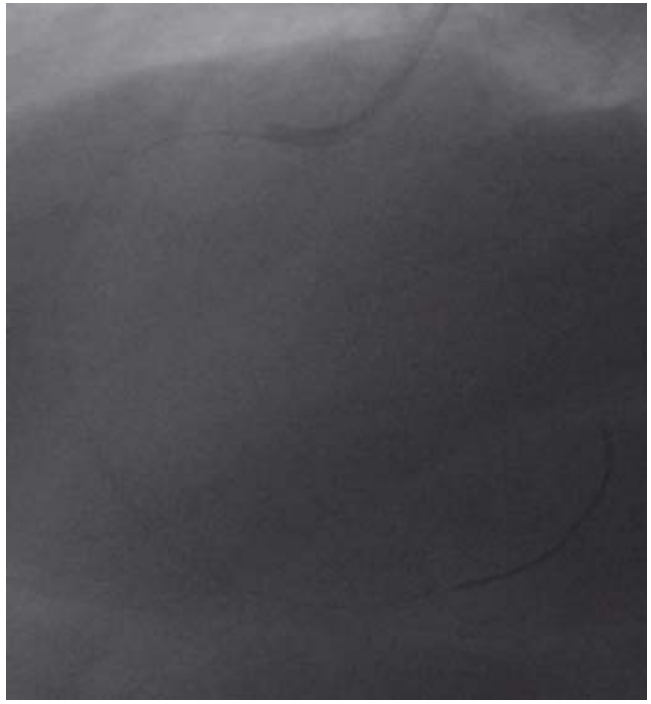
AMI: Myocardial Blush Grade vs. Mortality

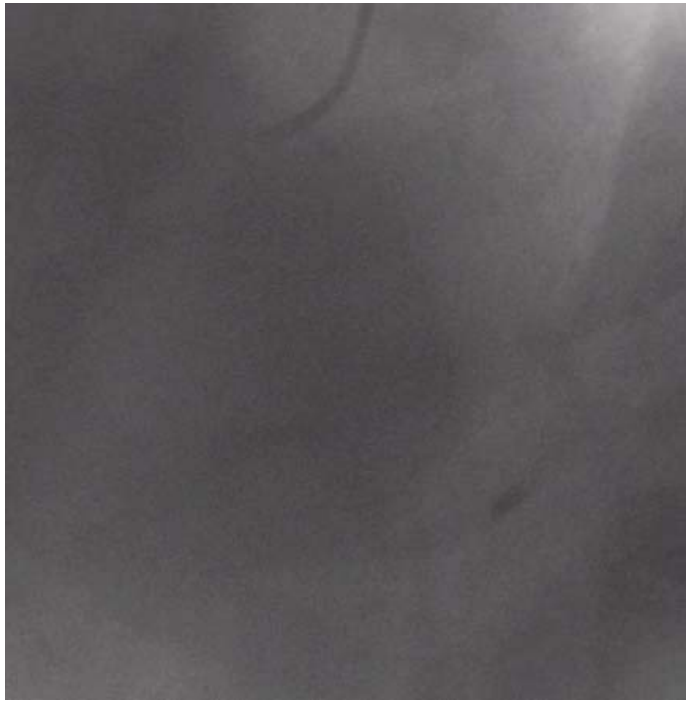




Stone, G. W. et al. J Am Coll Cardiol 2002;39:591-597

Beispiel konventionelle Stent-PCI





Unfallkrankenhaus Berlin

Ansatzpunkte für neue Methoden

Verbesserung der Myokardperfusion bei der PCI:

- Thrombektomie
- Stent mit protektiver Funktion (MGuard)

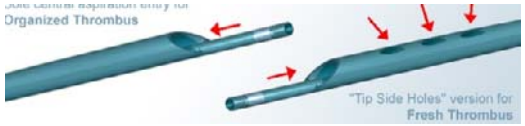
Verhinderung des Reperfusionsschadens:

- Medikamente (?)
- Kühlung (InnerCool RTx Endovascular System)

Thrombektomie - Aspiration

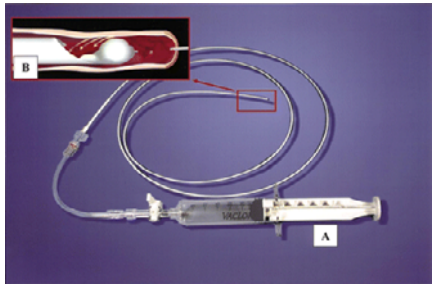
- Export® (Medtronic)

- Diver CE® (Invatec)



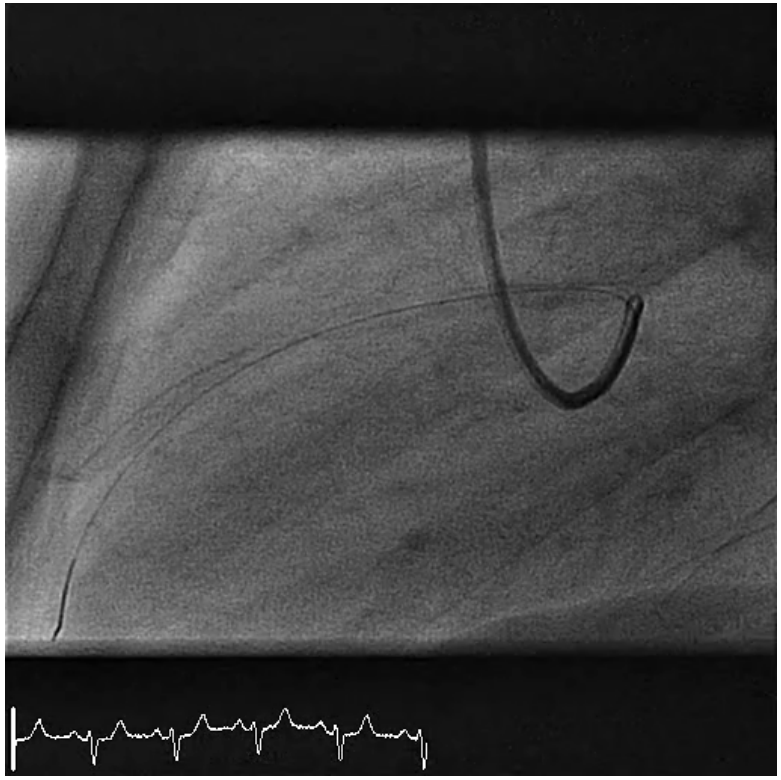
- QuickCat® (Spectranetics)

- Pronto® (Vascular Solutions)

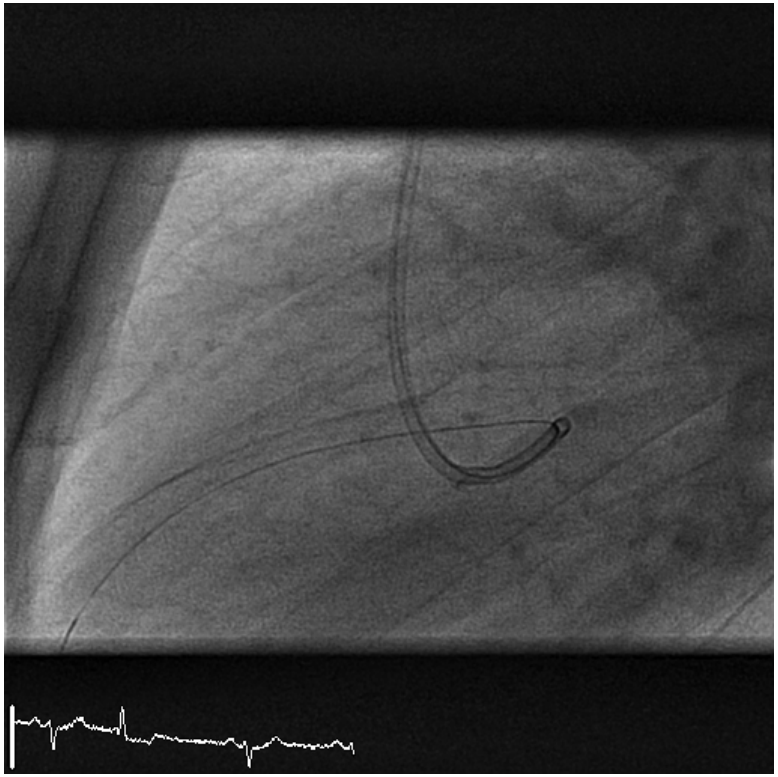


- Proxis® (St. Jude Med.)
  (with prox. balloon occlusion)

Beispiel Aspiration

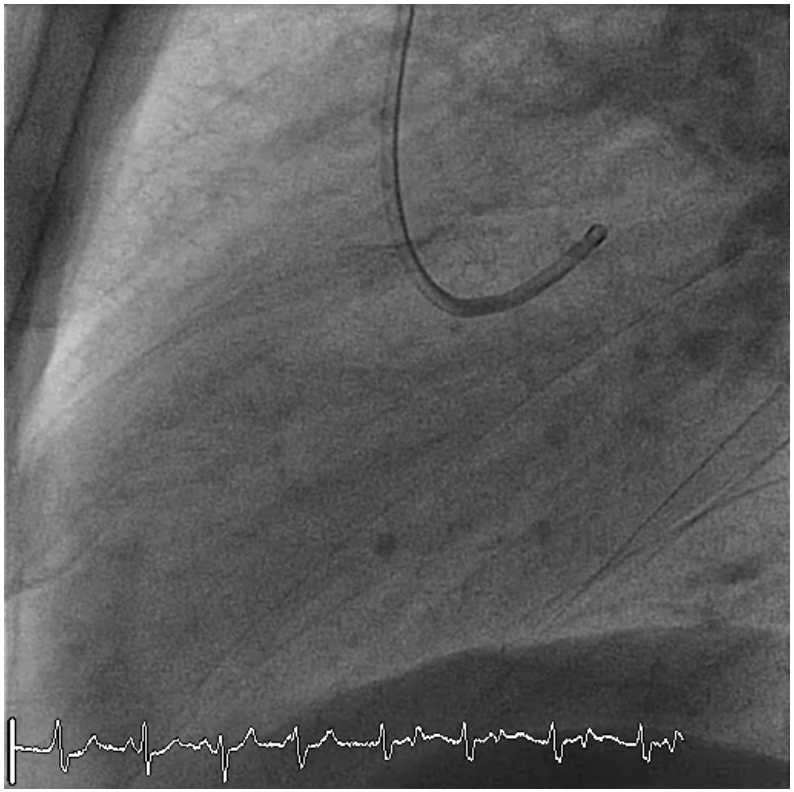


vor Aspiration



nach Aspiration

Beispiel Aspiration



nach Stenting

TAPAS Studie Setup

Single-center, Prospective, Randomized, Open Trial

All consecutive patients with a possible ST-elevated Acute Myocardial Infarction within 12 hours after onset of symptoms

1:1 pre-angiography randomization
N = 1'071 patients
University Medical Center Groningen, the Netherlands

Conventional PCI
n = 536

Thrombus Aspiration with Export®
n = 535

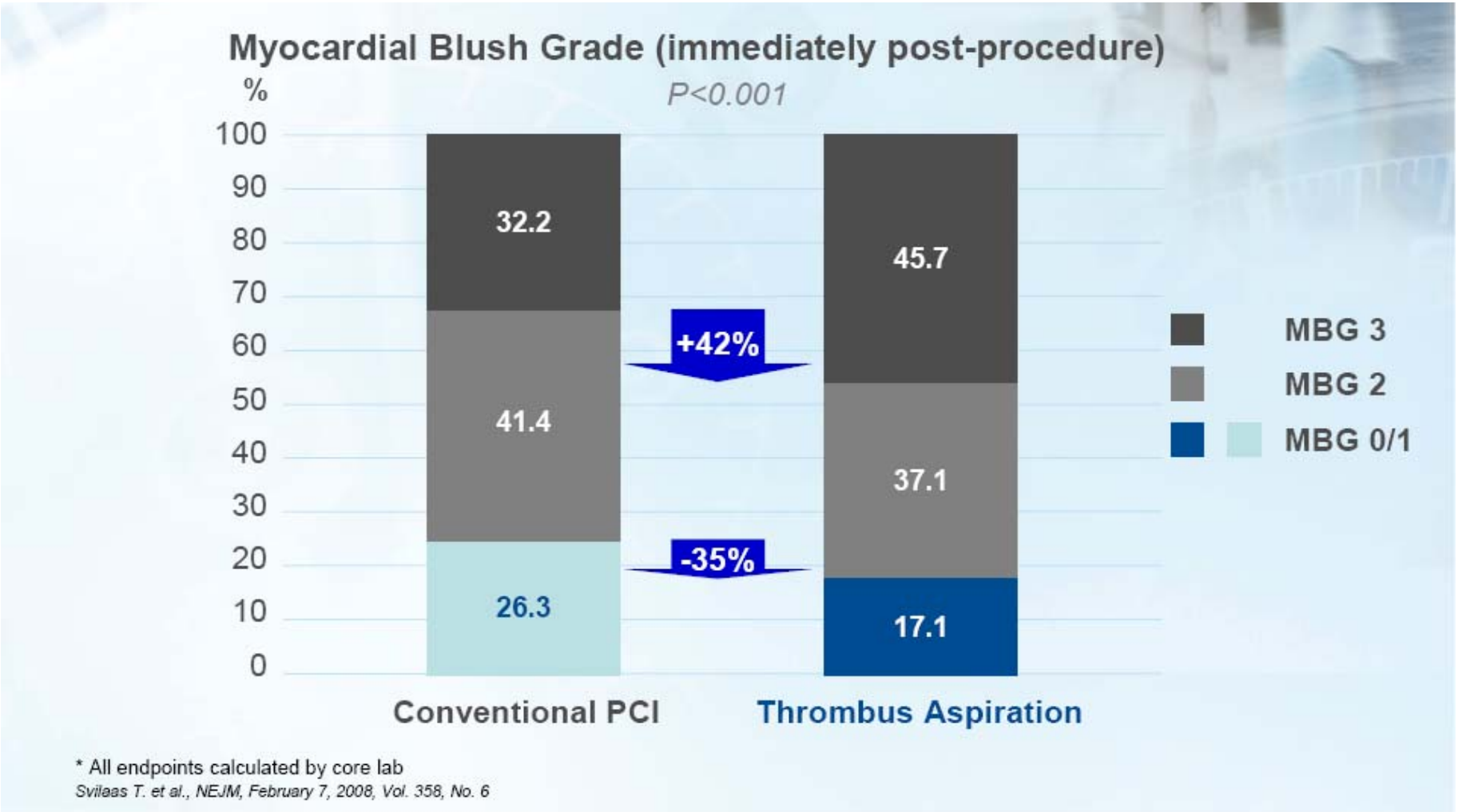
Clinical
Proc — 30d — 1yr

Primary Endpoint: MBG 0 or 1 as assessed by core lab

Secondary Endpoints: TIMI 3 flow, complete resolution of ST-segment elevation, absence of persistent ST-segment deviation, TVR, reinfarction, death, and MACE by 30 days

Svilaas T. et al., NEJM, February 7, 2008, Vol. 358, No. 6

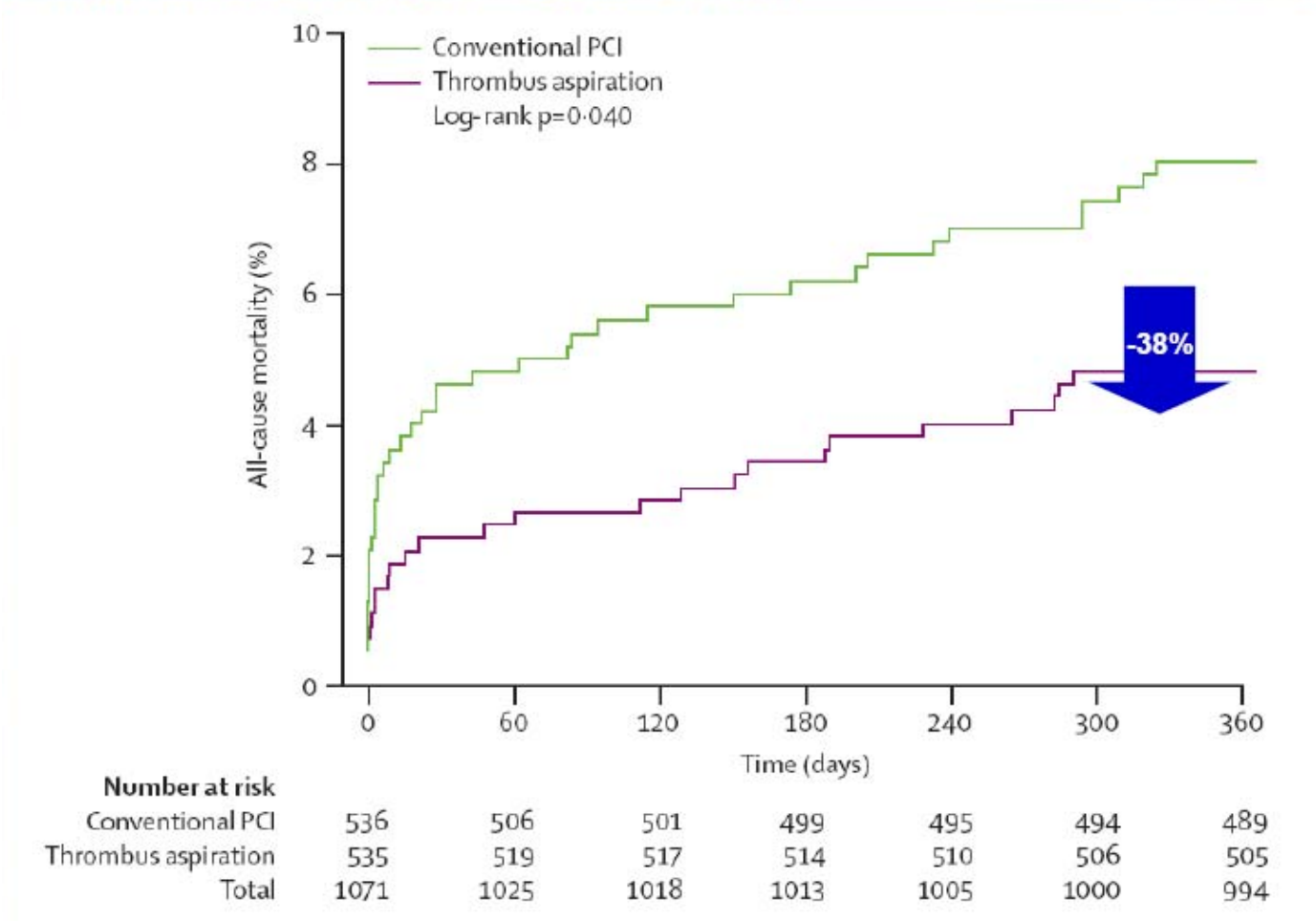
TAPAS Studie: Primärer Endpunkt



* All endpoints calculated by core lab

Svilaas T. et al., NEJM, February 7, 2008, Vol. 358, No. 6

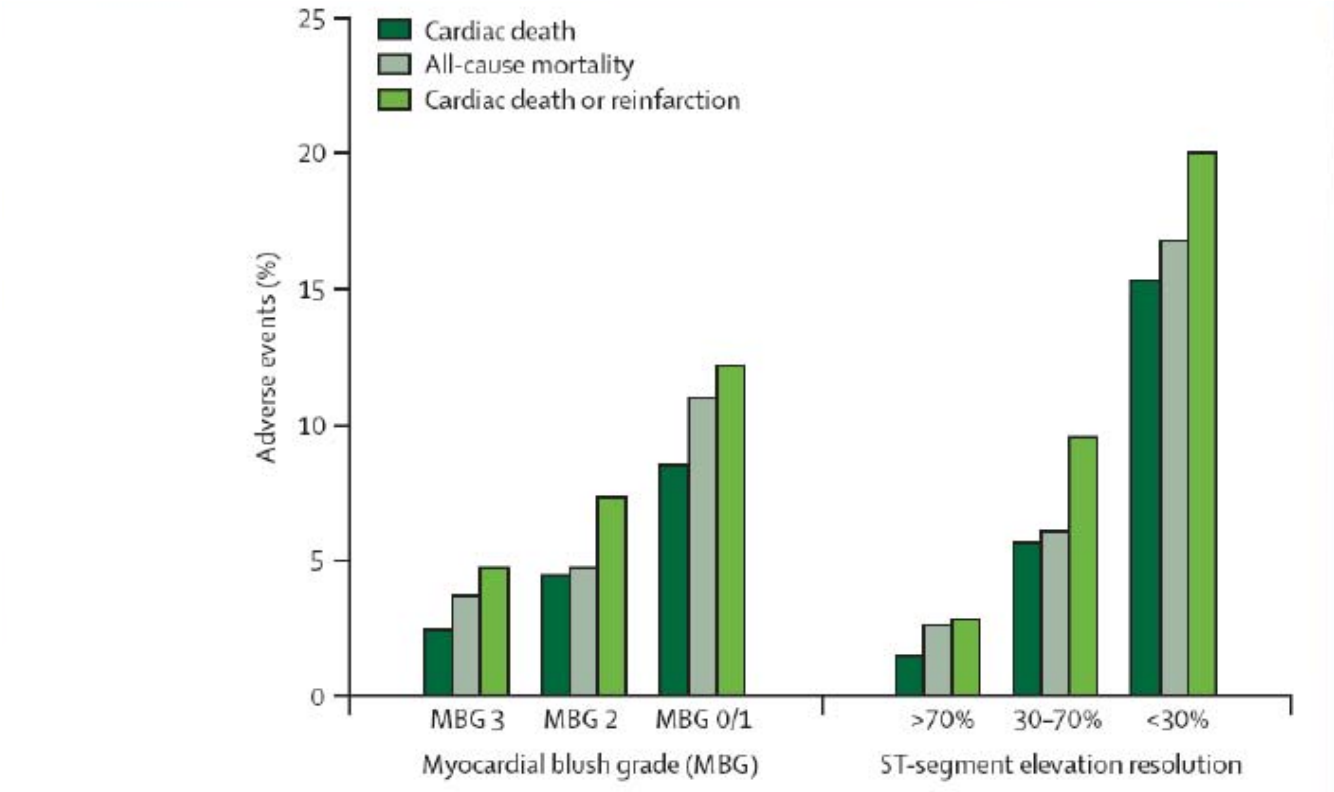
TAPAS Studie: Mortalität 1 Jahr



Number at risk							
Conventional PCI	536	506	501	499	495	494	489
Thrombus aspiration	535	519	517	514	510	506	505
Total	1071	1025	1018	1013	1005	1000	994

Vlaar et al., Lancet 2008; 371:1915-1920

TAPAS Studie: Myocardial Blush vs. Outcome

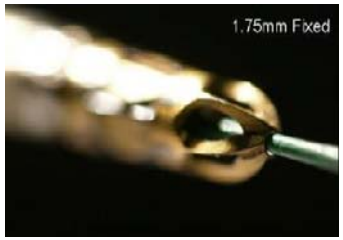


Rate of cardiac death (%)	2·4	4·4	8·5	p=0·003	1·4	5·6	15·3	p<0·0001
Rate of all-cause mortality (%)	3·7	4·7	11·0	p=0·001	2·6	6·0	16·8	p<0·0001
Rate of cardiac death or reinfarction (%)	4·7	7·3	12·2	p=0·004	2·8	9·5	20·0	p<0·0001

Vlaar et al., Lancet 2008; 371:1915-1920

Thrombektomie – Destruktion + Absaugung

- CardioPath® (Pathway Medical)

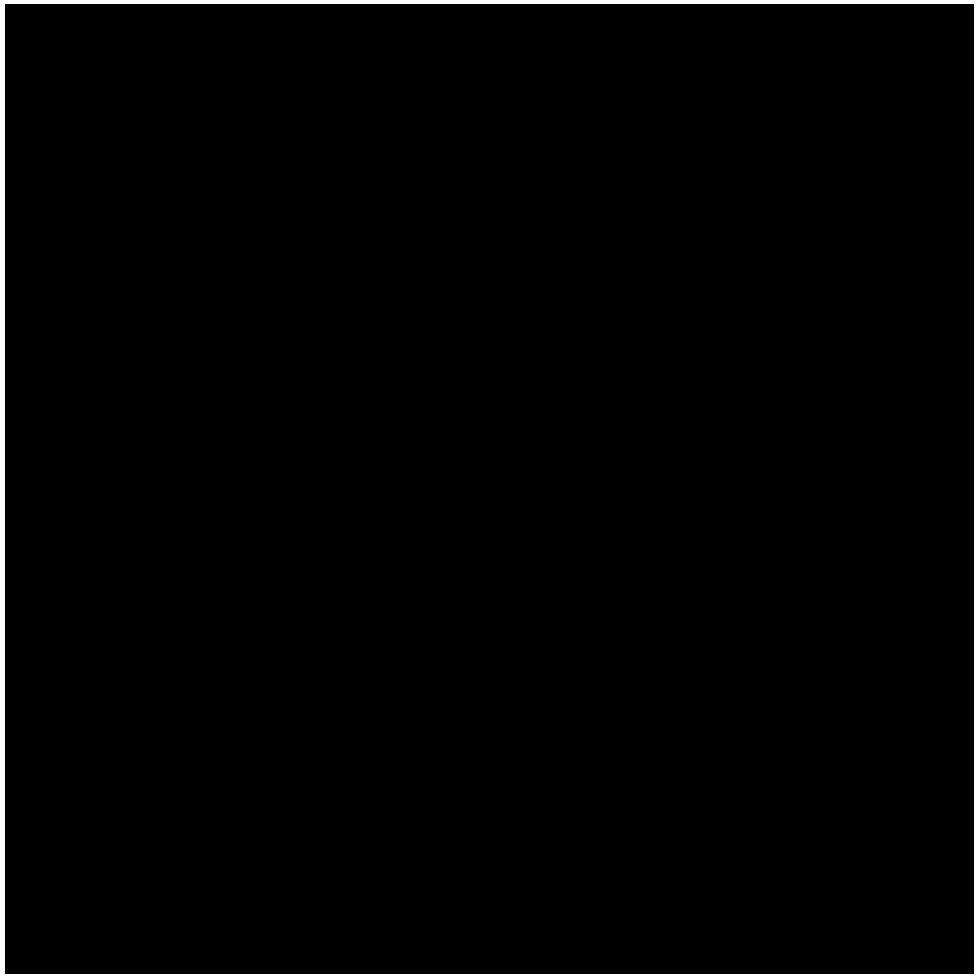


- XSizer® (ev3)

- ThromCat® (Spectranetics)

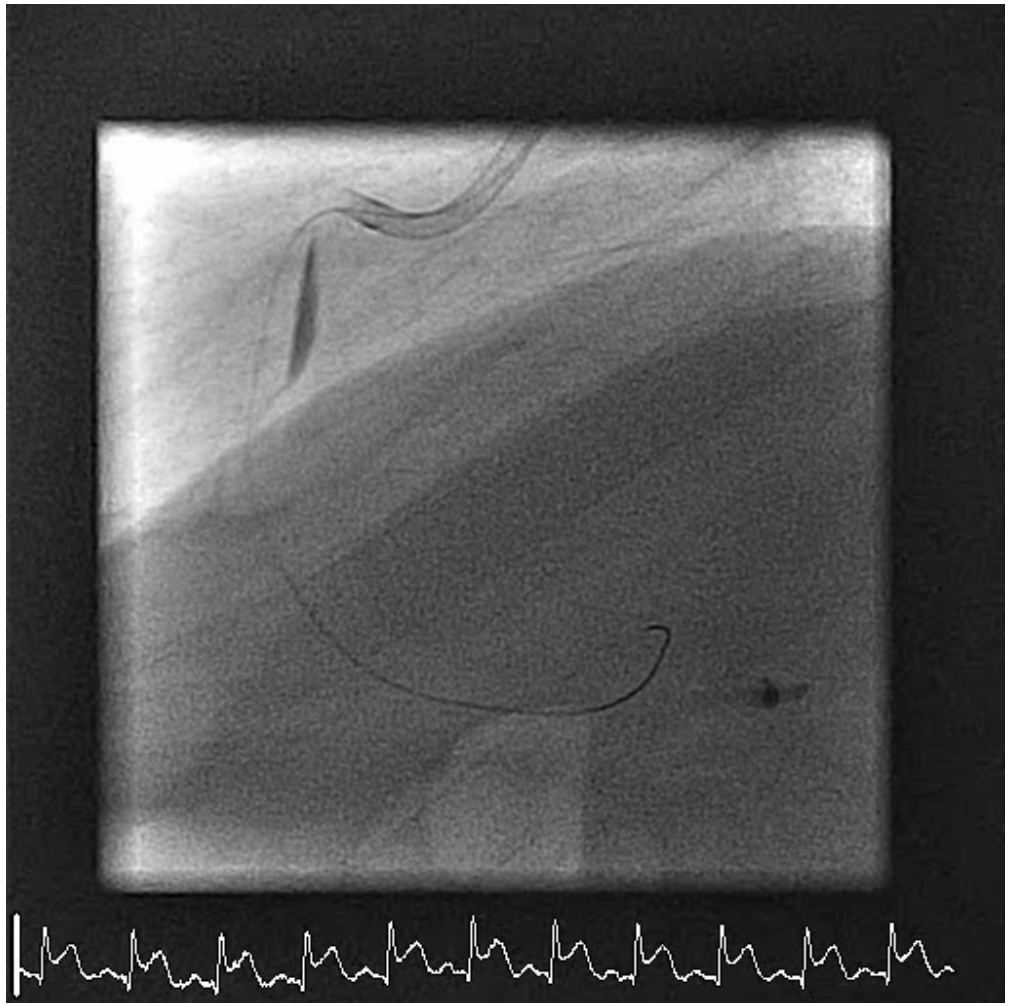
- AngioJet® (Possis Medical)

Thrombektomie – ThromCat XT



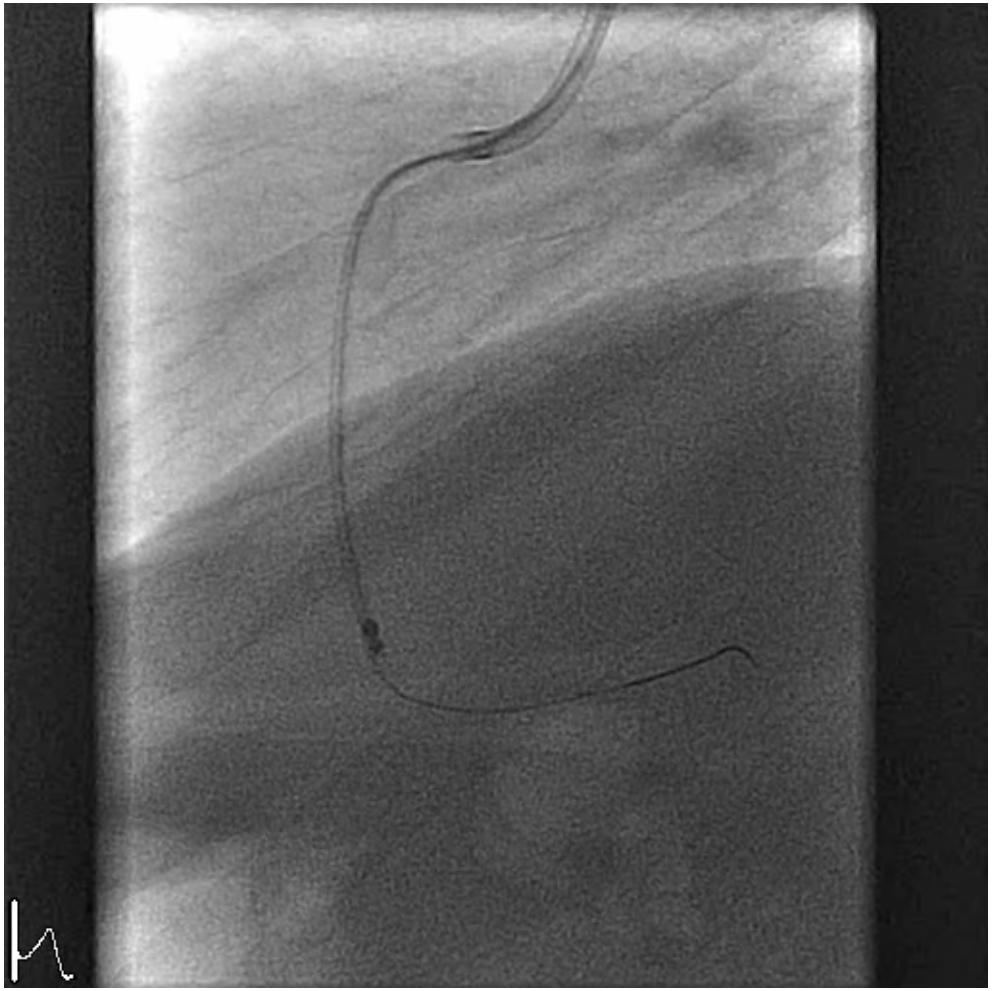
RCA-Verschluß
hohe Thrombuslast

Thrombektomie – ThromCat XT



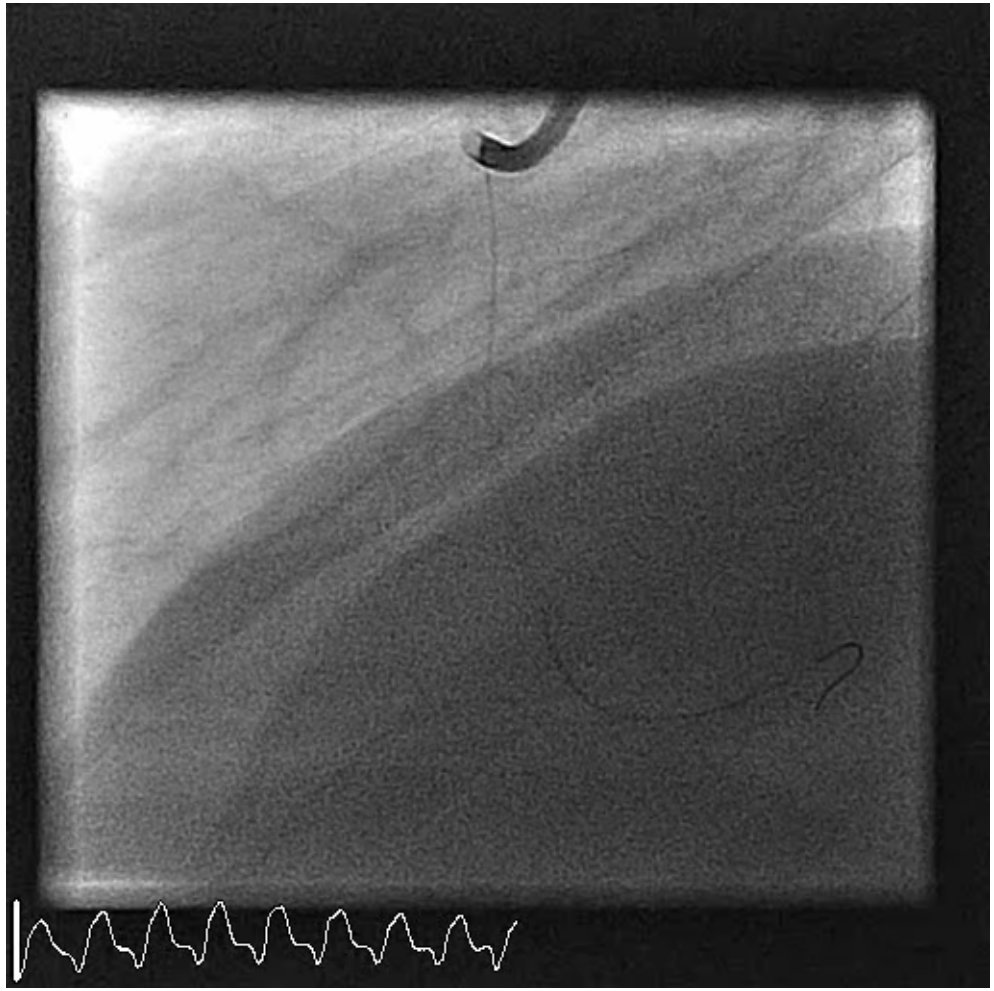
Drahtpassage

Thrombektomie – ThromCat XT



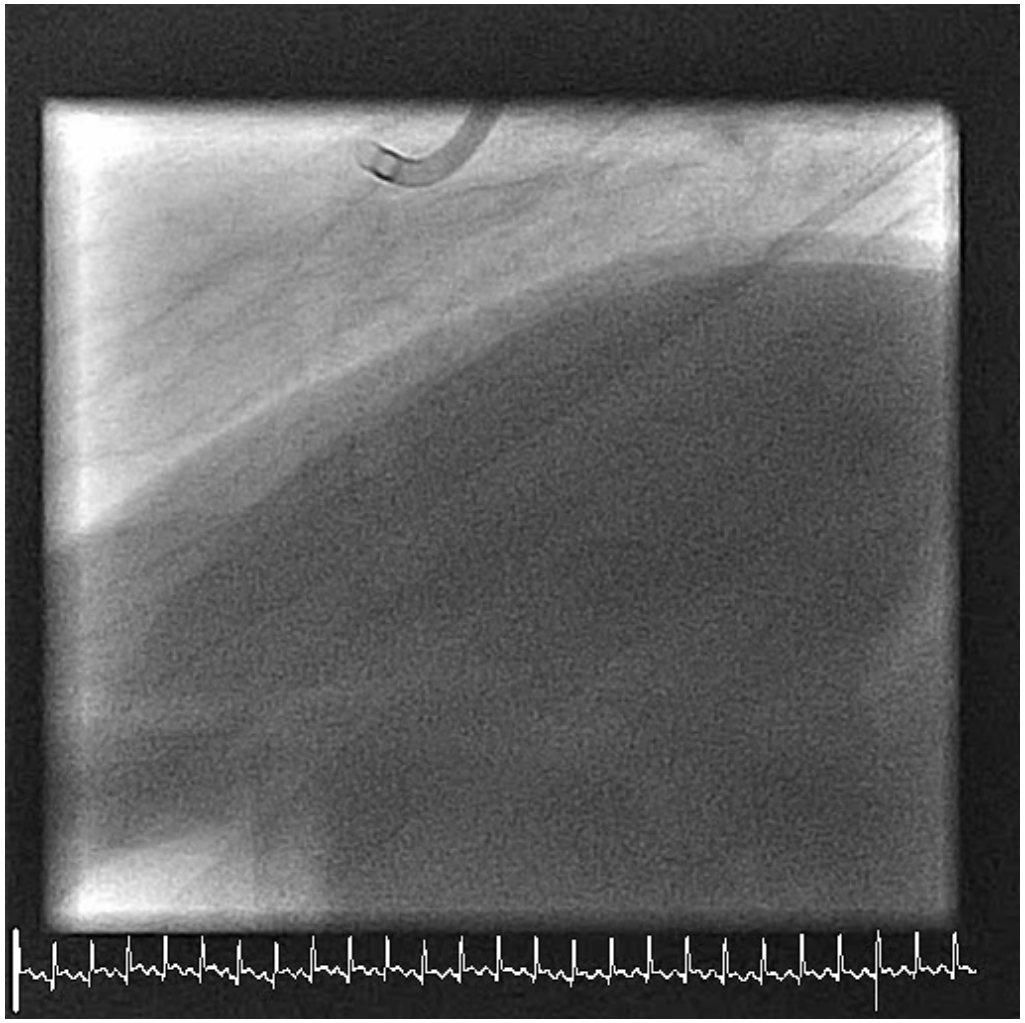
ThromCat 2 min

Thrombektomie – ThromCat XT



nach ThromCat

Thrombektomie – ThromCat XT

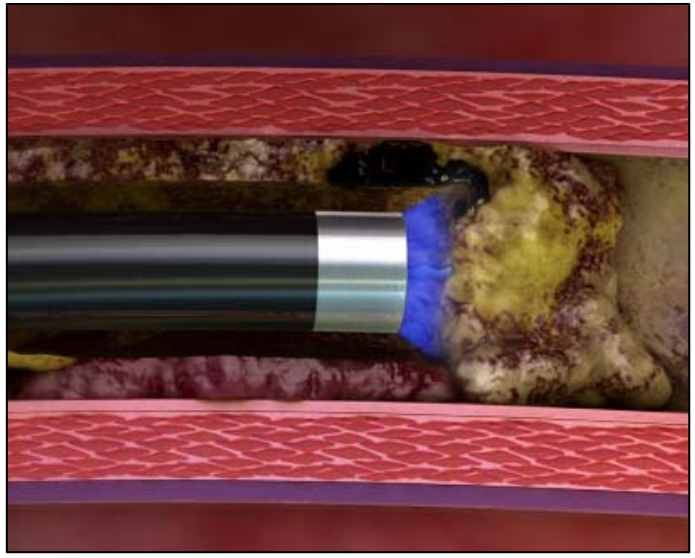


nach Stenting

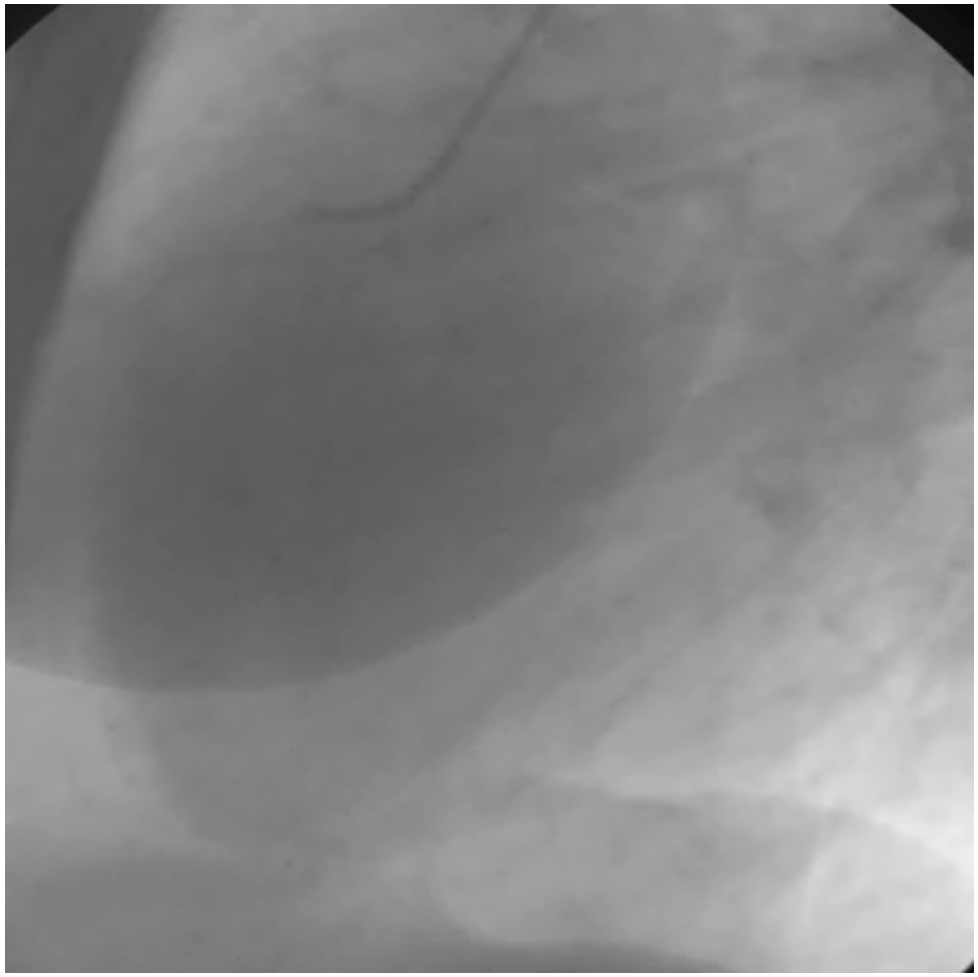
Thrombektomie – Laser

Excimer Laser Ablation System

Spectranetics

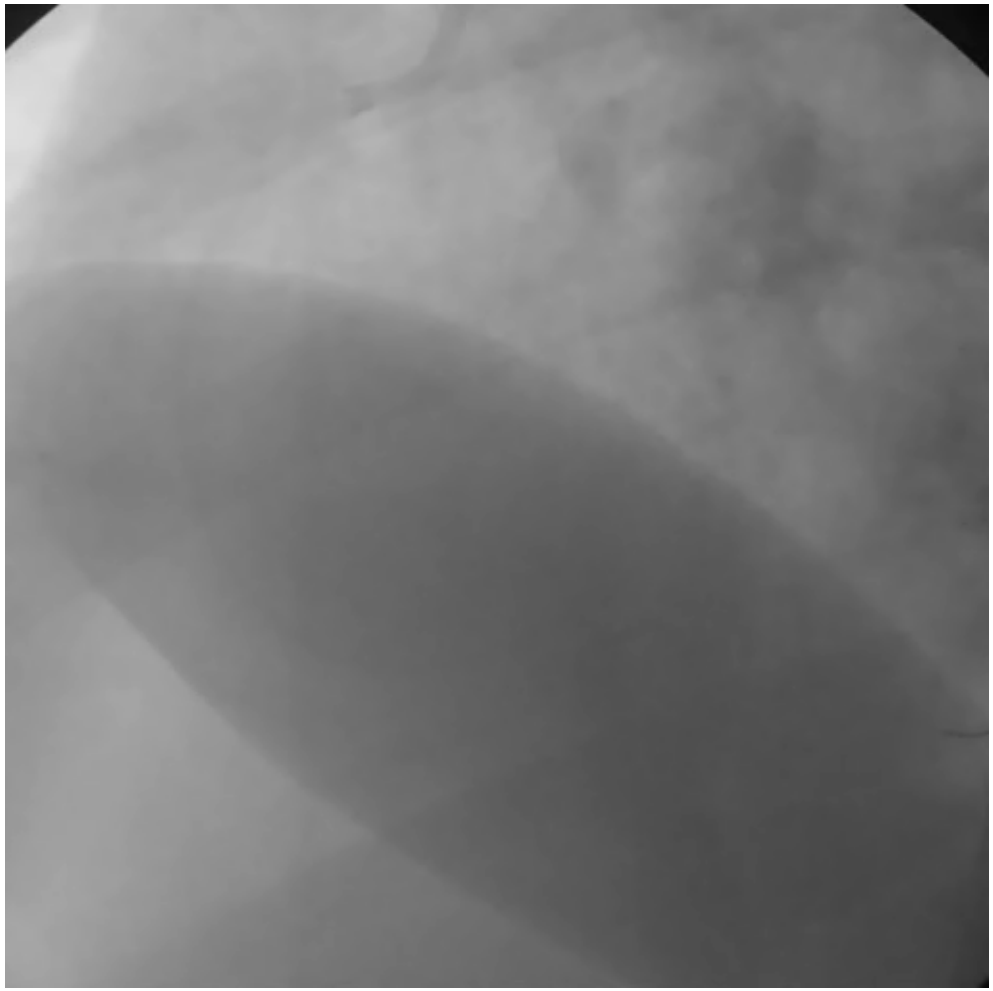


Thrombektomie – Laser



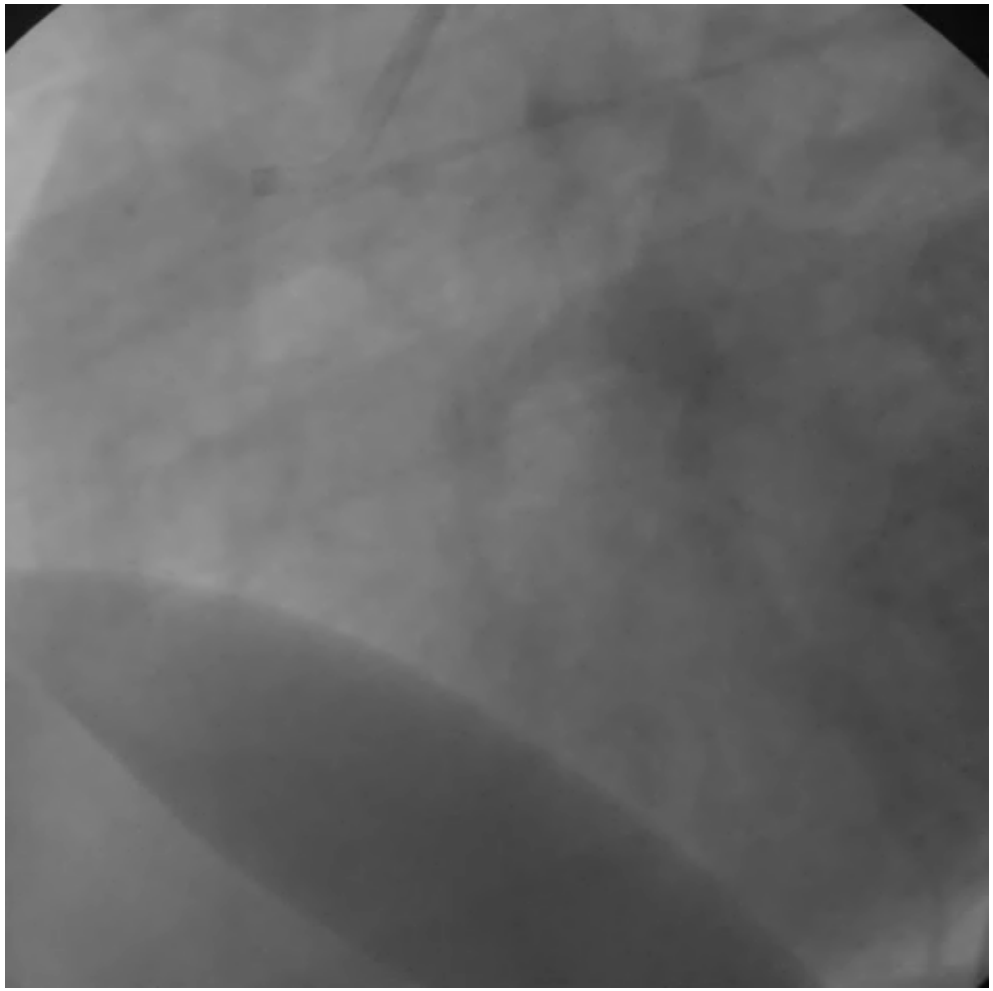
RCA-Verschluß
hohe Thrombuslast

Thrombektomie – Laser



nach Laser

Thrombektomie – Laser



nach Stent

Unfallkrankenhaus Berlin

Thrombektomie – Erfahrungen im ukb

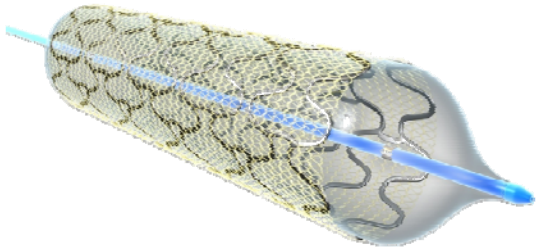
Methode	Blush 3
Laser	38%
ThromCat	54%
Aspiration	61%

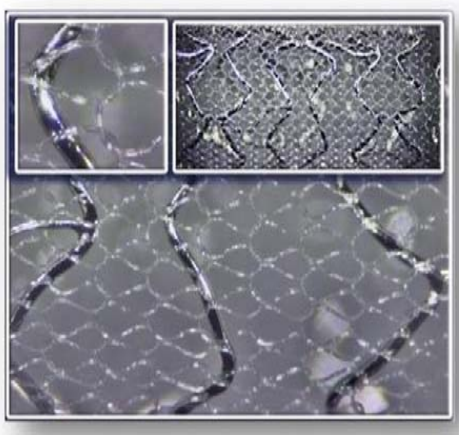
N ~ 100 pro Gruppe

Shayesteh S, Bruch L, unpublished data

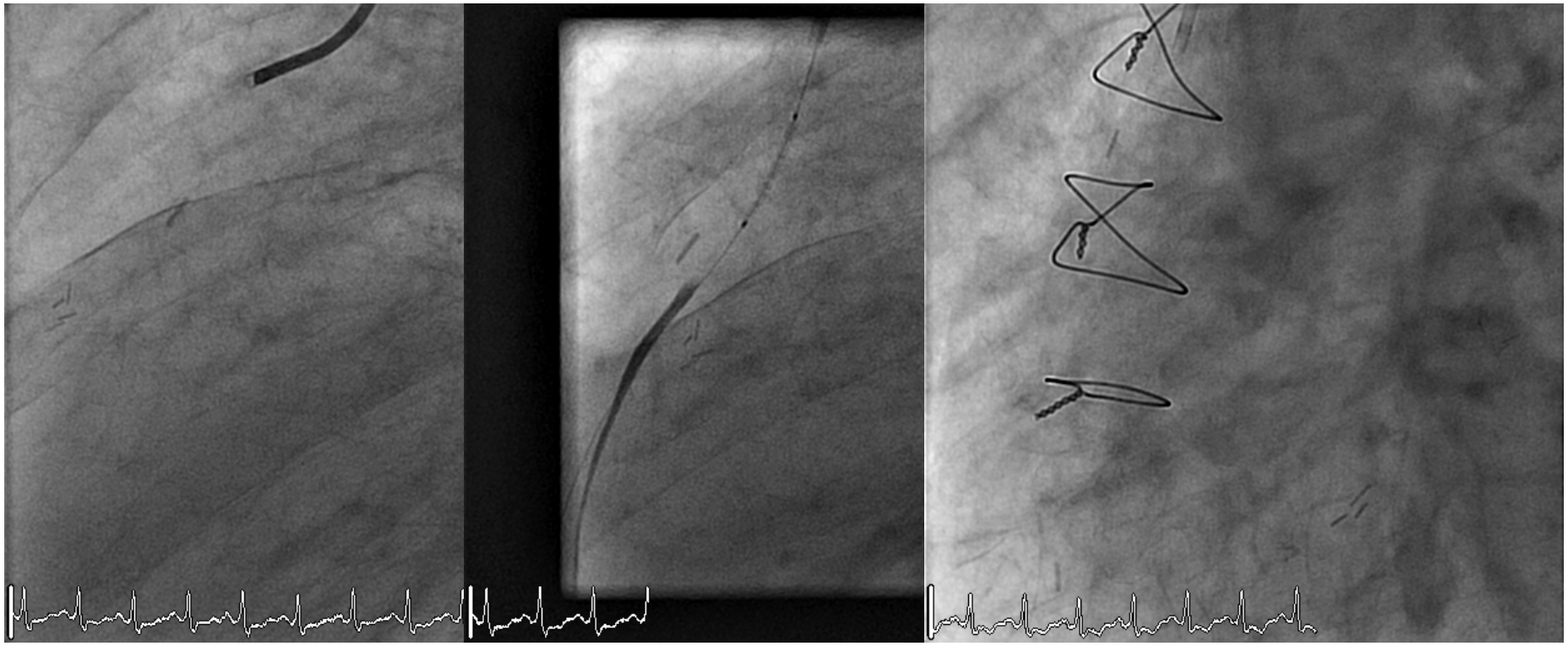
MGuard: Stent + Protektion

- MGuard is composed of a bare metal stent, wrapped with a flexible micron net and mounted on a rapid exchange delivery system
- MGuard net features:
  - Poly-Ethylene-Terephthalate (PET) fiber
  - 20 μ m thick
  - Single Fiber
  - Circular Knitting
  - Pores size when deployed: 180 μ m
  - Secured to proximal and distal crowns only

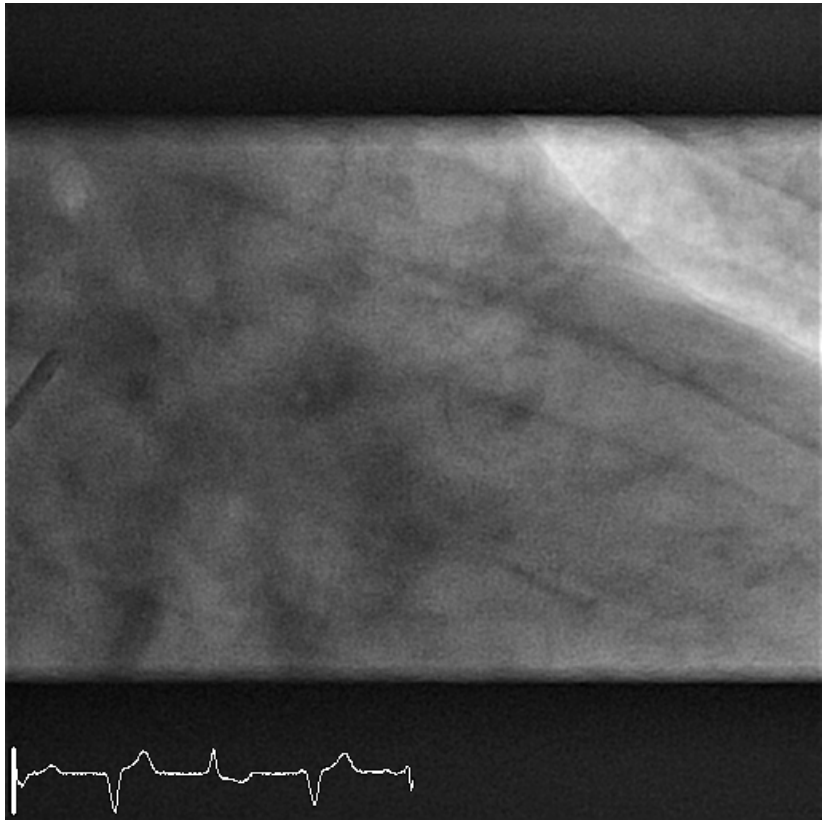


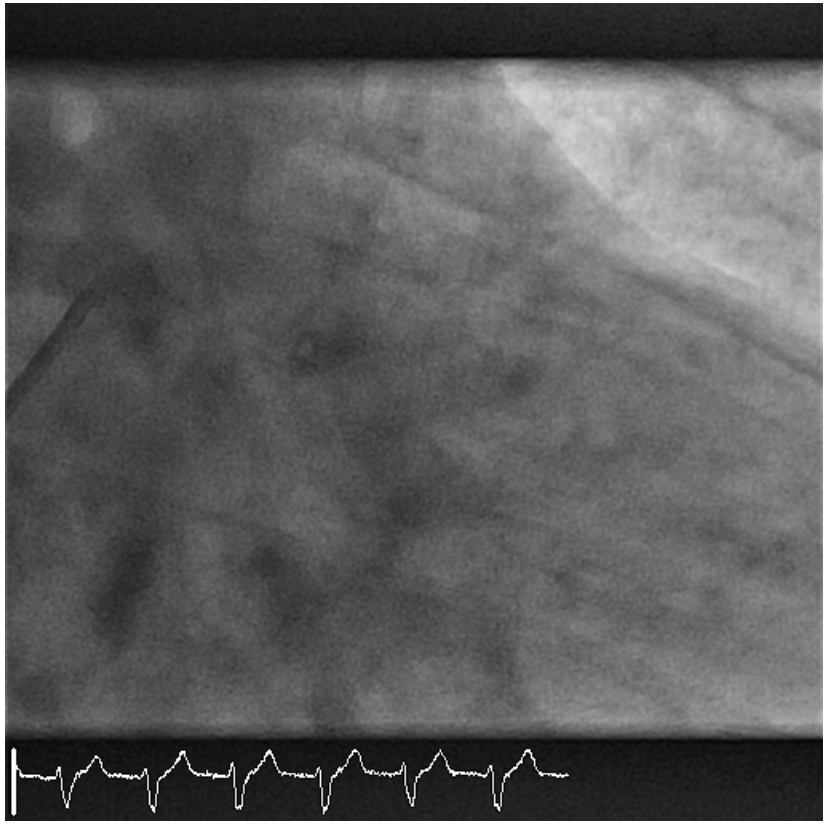


MGuard in ACVB

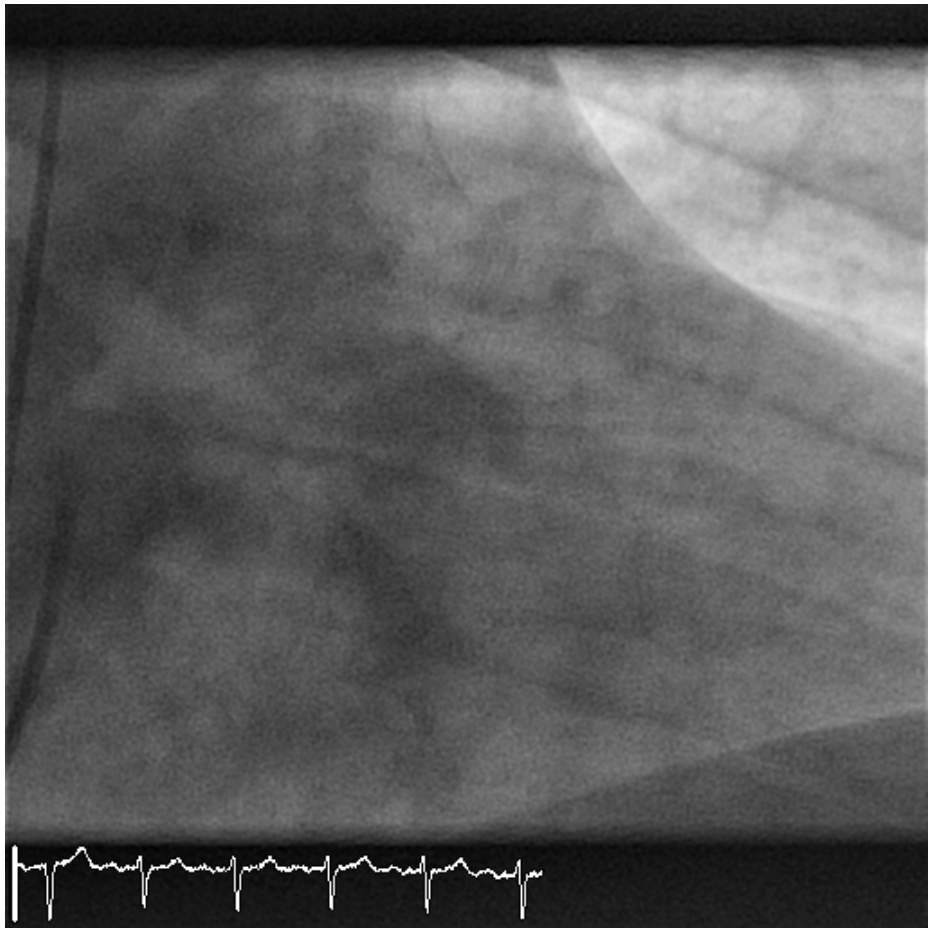


MGuard in AMI





MGuard in AMI, day 4 (DAP + LMWH)

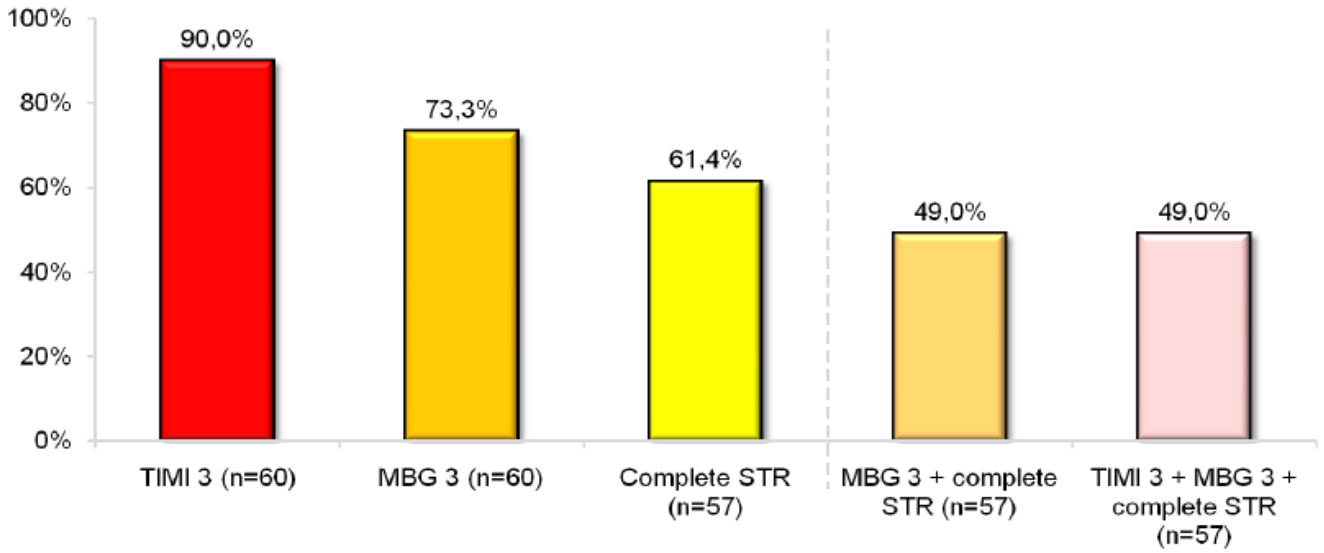


MGuard in AMI

euro PCR

The MAGICAL Trial

Primary and major secondary endpoints of MAGICAL Study*

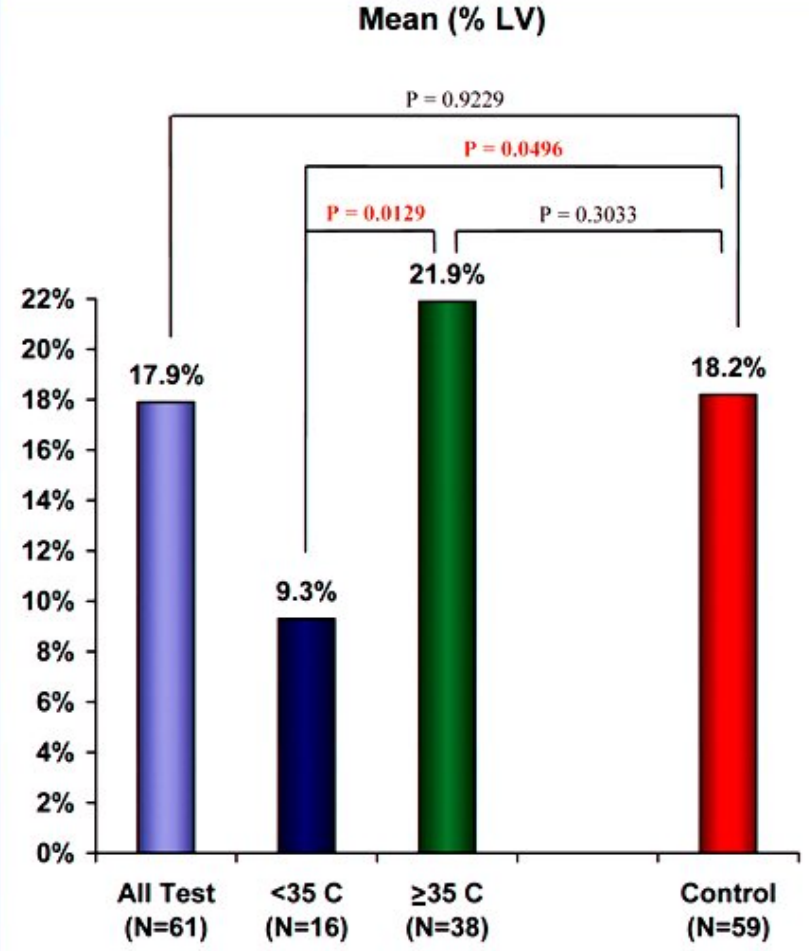


* ST resolution obtained from 57 patients due to technical issues

InspireMD

Dudek D et al., EuroPCR 2010

Kardioprotektion durch Hypothermie



COOL-MI (Radiant), 325 Pt.

prim. EP n.s. (SPECT 30d)

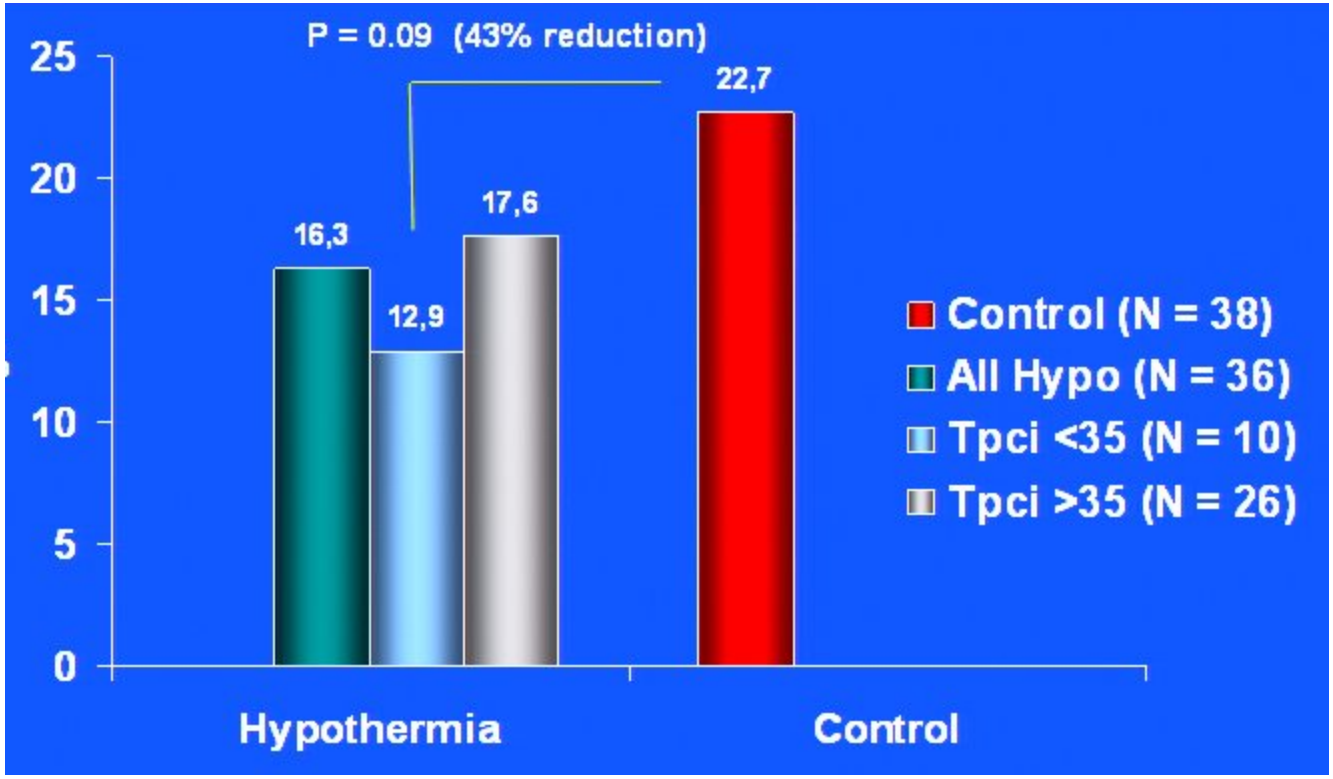
nur 26% < 35°C vor Reperfusion

wenn < 35°C: Reduktion der Infarktgröße um 49%

Grines CL, TCT 2004

Kardioprotektion durch Hypothermie

ICE-IT (InnerCool)

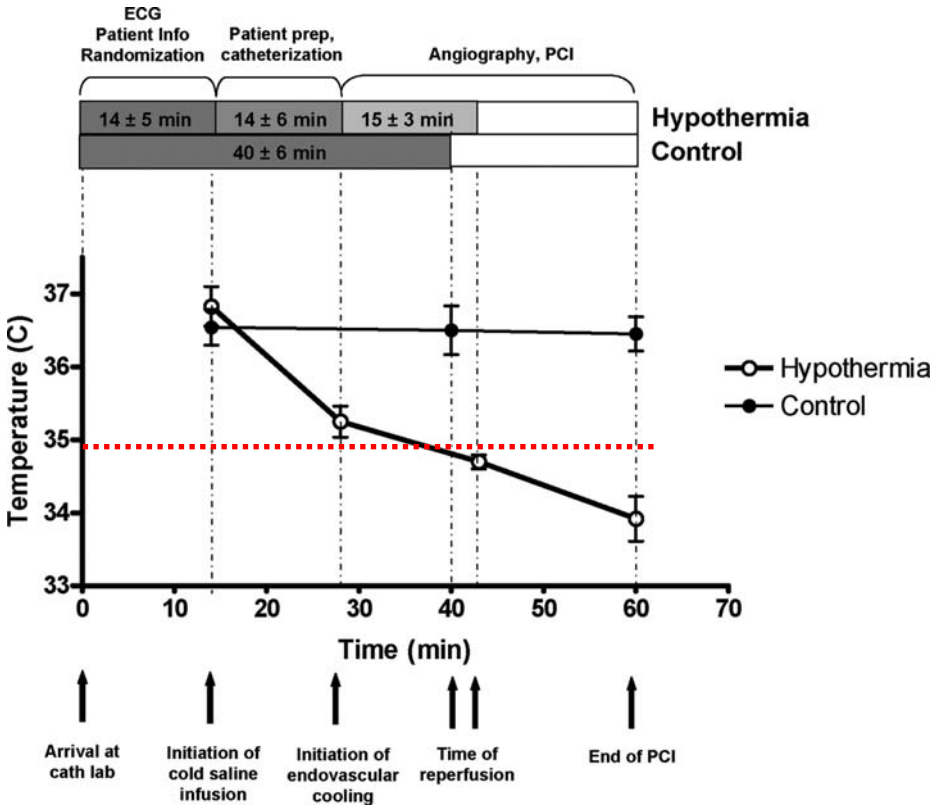


O´Neill WW, TCT 2004

Kardioprotektion durch Hypothermie

RAPID MI-ICE (InnerCool) Pilot Studie (2 x 10 Pat.)

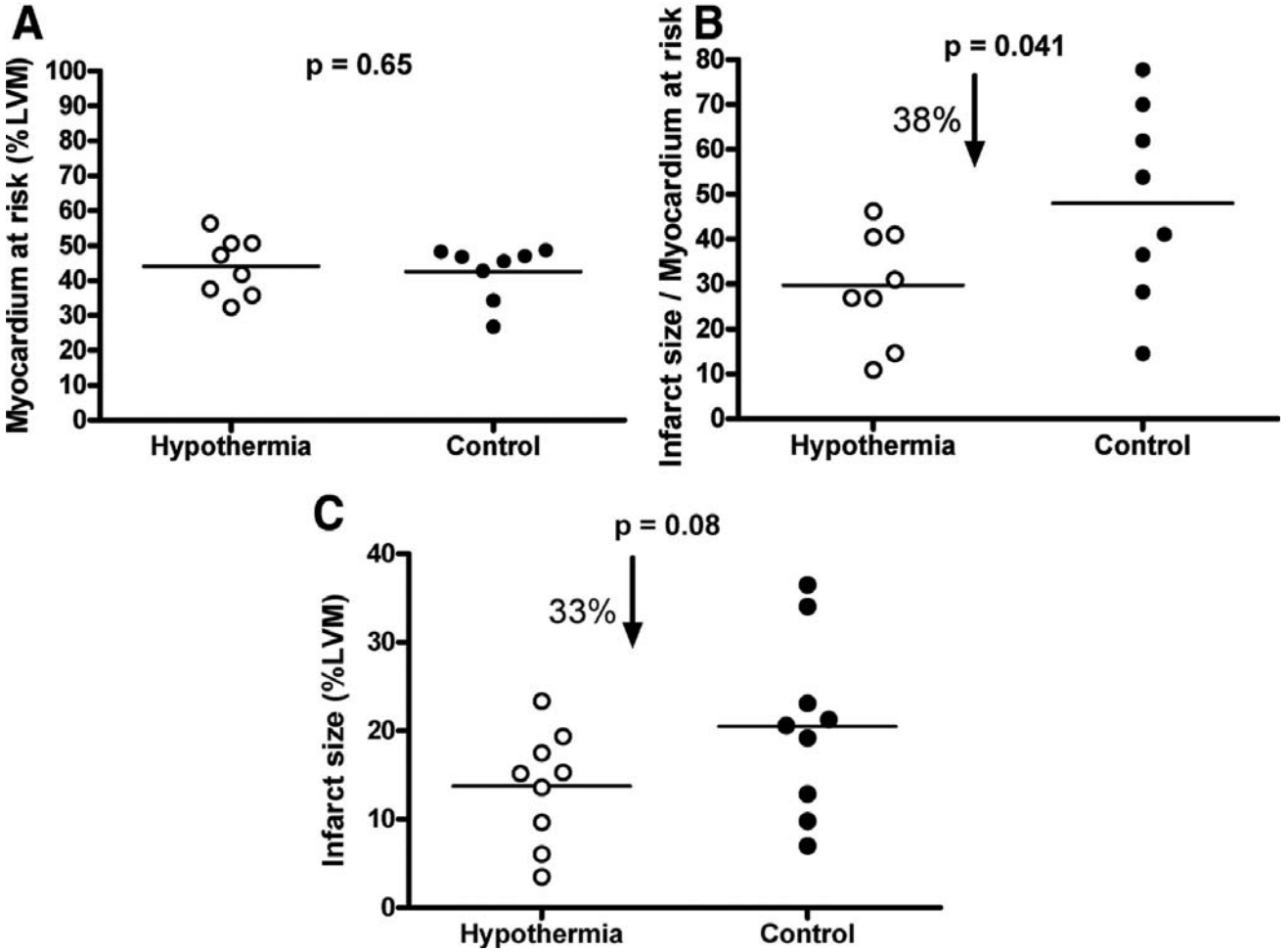
Kombination von NaCl-Infusion (4°C) und InnerCool RTx



14F i.v.

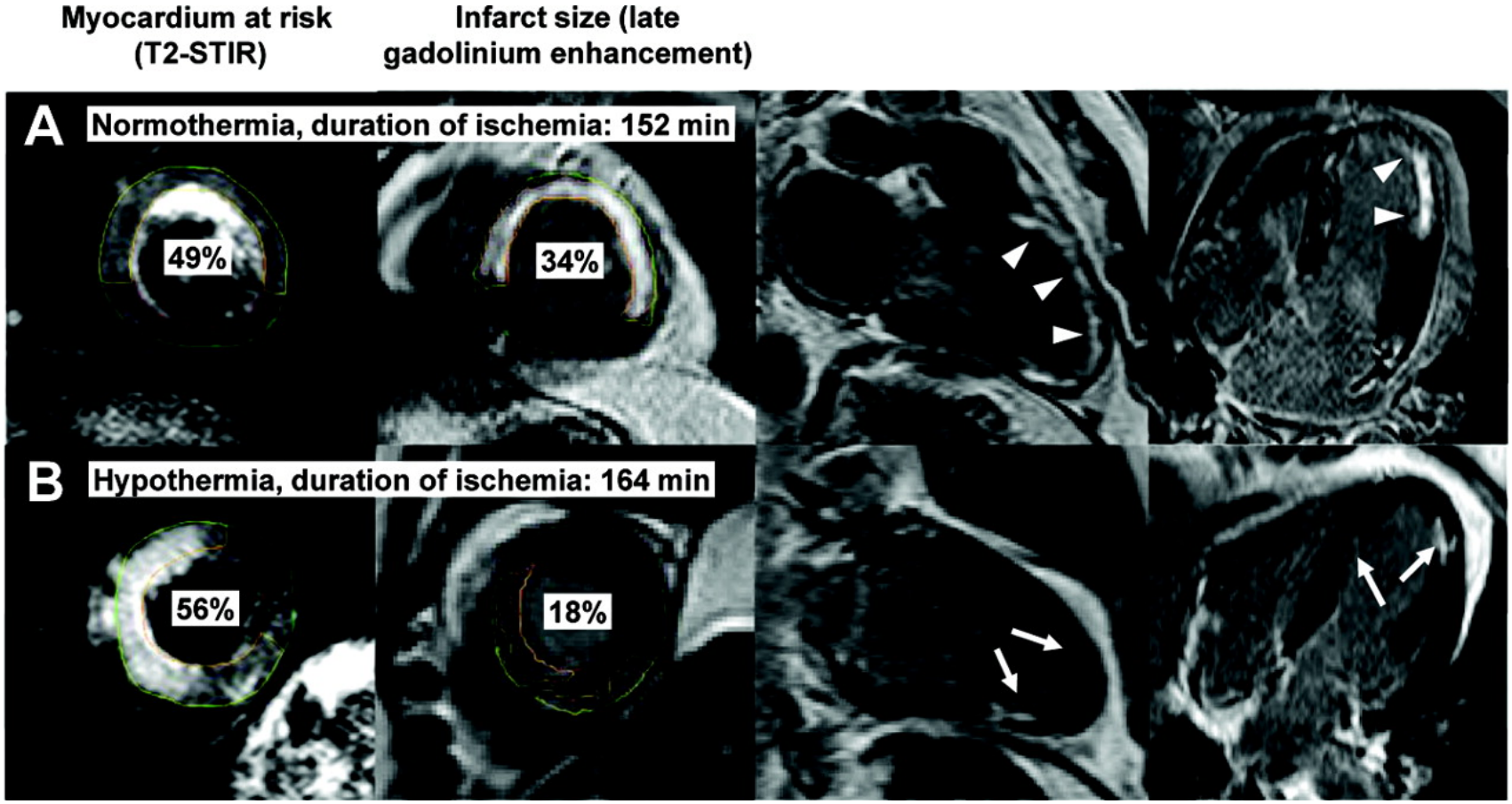
Götberg M, … Erlinge D, Circ Cardiovasc Interv 2010;3:400-407

RAPID MI-ICE: Infarktgröße



Götberg M, … Erlinge D, Circ Cardiovasc Interv 2010;3:400-407

RAPID MI-ICE: MRT



Götberg M, … Erlinge D, Circ Cardiovasc Interv 2010;3: 400-407

Unfallkrankenhaus Berlin

Zusammenfassung

Thrombektomie führt zu einer Verbesserung der Myokardperfusion bei der PCI.

Die einfache Aspiration ist in den meisten Fällen ausreichend.

Der Nutzen aufwendigerer Verfahren (mechanische oder Laser-thrombektomie) muß erst noch in randomisierten Studien gezeigt werden.

Der Protektionsstent (MGuard) könnte eine Alternative sein.

Die Anwendung einer kombinierten Hypothermie (Infusion + intravasal) scheint sicher und effektiv zu sein. Größere (Endpunkt-) Studien sind nötig (CHILL-MI in Vorbereitung).