RE-DUAL PCI: dual antithrombotic therapy with dabigatran after percutaneous coronary intervention in patients with atrial fibrillation


On behalf of the steering committee and RE-DUAL PCI investigators
Antithrombotic therapy for atrial fibrillation and PCI

**Anticoagulant therapy**
Anticoagulation superior to antiplatelet therapy

**Antiplatelet therapy**
Dual antiplatelet therapy superior to ASA alone

**BOTH anticoagulant and dual antiplatelet therapy = 'triple therapy'**

High bleeding risk

ASA, acetylsalicylic acid; PCI, percutaneous coronary intervention
*Study drug should be administered 6 hours after sheath removal and no later than ≤120 hrs post-PCI (≤72 hrs is preferable). PROBE, prospective, randomized, open, blinded end-point; R, randomization; BMS, bare metal stent; DES, drug-eluting stent. ClinicalTrials.gov: NCT02164864; Cannon et al. Clin Cardiol 2016
**Study objective and design**

RE-DUAL PCI tests the safety and efficacy of two regimens of dual therapy with dabigatran without aspirin vs triple therapy with warfarin

- The primary endpoint was time to first ISTH major or clinically relevant non-major bleeding
- **Formally tested and powered** endpoints included:
  - Non-inferiority of 110 mg and 150 mg dual therapy groups on time to first ISTH major or clinically relevant non-major bleeding event.
  - Non-inferiority of both dual therapy groups combined on time to first event of death, thromboembolic event (MI, stroke, systemic embolism) or unplanned revascularization
  - Superiority testing of the bleeding endpoints
- 100% of outcome events were independently adjudicated by blinded external committee

ISTH, International Society of Thrombosis and Haemostasis; MI, myocardial infarction  Non-inferiority testing (margin 1.38)
## Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Dabigatran 110 mg dual therapy (n=981)</th>
<th>Warfarin triple therapy (n=981)</th>
<th>Dabigatran 150 mg dual therapy (n=763)</th>
<th>Corresponding Warfarin triple therapy (n=764)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, years, mean</strong></td>
<td>71.5</td>
<td>71.7</td>
<td>68.6</td>
<td>68.8</td>
</tr>
<tr>
<td>≥80 (US, ROW), ≥70 (Japan), %</td>
<td>22.9</td>
<td>22.9</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>&lt;80 (US, ROW), &lt;70 (Japan), %</td>
<td>77.1</td>
<td>77.1</td>
<td>99.0</td>
<td>99.0</td>
</tr>
<tr>
<td><strong>Male, %</strong></td>
<td>74.2</td>
<td>76.5</td>
<td>77.6</td>
<td>77.7</td>
</tr>
<tr>
<td><strong>Baseline CrCl, mL/min, mean</strong></td>
<td>76.3</td>
<td>75.4</td>
<td>83.7</td>
<td>81.3</td>
</tr>
<tr>
<td><strong>Diabetes mellitus, %</strong></td>
<td>36.9</td>
<td>37.8</td>
<td>34.1</td>
<td>39.7</td>
</tr>
<tr>
<td><strong>CHA\textsubscript{2}DS\textsubscript{2}–VASc score (mean)</strong></td>
<td>3.7</td>
<td>3.8</td>
<td>3.3</td>
<td>3.6</td>
</tr>
<tr>
<td><strong>Modified HAS-BLED score at baseline (mean)</strong></td>
<td>2.7</td>
<td>2.8</td>
<td>2.6</td>
<td>2.7</td>
</tr>
<tr>
<td><strong>ACS indication for PCI, %</strong></td>
<td>51.9</td>
<td>48.4</td>
<td>51.2</td>
<td>48.3</td>
</tr>
<tr>
<td><strong>DES only, %</strong></td>
<td>82.0</td>
<td>84.2</td>
<td>81.4</td>
<td>83.5</td>
</tr>
</tbody>
</table>
Primary Endpoint: Time to first ISTH major or clinically relevant non-major bleeding event

HR: 0.52 (95% CI: 0.42–0.63)  
Non-inferiority P<0.0001  
P<0.0001

HR: 0.72 (95% CI: 0.58–0.88)  
Non-inferiority P<0.0001  
P=0.002

Full analysis set presented. HRs and Wald CIs from Cox proportional-hazard model. For the dabigatran 110 mg vs warfarin comparison, the model is stratified by age, non-elderly vs elderly (<70 or ≥70 in Japan and <80 or ≥80 years old elsewhere). For the dabigatran 150 mg vs warfarin comparison, an unstratified model is used, elderly patients outside the USA are excluded. Non-inferiority P value is one sided (alpha=0.025). Wald two-sided P value from (stratified) Cox proportional-hazard model (alpha=0.05)
Primary endpoint: ISTH major or clinically relevant non-major bleeding event

Dabigatran 110 mg dual therapy (n=981)

Warfarin triple therapy (n=981)

15.4%

26.9%

HR: 0.52 (95% CI: 0.42–0.63)  
P<0.0001

ARR: 11.5%

Dabigatran 150 mg dual therapy (n=763)

Warfarin triple therapy (n=764)

20.2%

25.7%

HR: 0.72 (95% CI: 0.58–0.88)  
P=0.002

ARR: 5.5%

Wald two-sided P value from (stratified) Cox proportional-hazard model (alpha=0.05). ARR, absolute risk reduction
Rates of ISTH major bleeding

Dabigatran 110 mg dual therapy (n=981) vs Warfarin triple therapy (n=981)
- Dabigatran: 5.0%
- Warfarin: 9.2%
- HR: 0.52 (95% CI: 0.37–0.74)
- P=0.0003

Dabigatran 150 mg dual therapy (n=763) vs Warfarin triple therapy (n=764)
- Dabigatran: 5.6%
- Warfarin: 8.4%
- HR: 0.64 (95% CI: 0.43–0.94)
- P=0.022

Patients with outcome event (%)

ARR: 4.2%

Wald two-sided P value from (stratified) Cox proportional-hazard model (alpha=0.05). ISTH major bleeding definition: fatal, critical organ (including intracranial haemorrhage), clinically overt bleeding with fall in Hb ≥2 g/dL. Hb, haemoglobin
Wald two-sided P value from (stratified) Cox proportional-hazard model (alpha=0.05)

Rate of intracranial haemorrhage

- **Dabigatran 110 mg dual therapy (n=981)**: HR: 0.30 (95% CI: 0.08–1.07) P=0.064
  - ARR: 0.7%
  - Patients with outcome event (%): 1.0%

- **Warfarin triple therapy (n=981)**: HR: 0.12 (95% CI: 0.02–0.98) P=0.047
  - ARR: 0.9%
  - Patients with outcome event (%): 1.0%

- **Dabigatran 150 mg dual therapy (n=763)**: HR: 0.12 (95% CI: 0.02–0.98) P=0.047
  - ARR: 0.9%
  - Patients with outcome event (%): 1.0%

- **Warfarin triple therapy (n=764)**: HR: 0.12 (95% CI: 0.02–0.98) P=0.047
  - ARR: 0.9%
  - Patients with outcome event (%): 1.0%

**Patients with outcome event (%)**

- Dabigatran 110 mg dual therapy: 0.3%
- Warfarin triple therapy: 1.0%
- Dabigatran 150 mg dual therapy: 0.1%
- Warfarin triple therapy: 1.0%
Dabigatran (combined dose) dual therapy

Warfarin triple therapy

HR: 1.04 (95% CI: 0.84–1.29)  
Non-inferiority P=0.0047

Non-inferiority P value is one sided (alpha=0.025). Results presented are Step 3 of hierarchical testing procedure, testing non-inferiority of dabigatran dual therapy (combined doses) to warfarin triple therapy in death or thromboembolic event and unplanned revascularization.
## Additional individual thromboembolic endpoints

<table>
<thead>
<tr>
<th>Event</th>
<th>Dabigatran 110 mg dual therapy (n=981) n (%)</th>
<th>Warfarin triple therapy (n=981) n (%)</th>
<th>D110 DT vs warfarin TT HR (95% CI)</th>
<th>P value</th>
<th>Dabigatran 150 mg dual therapy (n=763) n (%)</th>
<th>Warfarin triple therapy (n=764) n (%)</th>
<th>D150 DT vs warfarin TT HR (95% CI)</th>
<th>P value</th>
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<tbody>
<tr>
<td>All-cause death</td>
<td>55 (5.6)</td>
<td>48 (4.9)</td>
<td>1.12 (0.76–1.65)</td>
<td>0.56</td>
<td>30 (3.9)</td>
<td>35 (4.6)</td>
<td>0.83 (0.51–1.34)</td>
<td>0.44</td>
</tr>
<tr>
<td>Stroke</td>
<td>17 (1.7)</td>
<td>13 (1.3)</td>
<td>1.30 (0.63–2.67)</td>
<td>0.48</td>
<td>9 (1.2)</td>
<td>8 (1.0)</td>
<td>1.09 (0.42–2.83)</td>
<td>0.85</td>
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<td>Unplanned revascularization</td>
<td>76 (7.7)</td>
<td>69 (7.0)</td>
<td>1.09 (0.79–1.51)</td>
<td>0.61</td>
<td>51 (6.7)</td>
<td>52 (6.8)</td>
<td>0.96 (0.65–1.41)</td>
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<td>MI</td>
<td>44 (4.5)</td>
<td>29 (3.0)</td>
<td>1.51 (0.94–2.41)</td>
<td>0.09</td>
<td>26 (3.4)</td>
<td>22 (2.9)</td>
<td>1.16 (0.66–2.04)</td>
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<td>Stent thrombosis</td>
<td>15 (1.5)</td>
<td>8 (0.8)</td>
<td>1.86 (0.79–4.40)</td>
<td>0.15</td>
<td>7 (0.9)</td>
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<td>0.99 (0.35–2.81)</td>
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Results presented are times to event. Stent thrombosis is time to definite stent thrombosis.
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<td>HR (95% CI)</td>
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Results presented are times to event. Stent thrombosis is time to definite stent thrombosis.
Conclusions

In patients with AF who have undergone PCI:

- Dual therapy with dabigatran and a P2Y12 antagonist significantly reduced the risk of bleeding versus warfarin triple therapy, with non-inferiority for overall thromboembolic events.

- Absolute risk reductions with dabigatran dual therapy were 11.5% and 5.5% in ISTH major or clinically relevant non-major bleeding at the 110 mg and 150 mg doses, respectively, compared with warfarin triple therapy.

- These dabigatran dual therapy regimens, using doses approved worldwide for stroke prevention, offer clinicians two additional options for managing Afib patients post-PCI.
Algorithm for dual antiplatelet therapy (DAPT) in patients with an indication for oral anticoagulation undergoing percutaneous coronary intervention (PCI)

Patients with an indication for oral anticoagulation undergoing PCI

Concerns about ischaemic risk prevailing

Concerns about bleeding risk prevailing

Time from treatment initiation

1 mo.

3 mo.

6 mo.

12 mo.

Beyond 12 mo.

ACO
1 mo. Triple Therapy
(Class IIa B)

ACO
Triple Therapy
up to 6 mo.
(Class IIa B)

AO
Dual Therapy up to 12 mo.
(Class IIa A)

CO OR AD
Dual Therapy up to 12 mo.
(Class IIa A)

OAC alone
(Class IIa B)

ACO
Dual Therapy
up to 12 mo.
(Class IIa A)

CO
Dual Therapy
up to 12 mo.
(Class IIa A)

O = Oral anticoagulation
A = Aspirin
C = Clopidogrel

www.escardio.org/guidelines

2017 ESC Focused Update on DAPT in Coronary Artery Disease, developed in collaboration with FACTS (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx419)
2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology

Chairpersons: Borja Ibanez (Spain), Stefan James (Sweden).

Authors/Task Force Members: Stefan Agewall (Norway), Manuel J. Antunes (Portugal), Chiara Bucciarelli-Ducci (UK), Héctor Bueno (Spain), Alida L. P. Caforio (Italy), Filippo Crea (Italy), John A. Goudevenos (Greece), Sigrun Halvorsen (Norway), Gerhard Hindricks (Germany), Adnan Kastrati (Germany), Mattie J. Lenzen (The Netherlands), Eva Prescott (Denmark), Marco Roffi (Switzerland), Marco Valgimigli (Switzerland), Christoph Varenhorst (Sweden), Pascal Vranckx (Belgium), Petr Widimský (Czech Republic).

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## Level of evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Data derived from multiple randomized clinical trials or meta-analyses.</td>
</tr>
<tr>
<td>B</td>
<td>Data derived from a single randomized clinical trial or large non-randomized studies.</td>
</tr>
<tr>
<td>C</td>
<td>Consensus of opinion of the experts and/or small studies, retrospective studies, registries.</td>
</tr>
</tbody>
</table>

159 recommendations based on 477 references

- **A**: 37 recommendations (23%)
- **B**: 44 recommendations (28%)
- **C**: 78 recommendations (49%)
## Classes of recommendations

<table>
<thead>
<tr>
<th>Classes</th>
<th>Definition</th>
<th>Suggested wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.</td>
<td>Recommended/is indicated.</td>
</tr>
<tr>
<td><strong>Class IIa</strong></td>
<td>Weight of evidence/opinion is in favour of usefulness/efficacy.</td>
<td>Should be considered.</td>
</tr>
<tr>
<td><strong>Class IIb</strong></td>
<td>Usefulness/efficacy is less well established by evidence/opinion.</td>
<td>May be considered.</td>
</tr>
<tr>
<td>Class III</td>
<td>Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.</td>
<td>Not recommended.</td>
</tr>
</tbody>
</table>

159 recommendations

- **Class I**: 92 recommendations (58%)
  - Recommended/is indicated.
- **Class IIa**: 58 recommendations (36%)
  - Should be considered.
- **Class IIb**: 16 recommendations (10%)
  - May be considered.
- **Class III**: 13 recommendations (8%)
  - Not recommended.
What is new in 2017 Guidelines on AMI-STEMI

### 2017 NEW / REVISED CONCEPTS

<table>
<thead>
<tr>
<th><strong>MINOCA AND QUALITY INDICATORS:</strong></th>
<th>New chapters dedicated to these topics.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STRATEGY SELECTION AND TIME DELAYS:</strong></td>
<td>Clear definition of first medical contact (FMC).</td>
</tr>
<tr>
<td></td>
<td>Definition of “time 0” to choose reperfusion strategy (i.e. the strategy clock starts at the time of “STEMI diagnosis”).</td>
</tr>
<tr>
<td></td>
<td>Selection of PCI over fibrinolysis: when anticipated delay from “STEMI diagnosis” to wire crossing is ≤120 min.</td>
</tr>
<tr>
<td></td>
<td>Maximum delay time from “STEMI diagnosis” to bolus of fibrinolysis agent is set in 10 min.</td>
</tr>
<tr>
<td></td>
<td>“Door-to-Balloon” term eliminated from guidelines.</td>
</tr>
<tr>
<td><strong>TIME LIMITS FOR ROUTINE OPENING OF AN IRA:</strong></td>
<td>0-12h (Class I); 12-48h (Class IIa); &gt;48h (Class III).</td>
</tr>
<tr>
<td><strong>ELECTROCARDIOGRAM AT PRESENTATION:</strong></td>
<td>Left and right bundle branch block considered equal for recommending urgent angiography if ischaemic symptoms.</td>
</tr>
<tr>
<td><strong>TIME TO ANGIOGRAPHY AFTER FIBRINOLYSIS:</strong></td>
<td>Timeframe is set in 2-24h after successful fibrinolysis.</td>
</tr>
<tr>
<td><strong>PATIENTS TAKING ANTICOAGULANTS:</strong></td>
<td>Acute and chronic management presented.</td>
</tr>
</tbody>
</table>
Reperfusion strategies in the infarct-related artery according to time from symptoms onset
Modes of patient presentation, components of ischaemic time and flowchart for reperfusion strategy selection

**Total ischaemic time**

**Patient delay**

**EMS delay**

**System delay**

**FMC: EMS**

<10’

**STEMI diagnosis**

<10’

**FMC: Non-PCI centre**

<10’

**FMC: PCI centre**

<10’

**Time to PCI?**

≤120 min

Primary PCI strategy <90’

Reperfusion (Wire crossing)

>120 min

Fibrinolysis strategy <10’

Reperfusion (Lytic bolus)

≤60’

Primary PCI strategy <60’

Reperfusion (Wire crossing)

Modes of patient presentation, components of ischaemic time and flowchart for reperfusion strategy selection

Total ischaemic time

Patient delay

EMS delay

FMC: EMS

<10’

STEMI diagnosis

System delay

≤120 min

FMC: Non-PCI centre

<10’

Time to PCI?

Primary PCI strategy

<90’

Reperfusion (Wire crossing)

>120 min

Primary PCI strategy

<60’

Reperfusion (Wire crossing)

Fibrinolysis strategy

<10’

Reperfusion (Lytic bolus)

FMC: PCI centre

<10’

STEMI diagnosis

# What is new in 2017 Guidelines on AMI-STEMI

<table>
<thead>
<tr>
<th>2012</th>
<th>CHANGE IN RECOMMENDATIONS</th>
<th>2017</th>
</tr>
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<tbody>
<tr>
<td>Radial access</td>
<td>MATRIX</td>
<td></td>
</tr>
<tr>
<td>DES over BMS</td>
<td>EXAMINATION, COMFORTABLE-AMI, NORSTENT</td>
<td></td>
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<tr>
<td>Complete Revascularization</td>
<td>PRAMI, DANAMI-3-PRIMULTI, CVLPRIT, Compare-Acute</td>
<td></td>
</tr>
<tr>
<td>Thrombus Aspiration</td>
<td>TOTAL, TASTE</td>
<td></td>
</tr>
<tr>
<td>Bivalirudin</td>
<td>MATRIX, HEAT-PPCI</td>
<td></td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>ATOLL, Meta-analysis</td>
<td></td>
</tr>
<tr>
<td>Early Hospital Discharge</td>
<td>Small trials &amp; observational data</td>
<td></td>
</tr>
<tr>
<td>Oxygen when SaO2 &lt;95%</td>
<td>OXYGEN</td>
<td>Oxygen when SaO2 &lt;90% AVOID, DETOX</td>
</tr>
<tr>
<td>Same dose i.V in all patients</td>
<td>TNK-tPA</td>
<td>Half dose i.V. in Pts ≥75 years STREAM</td>
</tr>
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## What is new in 2017 Guidelines on AMI-STEMI

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*Sabate et al. Lancet 2012;380:1482-90*
What is new in 2017 Guidelines on AMI-STEMI

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### CHANGE IN RECOMMENDATIONS

- **2012** vs **2017**
  - **Radial access**: From **in all patients** to **Half dose i.V. in Pts ≥75 years**
  - **DES over BMS**: From **in all patients** to **Oxygen when SaO2 <90%**
  - **Complete Revascularization**: From **PRAMI, DANAMI-3-PRIMULTI, CVLPRIT, Compare-Acute** to **OXYGEN**

**Engstrom et al, Lancet 2015**

- **Oxygen when SaO2 <95%**
- **Total, TASTE**
- **Matrix, HEAT-PPCI**
- **Avoid, DETO2X**
- **Total, TASTE**
- **Matrix, HEAT-PPCI**
- **Avoid, DETO2X**
- **Small trials & observational data**
- **Oxygen when SaO2 <90%**
- **Avoid, DETO2X**
- **STREAM**
- **Half dose i.V. in Pts ≥75 years**

**Engstrom et al., Lancet 2015**

- **HR 0.56 (95% CI 0.38–0.83), p=0.004**

![Graph](chart.png)
What is new in 2017 Guidelines on AMI-STEMI

### CHANGE IN RECOMMENDATIONS

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<td>Thrombus Aspiration</td>
<td>TOTAL, TASTE</td>
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#### TABLE

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<th>No. at Risk</th>
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</table>

#### FIGURES

- Frobert et al, NEJM 2013: Comparison of PCI and PCI+TA over time.
- Jolly et al, NEJM 2015: Comparison of PCI, PCI+TA, and Thrombectomy over time.
What is new in 2017 Guidelines on AMI-STEMI

- **Change in Recommendations**
  - 2012: Same dose i.V in all patients
  - 2017: Half dose i.V. in Pts ≥75 years
- **Competition**
  - Bivalirudin
  - Enoxaparin
  - **Early Hospital Discharge**
  - **Oxygen when SaO2 <95%**
  - **Avoid, Detox**
  - **Valgimigli et al, NEJM 2015**

- **Matrix, HEAT-PPCI**
- **ATOLL, Meta-analysis**
- **Small trials & observational data**
- **OXYGEN**
  - Oxygen when SaO2 <90%
  - AVOID, DETOX
- **TNK-tPA**
  - Half dose i.V. in Pts ≥75 years
  - STREAM

- **Radial access**
- **DES over BMS**
- **Thrombus Aspiration**

- **Shazad et al, Lancet 2014**

---

What is new in 2017 Guidelines on AMI-STEMI

<table>
<thead>
<tr>
<th>2012</th>
<th>CHANGE IN RECOMMENDATIONS</th>
<th>2017</th>
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<tr>
<td>Radial access</td>
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<td>DES over BMS</td>
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<td>EXAMINATION, COMFORTABLE-AMI, NORSTENT</td>
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<td>Complete Revascularization</td>
<td></td>
<td>PRAMI, DANAMI-3-PRIMULTI, CVLPRIT, Compare-Acute</td>
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<tr>
<td>Thrombus Aspiration</td>
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<td>TOTAL, TASTE</td>
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<tr>
<td>Bivalirudin</td>
<td></td>
<td>MATRIX, HEAT-PPCI</td>
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<tr>
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<td>ATOLL, Meta-analysis</td>
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<tr>
<td>Early Hospital Discharge</td>
<td></td>
<td>Small trials &amp; observational data</td>
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<tr>
<td>Oxygen when SaO2 &lt;95%</td>
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<td>OXYGEN</td>
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<tr>
<td>Same dose i.V in all patients</td>
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<td>Oxygen when SaO2 &lt;90% AVOID, DETOX</td>
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<tr>
<td>TNK-tPA</td>
<td></td>
<td>Half dose i.V. in Pts ≥75 years STREAM</td>
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</table>

What is new in 2017 Guidelines on AMI-STEMI

- **CHANGE IN RECOMMENDATIONS 2012-2017**
  - Oxygen when SaO2 <95%
  - Oxygen when SaO2 <90%

- **SAME DOSE i.V. in all patients**
  - Same dose i.V. in all patients

- **HALF DOSE i.V. in Pts ≥75 years**
  - Half dose i.V. in Pts ≥75 years

- **RADIAL ACCESS**
  - Radial access

- **COMPLETE REvascularization**
  - Complete Revascularization

- **THROMBOLYSIS**
  - Thrombolysis

- **BYPASS SURGERY**
  - Bypass surgery

- **EARLY HOSPITAL DISCHARGE**
  - Early Hospital Discharge

- **SMALL TRIALS & OBSERVATIONAL DATA**
  - Small trials & observational data

- **OXYGEN**
  - OXYGEN

- **TNK-tPA**
  - TNK-tPA

- **META-ANALYSIS**
  - Meta-analysis

- **HEAT-PPCI, ATOLL**
  - HEAT-PPCI, ATOLL

- **EXAMINATION, COMFORTABLE-AMI, NORSTENT**
  - EXAMINATION, COMFORTABLE-AMI, NORSTENT

- **MATRIX DES OVER BMS**
  - MATRIX DES over BMS

- **COMPLETE REvascularization**
  - Complete Revascularization

- **THROMBUS ASPIRATION**
  - Thrombus Aspiration

- **BIVALIRUDIN**
  - Bivalirudin

- **ENOXAPARIN**
  - Enoxaparin

- **EARLY HOSPITAL DISCHARGE**
  - Early Hospital Discharge

- **OXYGEN**
  - Oxygen

- **TNK-tPA**
  - TNK-tPA

- **SAME DOSE i.V. in all patients**
  - Same dose i.V. in all patients

- **HALF DOSE i.V. in Pts ≥75 years**
  - Half dose i.V. in Pts ≥75 years

- **STREAM**
  - STREAM

- **AVOID, DETO2X**
  - AVOID, DETO2X

- **Hofman et al. NEJM 2017**
  - Hofman et al. NEJM 2017
What is new in 2017 Guidelines on AMI-STEMI

2017 NEW RECOMMENDATIONS

• Additional lipid lowering therapy if LDL > 1.8 mmol/L (70 mg/dL) despite on maximum tolerated statins. IMPROVE-IT, FOURIER

• Cangrelor if P2Y$_{12}$ inhibitors have not been given. CHAMPION

• Switch to potent P2Y$_{12}$ inhibitors 48 hours after fibrinolysis. Expert opinion

• Extend Ticagrelor up to 36 months in high-risk patients. PEGASUS-TIMI 54

• Use of polypill to increase adherence. FOCUS

• Complete revascularization during index primary PCI in STEMI patients in shock. Expert opinion

• Routine use of deferred stenting. DANAMI 3-DEFER
Recommendations

Class Level

Lipid lowering therapies

It is recommended to start high-intensity statin therapy as early as possible, unless contraindicated, and maintain it long term.

I A

An LDL-C goal of <1.8 mmol/L (70 mg/dL) or a reduction of at least 50% if the baseline LDL-C is between 1.8 and 3.5 mmol/L (70 and 135 mg/dL) is recommended.

I B

It is recommended to obtain a lipid profile in all STEMI patients as soon as possible after presentation.

I C

In patients with LDL-C ≥1.8 mmol/L (≥70 mg/dL) despite a maximally tolerated statin dose who remain at high risk, further therapy to reduce LDL-C should be considered.

IIa A

Routine therapies in the acute, subacute and long-term phases (continued)

FOURIER

IMPROVE-IT

No. at Risk
Placebo 13,780 13,278 13,278 13,278
Evolocumab 13,784 13,351 13,351 13,351

NEJM, March 17 2017

NEJM, June 18, 2015

Hazard ratio, 0.936 (95% CI, 0.89–0.99) P=0.016

Simvastatin monotherapy

Simvastatin–ezetimibe

30
What is new in 2017 Guidelines on AMI-STEMI

- Cangrelor if P2Y12 inhibitors have not been given.

- CHAMPION: Switch to potent P2Y12 inhibitors 48 hours after fibrinolysis. Expert opinion

- Extend Ticagrelor up to 36 months in high-risk patients. **PEGASUS-TIMI 54**

- Use of polypill to increase adherence. **FOCUS**

**OMMENDATIONS**

- Complete revascularization during index primary PCI in STEMI patients in shock. Expert opinion

- Routine use of deferred stenting. **DANAMI 3-DEFER**

---

**Bonaca et al, NEJM 2015**

**No. at Risk**

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Ticagrelor, 90 mg</th>
<th>Ticagrelor, 60 mg</th>
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</tbody>
</table>

**Event Rate (%)**

- Placebo: 9.04%
- Ticagrelor, 90 mg: 7.85%
- Ticagrelor, 60 mg: 7.77%
“Do not forget” interventions in STEMI patients undergoing a primary PCI strategy
## Summary of important time targets

<table>
<thead>
<tr>
<th>Intervals</th>
<th>Time targets</th>
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</thead>
<tbody>
<tr>
<td>Maximum time from FMC to ECG and diagnosis.</td>
<td>≤10 min</td>
</tr>
<tr>
<td>Maximum expected delay from STEMI diagnosis to primary PCI (wire crossing) to choose primary PCI strategy over fibrinolysis (if this target time cannot be met, consider fibrinolysis).</td>
<td>≤120 min</td>
</tr>
<tr>
<td>Maximum time from STEMI diagnosis to wire crossing in patients presenting at primary PCI hospitals.</td>
<td>≤60 min</td>
</tr>
<tr>
<td>Maximum time from STEMI diagnosis to wire crossing in transferred patients.</td>
<td>≤90 min</td>
</tr>
</tbody>
</table>

**NEW:** The strategy clock starts at the time of “STEMI diagnosis” (not FMC)