# Ticagrelor monotherapy beyond one month vs. standard dual antiplatelet therapy following drug eluting stent implantation: A randomised multicentre superiority trial

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# Declaration of interest

- Consulting/Royalties/Owner/ Stockholder of a healthcare company (Dr. Serruys reports personal fees from Abbott Laboratories, personal fees from AstraZeneca, personal fees from Biotrinik, personal fees from Cardialysis, personal fees from GLG Research, personal fees from Medtronic, personal fees from Sino Medical Sciences Technology, personal fees from Société Europa Digital Publishing, personal fees from Stentys France, personal fees from Svelte Medical Systems, personal fees from Philips/Volcano, personal fees from St. Jude Medical, personal fees from Qualimed, personal fees from Xeltis)

# Conclusion

- **The Global Leaders trial failed to demonstrate statistically (3.81% vs. 4.37%, RR 0.87 (95% CI 0.75-1.01), P value = 0.073) the superiority of an antiplatelet regimen consisting of one month of ticagrelor in combination with low dose aspirin followed by 23 months of ticagrelor alone in reducing the 2-year rate of all-cause mortality and non-fatal, new Q-wave MI when compared with the reference treatment (DAPT 12 months, ASA monotherapy 12 months).**
- **Further per protocol analysis will be performed to adjust for the difference in treatment adherence between the reference arm and the experimental arm.**

# Background: Global Leaders Vision

**Ticagrelor, a potent and consistent antiplatelet drug, may be a better foundation as monotherapy for long term antiplatelet therapy compared to ASA in at-risk patients**

**Avoid the higher risk of bleeding potentially associated with adding ASA (even low dose) to Ticagrelor**

**Maintain the clinical benefits of potent platelet inhibition after PCI, beyond the initial period of high stent thrombosis risk (30 days)**

**The trial may pave the way for future studies of Ticagrelor as a single foundation therapy**

# Primary endpoint status

- The composite of **all-cause mortality** or **non-fatal new Q-wave MI up to 2 years** post randomization (15,991 randomized)

❑ **15,991 pts randomized**

**23 pts : Data deletion requested**
**No search for vital status**

❑ **8 pts with unknown vital status**

❑ **15,960 pts with known vital status**

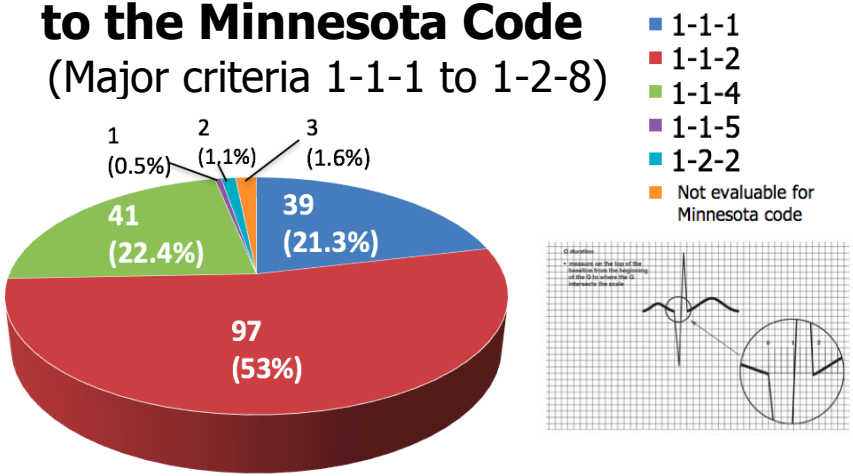
**15,259 pts : Site reported**

**701 pts : From public domain**

❑ **99.95% with known vital status**

❑ **ECG centrally adjudicated**

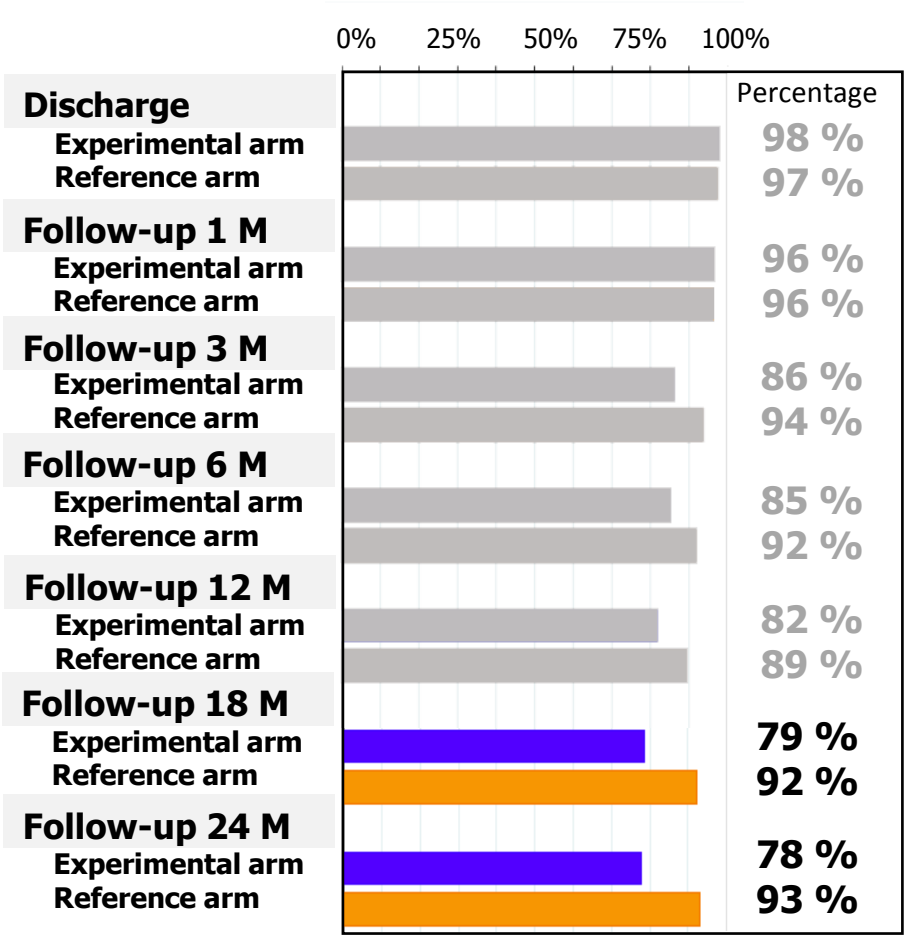
❑ **New Q-waves detected according to the Minnesota Code**
(Major criteria 1-1-1 to 1-2-8)




❑ **183 new Q waves diagnosed**

❑ **3 new LBBB (Q wave equivalent)**

# Adherence to treatment strategies




# Primary and secondary outcomes at 24 months (intention to treat)

| | Experimental group | Reference group | Risk Ratio (95% CI) | p-value |
|---|---|---|---|---|
| Number of pts. | N=7980 | N=7988 | | |
| **All-cause mortality or new Q-wave MI** | **3.81** %, (304) | **4.37** %, (349) | **0.87** (0.75-1.01) | **0.073** |
| **All-cause mortality** | **2.81** % (224) | **3.17** % (253) | **0.88** (0.74-1.06) | 0.18 |
| **New Q-wave MI** | **1.04** % (83) | **1.29** % (103) | **0.80** (0.60-1.07) | 0.14 |

**Ticagrelor monotherapy in ACS and SA**

**ASA monotherapy in ACS and SA**

# Key messages

- **Having stopped aspirin 1 month postprocedure, the trial showed at least up to 1 year in patients with ACS and stable angina the feasibility, safety and potential efficacy of a monotherapy with a potent and consistent antiplatelet P2Y12 inhibitor when compared to standard dual antiplatelet therapy.**
- **In the second year of follow up, lack of adherence to the experimental strategy may have compromised the assessment of superiority.**
- **After stent implantation, interruption of aspirin at 1 month and continuation of one specific antiplatelet therapy may be further explored as a preferred strategy in the near future.**