# Twenty-year trends in clinical outcome of randomized controlled trial for coronary intervention: systematic review and meta-regression analysis of 46 randomized controlled trials

T. Asano, M. Ono, A. Saito, T. Kanie, T. Takaoka, N. Komiyama

St. Luke's International Hospital, Cardiology, Tokyo, Japan Funding Acknowledgement: Type of funding source: None

Aim: The technology of percutaneous coronary intervention (PCI) has been developed after the advent of coronary stent. However, the impact of the technological development on clinical outcomes is still unclear, whereas a remarkable improvement of clinical outcomes after PCI has not been observed in the trials comparing to medical therapy or coronary bypass graft. The current analysis aims to investigate trends in clinical outcomes after PCI after the emargence of coronary stent, using the randomized controlled trials (RCTs) comparing coronary stents.

**Methods and results:** We performed a systematic review of RCTs investigating coronary stents in non-specific population (excluding the trials particularly enrolling diabetic or myocardial infarction etc.) conducted between 1996 and 2015 (publication between 1997 and 2019) with independent clinical event adjudication. The random-effect meta-regression analysis including 90 arms with 94,831 patients in 46 RCTs was performed investigating the 20-year trends in clinical outcomes such as death, cardiac death, myocardial infarction, target lesion revascularization (TLR) and stent thrombo-

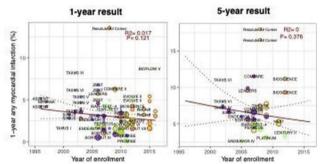
sis at one and five years after the index procedure. The sensitivity analysis was performed by limiting to 20 all comer trials. In the meta-regression analysis, we did not observe significant change in the incidences of cardiac death and myocardial infarction after PCI over 20 years (P values for cardiac death: 0.666 at one year, 0.256 at five years and P values for myocardial infarction: 0.121 at one year, 0.376 at five years; R2 for cardiac death: <0.01 at one year and five years and R2 for myocardial infarction: <0.01 at one year and five years), whereas the incidences of clinically indicated TLR (P value <0.001, R2 = 0.40 at one year, P value = 0.002, R2 = 0.22 at five years) and stent thrombosis were decreased steeply in the first decade and slightly in the second decade (P value = 0.040, R2 = 0.09 at one year; P value = 0.017, R2 = 0.17 at five year). The sencitivity analysis limiting all-comer population revealed the consistent results.

**Conclusion:** The development of PCI had an impact on the 20-year trends in TLR and ST, despite there were no trends in the cardiac death and myocardial infarction.

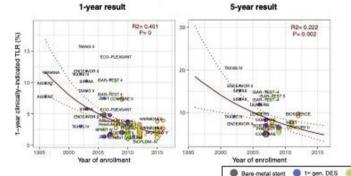
### Cardiac death

# 1-year result 5-year result 6-AA-TEST-4 P=0.898 1-AA-TEST-5 1-AA-TEST-5 1-AA-TEST-5 1-AA-TEST-5 1-AA-TEST-5 1-AA-TEST-6 1-AA-TEST-6 1-AA-TEST-6 1-AA-TEST-6 1-AA-TEST-6 1-AA-TEST-7 1-AA-

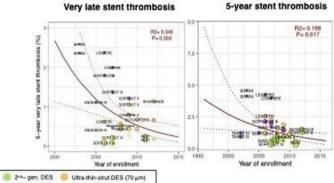
# Any myocardial infarction



# Clinically-indicated TLR



## Very late and 5-year stent thrombosis



Trends in the incidence of the outcomes