Methods: A retrospective single-center study of consecutive patients who underwent implantation of ICD or CRT-D after November 1995. The mean survival of patients undergoing 1st implant or generator replacement at an advanced age (≥75 years) was evaluated and compared to the effective longevity of the generators. Cumulative survival analyzes using the Kaplan Meier method were used.
Results: A total of 1312 cardiac devices were implanted, of which 163 generators in elderly patients (53% CDI and 47% CRT-D). Of these, 77% corresponded to the 1st implant.
The median survival after implantation of the elderly patients was 6.8 years, not differing according to the type of device (Log-rank P = NS). The median longevity of CDI generators was 6.9 years, in line with the expected survival of elderly patients. Conversely, the median CRT-D longevity was 5.8 years, lower than the average survival of the elderly. For this reason, 21% of these CRT-D carriers were subsequently subjected to generator replacement, due to battery exhaustion.
Conclusion: The effective longevity of ICDs is in agreement with an expected survival of elderly patients, for which it will not make sense to provide generators of shortened longevity for this population. The effective longevity of the CRTs is lower than the survival expectancy of the treatments, so that, paradoxically, generators with increased longevity should be favored.

LONG-TERM OUTCOME OF CORONARY STENTS AND SCAFFOLDS

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Four-year clinical outcome following randomised use of zotarolimus-eluting stents versus everolimus-eluting stents in all-comers: insights from the DUTCH PEERS trial

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Background: The DUTCH PEERS (TWENTE II) trial (clinicaltrials.gov NCT01331707) is a randomised, multicenter, single-blinded, investigator initiated all-comers trial. All coronary syndromes were permitted with no limit for lesion length, reference size, or number of lesions or diseased vessels to be treated. In total, 1811 patients were 1:1 randomised to cobalt chromium-based zotarolimus-eluting stents (ZES) versus platinum chromium-based everolimus-eluting stents (EES). These durable polymer-based drug-eluting stents (DES) were developed to facilitate device deliverability and to improve stent apposition to the vessel wall.
Purpose: We assessed the 4-year clinical outcome of the DUTCH PEERS trial in terms of safety and efficacy.
Methods: Clinical outcome was assessed by means of follow-up data of the trial participants. The primary endpoint target vessel failure (TVF) is a composite of cardiac death, target vessel-related myocardial infarction (MI) or target vessel revascularization. Secondary endpoints included the individual components of the TVF and the incidence of definite-or-probable stent thrombosis. Endpoints were analyzed by the logrank test by comparing the time to the endpoint, using the Kaplan-Meier method. Independent contract research organizations performed the study monitoring and clinical event adjudication.
Results: The 4-year clinical follow-up data were available in 1802 patients (99.5%; 4 patients were lost to follow-up and 5 withdrew consent). The ZES and EES groups showed favourable outcomes with a similar incidence of TVF (12.1% vs. 12.1%; Logrank p=0.95). The rates of the individual components of TVF were also similar for both stent arms: cardiac death (3.9% vs. 3.7%; Logrank p=0.78); target vessel-related MI (3.2% vs. 2.5%; Logrank p=0.38); and target vessel revascularization (6.8% vs. 7.5%; Logrank p=0.55), respectively. In addition, the incidence of definite-or-probable stent thrombosis was similar for patients treated with ZES versus EES (1.5% vs. 1.2%; Logrank p=0.67).
Conclusion: At 4-year follow-up, ZES and EES showed similar and sustained results in terms of safety and efficacy for treating all-comer patients.
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Long term outcomes of first and second generation drug-eluting stents in patients with diabetes: a pooled analysis of individual patient data from SORT OUT III, IV and V trials

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Background: Diabetes is associated with increased risk of target lesion failure after percutaneous coronary intervention (PCI). Comparisons of different drug-eluting stent (DES) types suggested possible differences in outcomes among diabetic patients.
Purpose: To compare 5-year risk of target lesion failure and definite stent thrombosis in patients with diabetes treated with first and second generation DES.
Methods: We pooled individual patient-level data from 3 randomized SORT OUT trials (SORT OUT III, IV and V). Target lesion failure was a composite of cardiac death, target lesion revascularization, or definite stent thrombosis. Definite stent thrombosis was defined according to the Academic Research Consortium definition and evaluated up to 5 years.
Results: Out of 1,091 patients with diabetes (14.5% of patients from the 3 SORT OUT trials) included in the present analysis, 548 received sirolimus-eluting Cypher (SES), 169 zotarolimus-eluting Endeavor (ZES-E), 184 biolimus-eluting Nobori (BES) and 190 everolimus-eluting (EES) Xience/Promus stents.
The 5-year target lesion failure proportion in diabetic patients was: SES 19.1%, ZES-E 25.0%, BES 16.7% and EES 11.5%. Compared to the first generation SES, neither the ZES-E [RR=1.31, 95% Confidence Interval (CI) 0.94–1.82] nor the biodegradable polymer BES [RR=0.87, 95% CI 0.59–1.28] were associated with a reduced target lesion failure rate, whereas EES [RR=0.60, 95% CI 0.38–0.96] improved the risk of target lesion failure compared to the first generation SES.
Overall the number of definite stent thrombosis within 5-year differed significantly between the 4 DES with the highest rate in the bioresorbable polymer BES and zero in the EES treated patients (first generation SES 2.0%, ZES-E 2.4%, BES 3.8%, and EES 0%; p=0.04, Fisher's Exact Test). Neither definite stent thrombosis within 1 year (first generation SES 0.9%, ZES-E 1.8%, BES 2.2%, and EES 0%; p=0.12, Fisher's Exact Test) nor very late definite stent thrombosis (SES 1.1%, ZES-E 0.6%, BES 1.7%, and EES 0%; p=0.36, Fisher's Exact Test) differed significantly between the stent types.
Conclusion: In diabetic patients, the EES was the only second generation drug-eluting stent which was associated with a lower risk of target lesion failure and definite stent thrombosis compared to the first generation SES.

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Sex-related differences in patients undergoing complex coronary interventions in the era of 2nd generation DES

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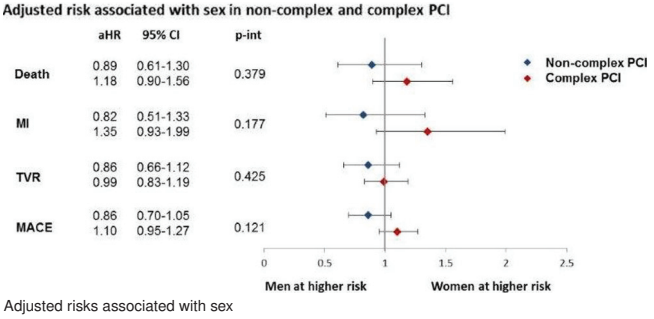
Background: The impact of sex on clinical outcomes in patients undergoing complex coronary interventions with 2nd generation drug eluting stents (DES) remains uncertain.
Purpose: To evaluate sex-related differences in clinical outcomes of patients stratified by complexity of PCI.
Methods: We analysed 14,917 consecutive patients enrolled in a single-center PCI registry between 2012 and 2015. Only patients receiving 2nd generation drug-eluting stents (DES) were considered and categorised into complex and non-complex PCI groups. Complex PCI was defined as the composite of ≥3 stents, <3.0 mm minimum stent diameter, severely calcified target lesion, chronic total occlusion, or saphenous vein bypass graft as target vessel. The primary endpoint was major adverse cardiac events (MACE) defined as a composite of death, myocardial infarction (MI) or target vessel revascularisation (TVR) at 1 year.
Results: Of the total cohort, 31.6% (n=2,005) of the non-complex PCI patients and 30.3% (n=2,598) of the complex PCI patients were women. Compared with men, women were older, more likely non-white with higher prevalence of diabetes and prior cerebrovascular disease but lower prevalence of smoking and prior MI irrespective of PCI complexity. In the non-complex PCI group women and men had similar MACE rates (5.5% vs. 5.3%; p=0.72), whereas in patients undergoing complex PCI women had significantly increased MACE rates (8.8% vs. 7.6%; p=0.022). Adjusted risks, however, were similar in women and men in both groups without evidence of interaction by sex and PCI complexity (Figure).



Adjusted risks associated with sex

Conclusion: In this analysis of patients treated with 2nd generation DES, sex did not modify risk for MACE associated with PCI complexity, underlining the efficacy of next generation DES even in complex settings.