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Stent thrombosis and bleeding complications after implantation of sirolimus-eluting coronary stents in an unselected worldwide population: a report from the e-SELECT (Multi-Center Post-Market Surveillance) registry.

Urban P, Abizaid A, Banning A, Bartorelli AL, Baux AC, Džavík V, Ellis S, Gao R, Holmes D, Jeong MH, Legrand V, Neumann FJ, Nyakern M, Spaulding C, Worthley S; e-SELECT Investigators.

Collaborators (318)

Mendiz O, Rojas Matas CA, Belardi J, Palacios A, Telayna JM, Vahagn S, Helmreich G, Gaul G, Wallner H, Walters D, Chew D, Shetty S, Horrigan M, Ward M, Worthley S, Juergens C, Meredith I, Kader FA, Perin M, Costatini C, Marino MA, Legrand V, Convens C, Coussement P, Scott B, Dujardin K, Bosmans J, Boland J, Schröder E, De Wagter X, Desmet W, Vrolix M, Castadot M, Lalmand J, Carlier M, Stoupel E, El-Khoury E, Jorgova J, Dimitrov N, Dzavik V, Schampaert E, Plante S, Kassam S, Teefy P, Bilodeau L, Reeves F, Watson KR, Pilon C, Brass N, Labinaz M, Kutryk M, Wang HC, Chen JY, Ge JB, Chen JZ, Chen JL, Lv SZ, Gao W, Shen WF, Wang WM, Huo Y, Wang LF, Fang Q, Escobar A, Gomez MC, Dager AE, Hurtado E, Guevara OC, Andres Carvajal JM, Escoria E, Strozzi M, Cerny P, Branny M, Jensen J, Thayssen P, Ureña P, Margus S, Farag N, Khamis H, Ashraf M, Taher Khalil MA, Sobhy M, Gendy R, Warda M, Abelaziz A, Hartikainen J, Kervinen K, Nyman K, Barragan P, Lefèvre T, Spaulding C, Lablanche JM, Leborgne L, Berland J, Eltchaninoff H, Rangé G, Cattan S, Elhadad S, Schiele F, Carrié D, Brunel P, Darremont O, Gilard M, Maupas E, Machecourt J, Caussin C, Sainsous J, Piot C, De Boisgelin X, Grollier G, Bedossa M, Ledain L, Bar O, Teiger E, Claudel JP, Cabrol P, Paganelli F, Salengro E, Lhoest N, Fourrier JL, Amor M, Maillard L, Karsenty B, Neumann FJ, Haude M, Richardt G, Brachmann J, Drexler H, Jung W, Adamopoulos S, Alexopoulos D, Triantis G, Kochiadakis G, Chamouratidis N, Manginas A, Moutoudis N, Tsikaderis DD, Lee MK, Merkely B, Edes I, Apro D, Ungi I, Lupkovich G, Balachand AM, Seth A, Chandra P, Gambhir DS, Parikh K, Hiremath MS, Rath PC, Nayak PR, Samuel MK, Kler TS, Kaul U, Munawar M, Tedjokusumo P, Santoso T, Crowley J, O'Shea C, Foley D, Crean P, Mark B, Ariel R, Bartorelli A, Nicosia A, Tolaro S, Romeo F, Sauro R, Bonzani G, Manari A, Piovaccari G, Comeglio M, Ramondo A, Presbitero P, Bramucci E, Bevilacqua R, Limbruno U, Tespili M, Haddad I, Gwon HC, Kim D, Kim KB, Jang YS, Jeong MH, Kim HS, Lim DS, Park SJ, Seung KB, Tahk SJ, Erglis A, Kalnins A, Wagner D, Zambahari DS, Sim KH, bin Wan Ahmad WA, Charaa A, Campa JF, Stella PR, den Heijer P, Koolen J, Suttorp MJ, Appelman YJ, McClean D, Ormiston J, Devlin G, Stavnes S, Gonzalez B, Ciszewski M, Lesiak M, Koźmider M, Wójcik J, Peruga JZ, Rzeźniczak J, Ferreira R, Canas da Silva P, Pereira H, Almeida M, Carvalho H, Abreu P, Martins D, Carvalho H, Alekyan B, Samko A, Iosseliani D, Savchenko A, Abugov S, Chestukhin V, Vasilieva E, Osiev A, Kochanov I, Nikolay S, Esipovich I, Zyrianov I, Al Turki F, Ostojic M, Mangovski L, Ljupco D, Low A, Wong A, Horak A, Bennett J, Corbett C, Gillmer D, Dalby AJ, Hellig F, Ebrahim IO, Patel JJ, Salitan JL, Kalliatkis NB, van der Merwe N, Blomerus P, Mabin TA, Sabaté M, Ferrer JA, Serra A, Larman M, Rumoroso JR, Bassaganyas J, Carballo J, Bethencourt A, Mauri J, Cequier A, Loubad A, Jiménez F, Pico F, Ruiz Nodar JM, Goicolea J, Elbal LM, Moreno R, Tascón J, Botas J, Durán JM, Galache JG, Moreu J, Iñiguez A, Vázquez N, Trillo R, Moris C, Santos I, Torres A, Masotti M, Baello P, Björklind U, Tödt T, Sjögren I, Aasa M, Toomas S, Urban P, Goy JJ, Kaiser C, Amann W, Roguelov C, Roffi M, Hsieh IC, Kao HL, Cheng JJ, Yin WH, Wu CJ, Buddhari W, Boonsom W, Kuanprasert S, M'Henni H, Maksym S, Salo S, Nuaimi A, Binbrek A, Al Nooryani A, Banning A, Hildick-Smith D, Fath-Ordoubadi F, De Belder M, MacCarthy P, Talwar S, Ludman P, Bellenger N, Casal H, Lopez JA, Lairet A.

Abstract

OBJECTIVES:

The aim of this study was to ascertain the 1-year incidence of stent thrombosis (ST) and major bleeding (MB) in a large, unselected population treated with sirolimus-eluting stents (SES).

BACKGROUND:

Stent thrombosis and MB are major potential complications of drug-eluting stent implantation. Their relative incidence and predisposing factors among large populations treated worldwide are unclear.

METHODS:

The SES were implanted in 15,147 patients who were entered in a multinational registry. We analyzed the incidence of: 1) definite and probable ST as defined by the Academic Research Consortium; and 2) MB, with the STEEPLE (Safety and efficacy of Enoxaparin in PCI) definition, together with their relation to dual antiplatelet therapy (DAPT) and to 1-year clinical outcomes.

RESULTS:

The mean age of the sample was 62 ± 11 years, 30.4% were diabetic, 10% had a Charlson comorbidity index ≥ 3 , and 44% presented with acute coronary syndrome or myocardial infarction. At 1 year, the reported compliance with DAPT as recommended by the European Society of Cardiology guidelines was 86.3%. Adverse event rates were: ST 1.0%, MB 1.0%, mortality 1.7%, myocardial infarction 1.9%, and target lesion revascularization 2.3%. Multivariate analysis identified 9 correlates of ST and 4 correlates of MB. Advanced age and a high Charlson index were associated with an increased risk of both ST and MB. After ST, the 7-day and 1-year all-cause mortality was 30% and 35%, respectively, versus 1.5% and 10% after MB. Only 2 of 13,749 patients (0.015%) experienced both MB and ST during the entire 1-year follow-up period.

CONCLUSIONS:

In this worldwide population treated with ≥ 1 SES, the reported compliance with DAPT was good, and the incidence of ST and MB was low. Stent thrombosis and MB very rarely occurred in the same patient. (The e-SELECT Registry: a Multicenter Post-Market Surveillance; NCT00438919).

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