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CLINICAL RESEARCH

Immediate and 1-year follow-up with the novel nanosurface modified COBRA PzF stent

Résultats immédiats et à 1 an avec le stent COBRA PzF stent, à surface modifiée avec des nano-particules

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KEYWORDS
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Summary
Background. — The COBRA PzF coronary stent, which has a unique nano-coating of Polyzene-F, was developed to reduce the risk of stent thrombosis.
Aims. — To report procedural and 1-year clinical outcomes following COBRA PzF coronary stent implantation in a real-world percutaneous coronary intervention (PCI) registry.
Methods. — All patients assigned to treatment with the COBRA PzF in the GCS Axium Rambot Center, Aix-en-Provence, France between February 2013 to June 2014 were prospectively enrolled.
Results. — Among 100 patients (71% men, mean ± standard error age 71.4 ± 11.0 years), 38% had acute coronary syndromes. The population was consistent with real-world experience and included patients with multiple co-morbidities and 26% with diffuse multivessel disease. A total of 151 lesions were treated with 166 stents, including 26% of lesions with a type B2 or C classification. Pre- and post-procedural quantitative coronary angiography analyses showed a mean

Abbreviations: BMS, bare-metal stent; CABG, coronary artery bypass graft; DAPT, dual antiplatelet therapy; DES, drug-eluting stent; NSTEMI, non—ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; PzF, poly-bis(trifluoroethoxy) phosphazene; QCA, quantitative coronary angiography; SE, standard error; STEMI, ST-segment elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction.

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acute gain of 2.2 ± 0.2 mm. Angiographic success was achieved in all cases. One-year follow-up was available for all patients and the target vessel failure (composite of all-cause mortality, myocardial infarction or target vessel revascularization) rate was 12%, including 2% mortality (end-stage cardiomyopathy), 5% myocardial infarction (five periprocedural myocardial infarctions with isolated troponin elevation without chest pain or Q waves) and 5% target lesion revascularization. There were no cases of definite stent thrombosis. **Conclusion** The COBRA PzF stent was safe and effective in routine practice. One-year follow-up was associated with excellent clinical outcomes and compared favourably with current devices. These results are very promising in a real-world population of complex patients, and further study is warranted.

MOTS CLÉS
Stent ;
Endothalization ;
Guérison ;
COBRA PzF stent ;
Polyzène-F

Résumé
Contexte. — Le stent COBRA PzF, recouvert d'un *nano-coating* de Polyzène-F, a été développé pour réduire le risque de thrombose de stent.
Buts. — Rapporter les résultats de la procédure et à un an de l'implantation de stent Cobra PzF™ dans le monde réel.
Méthodes. — Tous les patients qui ont reçu au moins un stent Cobra PzF™ dans le centre GCS ES-Axium-Rambot, Aix-en-Provence, entre février 2013 et juin 2014 ont été prospectivement inclus.
Résultats. — Cent patients, 71 % de sexe masculin, avec un âge moyen de 71,4 ± 11 ans ont été suivis, avec 38 % de syndrome coronarien dont 10 % d'infarctus à la phase aiguë. La cohorte reflète le monde réel et comprend des patients avec de multiple comorbidité dont 26 % de multitronculaire. Un total de 151 lésions ont été traitées avec 166 stents, incluant 26 % de lésions de type B2 ou C. L'analyse du QCA montre un gain initial 2,2 ± 0,2 mm. Un succès angiographique a été obtenu dans tous les cas. Le suivi clinique est disponible pour tous les patients et le taux d'échec du vaisseau cible (TVF) est de 12 % (composite comprenant la mortalité de toute cause, infarctus aigu et la revascularization du vaisseau cible) incluant 5 % d'infarctus péri-procéduraux avec élévation isolée de la troponine, 0 % de thrombose de stent, 5 % de revascularization du vaisseau cible et 2 % de décès (cardiopathie avancée terminale).
Conclusion. — Le stent Cobra PzF stent est efficace dans la pratique courante. Le suivi à un an montre des résultats cliniques excellents et compare favorablement avec les dispositifs actuels. Ces résultats sont très prometteurs dans le monde réel, avec des patients complexes. Des études complémentaires sont justifiées.

Background

Outcomes after percutaneous coronary intervention (PCI) have improved greatly since the introduction of stents [1—4]; and dual antiplatelet therapy (DAPT) [5] with P2Y12 inhibitors has been shown to significantly reduce abrupt stent occlusion. Subsequently, drug-eluting stents (DES) [6] reduced the need for repeat intervention by inhibition of neointimal hyperplasia [7]. However, DES safety concerns surfaced in real-world scenarios when higher rates of late stent thrombosis were noted compared with bare-metal stents (BMS) [8—10]. Late stent thrombosis is associated with high mortality [11] and may be a limitation for any technologies that inhibit healing, including bioresorbable DES [2,12—14]. Consequently, patients who receive DES require long-term DAPT, which increases both the cost and the risk of severe bleeding [15]. The latter is also associated with increased mortality [16,17]. The optimal duration of DAPT after DES implantation remains a matter of debate [18,19]. Furthermore, increasing numbers of patients require coronary revascularization and are at high risk of bleeding on DAPT (e.g. frail or elderly patients, those who require chronic oral anticoagulation, those awaiting urgent surgery, and those with major liver or kidney dysfunction or anaemia). In such patients, short-term DAPT treatment could reduce complications and enhance outcomes.

Work has therefore been undertaken to develop a DES with a lower risk of late stent thrombosis. Pre-clinical testing has demonstrated that a nano-thin coating of poly-bis(trifluoroethoxy) phosphazene (Polyzene-F or PzF) has a unique biocompatibility profile that is associated with preferential adsorption of albumin without denaturing or alteration to quaternary protein structures [20—27]. Rapid population of the stent surface with structurally intact albumin results in very low platelet and fibrinogen adhesion,

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