New cobalt-chromium stent design in the treatment of real world coronary artery disease: rationality and study design of the all comers observational, multicenter WALTZ Registry

Nuevo *stent* de cromo cobalto para el tratamiento de enfermedad coronaria en el mundo real: diseño de un estudio observacional, prospectivo y multicéntrico

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ABSTRACT

The Waltz Registry was a multicenter and prospective open label study that evaluates the cobalt-chromium alloy Bare Metal Stent, Waltz™ Stent (Microport Inc Shangay, China) for the treatment of patients with coronary artery disease and indication for revascularization. Two hundred twenty patients were evaluated and included in the registry. Patients inclusion criteria were patient with stable and acute coronary syndrome, reference vessel diameter ≥ 2.5 mm and and ≤ 4.0 mm target lesion diameter stenosis ≥ 50%. Exclusion criteria were poor left ventricular ejection fraction, previous treatment with DES or in-stent restenosis an epicardial vessel or contraindication treatment to ASA or thienopyridines. All patients signed an informed consent form according to the National Direction of Protection Personal Data from Argentina following the current law. All data will be incorporate to a database by an electronic case report form. Primary end-point was endpoint is 12-month Major Adverse Cardiac Event (MACCE) rate. Secondary endpoints were TLF, MI and TLR; incidence of TVR, cardiac death and non cardiac death, MACCE at 30 days and 6 moths and stent thrombosis, according to Academic Research Consortium (ARC) definition. An independent clinical events committee will adjudicate adverse events.

Keywords: *percutaneous coronary interventions, stents, bare metal stents, coronary artery disease.*

RESUMEN

El Waltz Registry es un estudio multicéntrico y prospectivo de marca abierta que evalúa un *stent* desnudo de aleación de cromo cobalto, *stent* Waltz™ (Microport Inc. Shangay, China) para el tratamiento de pacientes con enfermedad coronaria e indicación de revascularización. Doscientos veinte pacientes fueron evaluados e incluidos en el registro. Los criterios de inclusión de los pacientes fueron pacientes con síndrome coronario estable y agudo, diámetro del vaso de referencia ≥ 2,5 mm y ≤ 4.0 mm y estenosis del diámetro de la lesión ≥ 50%. Los criterios de exclusión fueron deterioro severo de la fracción de eyección del ventrículo izquierdo, tratamiento previo con *stent* liberador de fármacos o reestenosis intra*stent* en un vaso coronario a ser revascularizado o contraindicación a ser tratado con ASA o tienopiridinas. Todos los pacientes firmaron un formulario de consentimiento informado de acuerdo con la Dirección Nacional de Protección de Datos Personales de Argentina siguiendo la ley vigente. Todos los datos serán incorporados a una base de datos con un formulario de reporte de caso electrónico. El punto final primario fueron los eventos cardíacos adversos mayores a 12 meses (MACCE). Los criterios secundarios incluyen la incidencia de TLF, muerte cardíaca y no cardíaca, MI y TLR, TVR), MACCE a los 30 días y 6 meses y trombosis del *stent*, según la definición de Academic Research Consortium (ARC). Un comité independiente de eventos clínicos decidirá los eventos adversos a adjudicar al registro.

Palabras claves: *intervención coronaria percutánea, stents, stent desnudo, enfermedad coronaria.*

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BACKGROUND

The stent restenosis was the major drawback of percutaneous coronary interventions (PCI) either with balloon angioplasty or bare metal stents (BMS).

The use of stents eluting immunosuppressive drugs (drug-eluting stents, DES) aimed at minimize the high frequency of restenosis observed after PCI with BMS[1-3]. Indeed, DES reduced the relative risk of reintervention from 50% to 70% as compared to BMS[3-7].

In fact, introduction of 2nd generation DES allow to expand PCI indications in more complex lesions sub-

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1. Both are employees of Microport Inc (Shanghai, China)
2. Received modest speakers fee from Microport Inc.

Others authors have no disclose to report

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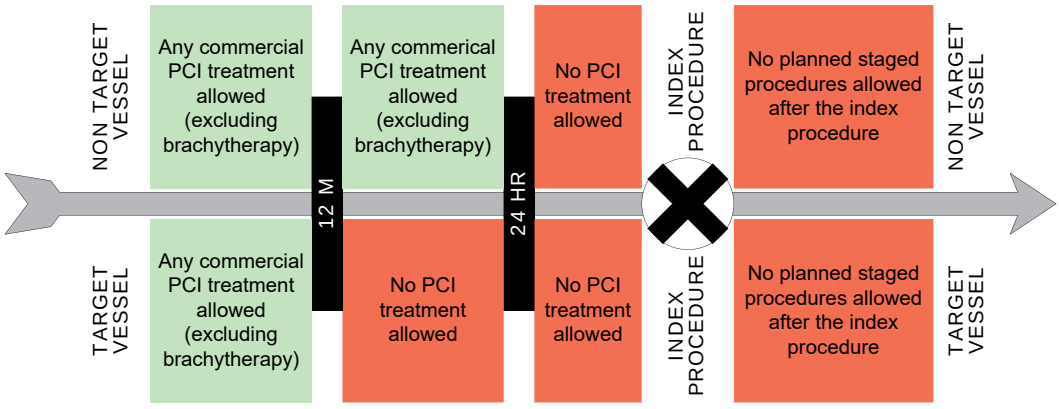

Figure 1. *Study design.*

sets such as left main or complex three vessel coronary artery disease[8-17].

However, in spite that 2nd DES designs are associated with very low incidence of stent and very late stent thrombosis, other shortcomings of DES such neo-atherosclerosis and endothelial dysfunction remained[18-20].

Therefore, notwithstanding undisputed merits of DES, BMS have not been abandoned. Concerns about a higher risk of bleeding or non-compliance with the mandatory dual antiplatelet therapy suggest some relative contraindications to DES in PCI-patients with specific clinical and socioeconomic conditions. In fact, BMS are still used in 25% of patients receiving a PCI in USA[21,22]. However, these numbers increased significantly in certain geographic areas when socioeconomic considerations are taking into account.

Additionally, more recently the largest randomized comparison between DES and BMS ever performed[23], in where 9013 patients enrolled and randomized, showed at 6 years of follow up advantages of 2nd DES generation over BMS only in rates of repeat revascularization procedures, p<0.001, without any differences in any cause of death, myocardial infarction and quality of life. Primary outcome of this study was 16.6% vs 17.1% with DES and BMS respectively p=0.58, death was 8.5% and 8.4% and myocardial infarction, 9,8% and 10.5% with DES and BMS respectively p=0.66 and p=0.14: whereas quality of life was identical with both treatments through all follow up period[23].

Therefore, the role of newer generation of BMS during PCI was not abandoned in spite of the greater improvements of DES designs.

The purpose of WALTZ registry was to perform a multicenter single arm observational study with a novel chromo cobalt stent design in a wide clinical spectrum of patients with coronary artery disease including left main, multiple vessel disease and evolving myocardial infarction without any major exclusion criteria usually seen in randomized clinical trials.

METHODS/DESIGN

Device description

The WALTZ™ Cobalt Chromium Coronary Stent System is a L605 Cobalt-Chromium alloy stent designs with architecture and three different stent designs with enhanced radial strength and excellent flexibility, trackability and pushability to provide premier outcomes. It has a strut thickness of 0.0034'' and a crossing profile or 0.037'', thin strut technology enhances lesion access and vessel wall conformability. Uniform sine wave and "S" links offer excellent balance between supporting strength and flexibility. Different design of 3 stents models achieves better vascular coverage and conformability. Its strut with open cells provides an excellent side branch access. Its superior tip design increases flexibility and crossability. Its low profile improves trackability and pushability. Metal covered area is 11.6 % - 14.3 %.

Study design (Figure 1)

The Waltz Registry is a prospective, single-arm, multicenter trial to enroll approximately 200/220 subjects with a real world atherosclerotic coronary artery lesion in a native coronary artery ≥2.50 mm to ≤4.00 mm in diameter (by visual estimate) in a consecutive all-comers population. The study will be considered complete (with regard to the primary endpoint) after all subjects have completed the 12-month primary endpoint is 12-month Major Adverse Cardiac Event (MACCE) rate. Additional end points are clinical endpoints measured are in-hospital at 30 days, 6 months and 12 months: that included target lesion revascularization (TLR) rate, TLF (target lesion failure) rate, target vessel revascularization (TVR) rate, Major Adverse Cardiac Event (MACCE) rate (the primary endpoint is 12- month MACCE rate), MI (Myocardial infarction) rate, Cardiac death rate, all death rate, car-

diac death o MI rate, all death or MI rate, all death/MI/TVR rate and stent thrombosis rate (definite or probable by Academic Research Consortium [ARC] definitions). The **periprocedural endpoints are the technical success rate, clinical procedural success rate.**

Endpoints definitions

MACCE is defined as the composite of any cause of death, MI(both ST elevation and Non-ST elevation), cerebro-vascular accident (CVA) and any ischemia-driven revascularization of the target lesion (TLR). Target lesion failure (TLF) is defined as any ischemia driven revascularization of the target lesion, cardiac death (if the event could not be determined with certainty, it will be assumed to be cardiac), MI and TLR. Target vessel revascularization (TVR) refers to an ischemic driven revascularization of the treated coronary artery. Stent thrombosis is defined per the Academic Research Consortium (A.R.C.) definition.

Follow up schedule

For the study, clinical endpoints measurements were conducted in-hospital and at 30 days and are planned at 6 and 12 months. After the first follow-up visit, the next ones could be done by personal visit, telephone or reference physician.

Antiplatelet and other concomitant medical therapy

Dual Anti-Platelet Therapy (DAPT) was required for all included patients. Aspirin ≥ 300 mg was administrated orally at least 1 hour prior to catheterization and an oral loading dose of tienopiridines: either clopidogrel (300 to 600 mg), prasugrel (60 mg) or ticagrelor (180 mg), preferably ≥6 hours prior to procedure. During PCI unfractionated heparin was recommended as necessary to maintain an activated clotting time as current guidelines suggested. Alternatively, enoxaparin, bivalirudin or others antithrombotic agents could be administrated per standard of care and operator´s choice. DAPT will be maintained at least 1 months and, following the index procedure followed by ASA monotherapy indefinitely. Extended DAPT will be at the discretion of the investigator. Clopidogrel: a maintenance dose of 75 mg od. Prasugrel: a maintenance dose of 10 mg od (the dose of prasugrel may be decreased to 5 mg od in subjects with a weight <60 kg or age >75 years). Ticagrelor: a maintenance dose 90 mg bid. DAPT wasrecommended for one year in the patients with acute coronary syndrome (STEMI and non STEMI).

Criteria for multiple and staged interventions

PCI procedures are allowed prior to the index procedure as shown in the diagram below **Figure 1.** No planned staged procedures are allowed after the index procedure.

Subjects are excluded from the study based on prior procedures if they have had any of the following:

- Previous treatment at any time with coronary intravascular brachytherapy.
- PCI of a non-target vessel or side branch within 1 day prior to the index procedure.
- PCI of the target vessel or side branch within 12 months prior to the index procedure.
- PCI within 10 mm proximal or distal to the target lesion (by visual estimate) at any time prior to the index procedure.

Statistical analysis. Plan for the primary endpoints

For the primary endpoint analysis, most frequent methods will be use. No power calculation were done taking in account that this is an observational study.

Study organization and ethical considerations

An independent clinical events committee will adjudicate all reports events of MACCE and other clinical events, including stent thrombosis. An independent data monitoring committee is responsible for oversight of all reported adverse events and evaluate safety data. All the required patient´s information needed to fulfill the research was incorporated to the database by each site researchers, trained with that purpose, using a password protected electronic case report form (CRF). The Centro de EstudiosenCardiologíaIntervencionista (CECI) is responsible for the development of the protocol registry, database, e-CRF and statistics analyses. The Informed Consent Form (ICF) was presented to the justice of department of protection of people data (Inspección General de Justicia –IGJ-) from Argentina, and the database was approved by this national bureau, following the personal data protection law (Case file Number SO4:0032164/16). The protocol was presented to the National Administration of food, Drug and Medical Technology(Administración Nacional de Medicamentos, Alimentos y TecnologíaMédica -ANMAT-) from Argentina on 6th of July of 2016. This is stent was approved for routine PCI by ANMAT on 19th of February of 2016. (Case file number 1-47-3110-3045/15-6). The registry follows Good Clinical Practice (GCP) and Helsinki declaration for human research. All patients signed an Informed Consent Form (ICF). During the entire study authorities from ANMAT will be aware of study recruitment and adverse events.

Limitations of the study design.
Taking in account this is a single arm multicenter registry that evaluates a "real world" population, not a randomized clinical trial.

LIST OF ABBREVIATIONS

ANMAT: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica
ARC: Academic Research Consortium
BMS: Bare metal stent
CECI: Centro de Estudios en Cardiología Intervencionista.
CRF: Case report form
CABG: Coronary artery by-pass graft surgery.
CVA: Cerebro-vascular accident
DES: Drug eluting stent.
ERACI: Estudio Randomizado Argentino Angioplastia versus cirugía.
GCP: Good clinical practice.
ICF: Informed consent form.
IGJ: Inspección General de Justicia
MI: Myocardial infarction.
MACCE: Major adverse cardiovascular events.
PCI: Percutaneous coronary intervention.
SYNTAX: Th e SYNergy between PCI with TAXUS Cardiac Surgery Trial
ULMD: Unprotected left main disease.
TLF: Target lesion failure.
TLR: Target lesion revascularization.
TVR: Target vessel revascularization.

APPENDIX

TABLE 1.

Component & characteristics	WALTZ™
Stent material	L605 CoCr
Stent design	Open cell
Strut thickness	0.0034´´
Crossing profile	0.037´´ (min)
Metal coverage area	11.6 % - 14.3 %
Delivery system	Rapid exchange
Nominal pressure (NP)	9 atm
Rate burst pressure (RBP)	16 atm for 2.5 mm – 3.5 14 atm for 4.0 mm

1. Inclusion criteria. Clinical and angiographic

CI1. Subject must be at least 18 years of age.
CI2. Subject (or legal guardian) indicates understanding of the trial requirements and the treatment procedures and provides written informed consent before procedures are performed.
CI3. Subject is eligible for percutaneous coronary intervention (PCI).
CI4. Subject has symptomatic coronary artery disease or silent ischemia with objective evidence of ischemia, or acute coronary syndromes, and qualifies for PCI.
CI5. Subject is an acceptable candidate for coronary artery bypass grafting (CABG).
CI6. Subject has a left ventricular ejection fraction (LVEF) >34% as measured within 60 days prior to enrollment.
CI7. Subject is willing to comply with all protocol-required follow-up evaluations.
AI1. Subject has one or more coronary artery stenosis of ≥50% in a native coronary artery with visually estimated reference vessel diameter (RVD) ≥2.50 mm and ≤4.0 mm.
AI2. Coronary anatomy is likely to allow delivery of a study stent to the target lesions(s).

2. Exclusioncriteria. Clinical and angiographic

CE1. Subject has a known allergy to contrast (that cannot be adequately pre-medicated) and/or the trial stent system or protocol-required concomitant medications (e.g., cobalt chromium alloy, stainless steel, all P2Y12 inhibitors, or aspirin).
CE2. Planned surgery within 30 days after the index procedure.
CE3. Subject has one of the following (as assessed prior to the index procedure):
- Other serious medical illness (e.g., cancer, congestive heart failure) with estimated life expectancy of less than 12 months.
- Current problems with substance abuse (e.g., alcohol, cocaine, heroin, etc.).
- Planned procedure that may cause non-compliance with the protocol or confound data interpretation.

CE4. Subject has a history of bleeding diathesis or coagulopathy or will refuse blood transfusions.
CE5. Subject is participating in another investigational drug or device clinical trial that has not reached its primary endpoint, or that, in the opinion of the investigator, may cause non-compliance with the protocol or confound data interpretation.

CE6. Subject intends to participate in another investigational drug or device clinical trial within 12 months after the index procedure.
CE7. Subject with known intention to procreate within 12 months after the index procedure (women of child-bearing potential who are sexually active must agree to use a reliable method of contraception from the time of screening through 12 months after the index procedure).
CE8. Subject is a woman who is pregnant or nursing (a pregnancy test must be performed within 7 days prior to the index procedure in women of child-bearing potential).
Note: No restrictions are placed on the total number of treated lesions, treated vessels, lesion length, or number of stents implanted.
AE1. Target lesion meets any of the following criteria:
- Restenotic from previous intervention

AE3. Subject has protected left main coronary artery disease
AE4. Subject has an additional clinically significant lesion(s) in the target vessel for which an intervention within 12 months after the index procedure may be required.

3. Criteria for planned staged PCI procedures

PCI procedures are allowed prior to the index procedure as shown in the Figure. No planned staged procedures are allowed after the index procedure.

DEFINITIONS

Death

Death is divided in two categories: Cardiac and non-cardiac.

1. Cardiac death is defined as death due to any of the following: - Acute myocardial infarction. - Arrythmia or any conduction abnormality. - Cerebrovascular accident aft er hospital discharge or cerebrovascular accident suspected to be related to the index procedure. - Death due to procedure complication, including bleeding, vascular repair, transfusion reaction or by-pass surgery. - Any death in which cardiac cause cannot be excluded. - Cardiac perforation/pericardial tamponade.
2. Non-cardiac death is defined as a death not due to any of the above.

Major adverse cardiovascular event (MACCE).

MACCE is defined as the composite of any cause of death, myocardial infarction (MI; both Q and non Q), cerebro-vascular accident (CVA) and any ischemia-driven revascularization of the target lesion (TLR).

Myocardial infarction (MI)

MI will be defined as either: - Q wave: development of new pathological Q-waves in 2 or more leads lasting ≥ 0.04 segs with post procedure cardiac enzyme levels elevated above normal. - Non Q wave: de novo elevation of enzyme levels (CK > 2 the upper normal limit without the presence of new Q waves).

Target lesion revascularization (TLR)

TLR is defined as any ischemia driven repeat revascularization procedure of the previously successfully treated lesion. It will be considered ischemia driven if the diameter stenosis is ≥ 50% by QCA and there is presence of clinical or functional ischemia which cannot be explained by other coronary or graft lesions.

Target lesion failure (TLF)

TLF is defined as any ischemia driven revascularization of the target lesion, cardiac death (if the event could not be determined with certainty, it will be assumed to be cardiac), MI and TLR.

Stent thrombosis

Stent thrombosis is defined per the Academic Research Consortium (ARC): - Definite: symptoms suggestive of an acute coronary syndrome and angiographic or pathologic confirmation of stent thrombosis) - Probable: unexplained death within 30 days or target vessel myocardial infarction without angiographic confirmation of stent thrombosis. - Possible: any unexplained death aft er 30 days. Based on the elapsed time since stent implantation, stent thrombosis can be classified as: - Acute: 0-24 hours post stent implantation. - Subacute: > 24 hours – 30 days post implantation. - Late: > 30 days – 1 year post implantation. - Very Late: > 1 year post implantation.

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WALTZ REGISTRY STUDY ORGANIZATION

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Data monitoring committee: Clinical Events Committee: David Antoniucci, MD (CEC Chairperson); Eduardo Gabe, MD (Sanatorio Otamendi y Miroli, Buenos Aires, Argentina) and Pablo Stutzbach, MD (Sanatorio Las Lomas. San Isidro, Argentina). Angiocore laboratory: Santiago Burda, Bs and Yasmin Navarro, Bs (Centro de Estudios en Cardiología Intervencionista. Buenos Aires, Argentina). Clinical Project Management: Centro de Estudios en Cardiología Intervencionista (Alfredo M. Rodriguez-Granillo MD & Graciela Romero MD Project Manager; Claudia Masclef Secretary) Biostatistical analysis: Centro

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