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The use of heart imaging to study the benefits of a new technique adjustment for treating heart artery narrowing with a stent

Submission date
07/02/2022

Recruitment status
No longer recruiting

Registration date
13/02/2022

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The coronary arteries (heart blood vessels) have multiple side branches that emerge from the main branch. A bifurcation lesion is a coronary artery narrowing involving both a main and side branch at the point of their division. The double kissing crush (DK crush) procedure is an established treatment algorithm for coronary artery bifurcations. It consists of multiple steps. A coronary stent (mesh tube) is implanted in the side branch, "crushing" the segment of the implanted stent that protrudes into the main vessel. The "crushing" stands for forcing to fold and squeeze a part of the stent that was deployed in the side branch to the vessel walls of the main branch by inflating a coronary balloon in the main branch. "Rewiring" of the side branch involves tracking again the coronary wire to the side branch by directing it to pass through the folded part of the stent into the stent lumen. Balloons are inflated in the main and side branches, creating a new orifice in the bent part of the side branch stent for further steps. A stent is deployed in the main branch followed by a second "rewiring" of the side branch, meaning tracking again the coronary wire to the side branch by directing it to pass through the cells of the main branch stent towards the lumen of the side branch stent, also passing through the new orifice of the side branch stent. A second balloon inflation is done to optimize stent scaffolding to the vessel wall at the bifurcation point. The most delicate and laborious step is the first rewiring since there is a risk of inappropriate coronary wire passage in the space between the stent and vessel wall, instead of the stent lumen. The consequence is a distortion of the side branch stent by the following steps that results in areas of the vessel in the bifurcation segment that are not covered by the stent. Proximal side optimization (PSO) is an additional step, a technique adjustment of DK crush performed before step 2 that consists of side branch stent post-dilatation by inflating the delivery balloon that is pulled halfway back and a non-compliant coronary balloon at high pressure, before the crush. This additional step in the procedure algorithm makes the following steps safer and faster. It is important to note that this modification does not require additional material, it changes only the timing of a step that is performed during the procedure anyway. Optical coherence tomography is an established heart imaging technique. The high resolution of OCT allows 3D reconstruction of the heart

environment and high precision measurements. The aim of this study is to evaluate the benefits of this additional step (proximal side optimization) by using OCT pullbacks at different steps of the procedure.

Who can participate?
Patients with bifurcation coronary lesions that are deemed eligible for PCI using the DK Crush algorithm

What does the study involve?
Participants are randomly allocated to undergo treatment using either the new or old DK Crush algorithm.

What are the possible benefits and risks of participating?
Both modifications of the DK Crush are universally accepted as state-of-the-art procedures and are using approved devices and techniques. OCT is known to be safe and effective when used for the approved indications. The risks of the DK Crush procedure are related to the risks of percutaneous coronary intervention. The main risk of OCT is a mild increase in the total amount of contrast agent, which can be harmful to kidney function. Considering this the patients are carefully selected based on their kidney function and specific interventions are used to avoid function reduction by the procedure.

Where is the study run from?
Jilin Heart Hospital (China)

When is the study starting and how long is it expected to run for?
December 2020 to June 2021

Who is funding the study?
Jilin Heart Hospital (China)

Who is the main contact?
Dr Vasile Sirbu
dr.sirbu@jlheart.org

Contact information

Type(s)
Principal investigator

Contact name
Dr Vasile Sirbu

Contact details
Jilin Heart Hospital
Changchun
China
130117
+86 (0)15568844551
dr_sarbu@yahoo.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
researchregistry7587

Study information

Scientific Title
Optical coherence tomography to assess proximal side optimization technique

Acronym
OCTOPUS

Study objectives
The principal hypothesis addressed by the study is that the addition of the proximal side optimization (PSO) technique to the established double kissing (DK) crush technique during double stent percutaneous coronary intervention (PCI) will result in:
1. Increased DES areas in the ostial segment of the side branch drug-eluting stent (DES)
2. Increased areas of the protruding DES in the main branch before the crush
3. Increased space of optimal wiring (SOW) areas

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2021, Jilin Heart Hospital Ethics Committee (Zhong Guo Jilin Sheng Chang Chun Shi Jing Yue Kai Fa Qu Jing Yue Da Jie 5558 Hao, 130117, China; +86 (0)431 81953018; jia.mi@jlheart.org), ref: R 15/21-JHH45

Study design
Single-center prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention of side branch stent under-expansion during double stent crush percutaneous intervention procedure to treat coronary artery bifurcation lesions

Interventions
10 patients presenting with severe bifurcation stenosis of the LAD-D eligible for two stenting DK Crush procedures, five with proximal side optimization (PSO) modification (control arm), and five DK Crushes without PSO modification (study arm), will be analyzed by means of intracoronary optical coherence tomography (OCT). DES areas in the ostial segment of the side branch (SB), protruding DES areas in the main branch (MB) before crush, SOW areas after crush,

and gaps in scaffolding within the ostial segment of the SB DES, will be analyzed by means of OCT examination during the DK crush procedure. Coronary angiography and DK Crush PCI are performed according to standard techniques with or without PSO modification, according to the assigned arm. All decisions about the adequacy of stent placement and expansion are based on an angiographic evaluation only.
OCT pullbacks were performed in all patients four times during the PCI procedure.
1. The first pullback from the SB to the MB will be done prior to crushing the SB stent
2. The second pullback will be performed in the MB from the distal to the proximal segment after crushing the SB stent
3. The third pullback - after the first KBI from SB to MB
4. The fourth pullback will be performed from SB to MB, after final angiography

Randomization process
To obtain a 1:1 randomization the researchers used the “randomize” function of the Excel program. After obtaining the randomization all the individual assignments were separately printed, and the paper placed in sealed envelopes. When a patient was meeting the inclusion criteria and had no exclusion criteria the operator opened the respective envelope and performed the modification of the procedure to which the patient was assigned.

Ten bifurcation lesions, all left anterior descending artery – diagonal branch bifurcation (LAD-D) Medina 1.1.1, with long (>10 mm) and severe stenoses (>75%) of the long (>75 mm) side branch (SB) were randomly assigned in a 1:1 ratio to either Double Kissing Crush bifurcation stenting (DK Crush)- (the non-PSO group) or DK Crush in PSO modification (the PSO group). All percutaneous coronary intervention (PCI) procedures were angiography guided and all lesions were treated using Xience V (Abbott Vascular, CA, USA) DES. All side branch (SB) drug-eluting stents (DES) were positioned with adequate protrusion in the main branch (MB)- (3-5 mm depending on bifurcation angle) and deployed at nominal pressure. Five patients had further PSO modification (PSO group), which briefly consists of post-dilatation of the SB DES with the delivery balloon pulled back halfway in the MB at nominal + 6 atm pressure followed by 0.5 mm larger non-compliant balloon prior to the crush step. Kissing balloon inflation (KBI) first and second were performed with the non-compliant balloons intended for the proximal optimization technique (POT) in MB and 0.5 mm larger than stent diameter in the SB in all patients. Sequential high-pressure dilatations before KBI were performed in all patients. POT first and second was used for all MB stents in all patients. OCT pullbacks were performed in all patients four times during the PCI procedure using a commercially available frequency-domain optical coherence tomography (FD-OCT) system (Cornaris™, Intravascular Imaging System, Clear View, Shenzhen, China). The first pullback from SB to MB was done prior to crushing the SB stent, the second pullback was performed in the MB from distal to proximal segment, after crushing the SB stent, the third pullback was performed after the first KBI from the SB to the MB, the fourth pullback was performed from the SB to the MB after final angiography. The rationale for the first pullback was:
1. To assess the distal reference segment in terms of diameters and areas
2. To assess distal stent segment expansion in terms of diameters and areas as compared to the distal reference segment
3. To assess the ostial segment of the SB DES in terms of expansion ad area as compared to the distal DES segment
4. To assess the diameters and areas of the protruding into the MB SB DES as compared to its ostial segment
The rationale for the second pullback was to assess the space of optimal wiring (SOW) after SB DES being crushed in terms of area using the 3D reconstruction. The rationale of the third pullback was to assess the SB stent expansion and analyze for possible stent distortions following KBI 1. The fourth pullback was done after final angiography to assess for possible gaps

in the polygon of confluence. An automated contrast delivery system (ACIST Medical Systems, Eden Prairie, MN) was used for contrast delivery through the guide catheter at a rate of 4 ml/s, zero rate of rise and pressure of 400 psi. An average of 14 ml of contrast (Visipaque GE Healthcare, Piscataway, NJ, USA) was used in each run. Images were calibrated by automated adjustment of the Z-offset, and an automated pullback was set at 20 mm/s for 3 s. Hemodynamic and electrocardiogram changes were monitored during each injection of contrast for image acquisition. Adequate hydration protocols were applied to all study patients pre- and post-procedure and kidney function was monitored for eventual contrast-induced nephropathy. OCT pull-backs were anonymized, and the randomization arm was blinded and stored. Analysis was performed after all ten procedures were done and patients were discharged from hospital. All the measurements were performed automatically by the OCT software, after thorough calibration and elimination of the eventual artifacts by an experienced imaging technician blinded to the randomization arm, thus excluding the bias of human factor in results. All obtained data were compared between the two groups (non-PSO vs PSO).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Stent areas in the ostial segment of the side branch and protruding DES areas in the main branch before the side branch stent is crushed, measured with optical coherence tomography (OCT) during the index procedure, after side branch stent implantation
2. Space of optimal wiring (SOW) measured with OCT after crush

Key secondary outcome(s))
Gaps in the scaffolding within the ostial segment of the SB DES measured with OCT at the end of the PCI procedure

Completion date
15/06/2021

Eligibility

Key inclusion criteria
1. 18 to 75 years old
2. Left anterior descending artery – diagonal branch bifurcation (LAD-D) Medina 1.1.1, with long (>10 mm) and severe stenoses (>75%) of the long (>75 mm) side branch (SB)
3. Undergoing two stent bifurcation PCI with Crush technique

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Patients less than 18 years old
2. Cardiogenic shock
3. Renal failure
4. Recent major bleeding
5. Allergy to aspirin or clopidogrel
6. On anticoagulant therapy
7. No suitable anatomy for OCT (extreme tortuosity, very small vessels<2.25 mm in diameter)

Date of first enrolment
15/01/2021

Date of final enrolment
15/06/2021

Locations

Countries of recruitment
China

Study participating centre
Jilin Heart Hospital
Zhong Guo Jilin Sheng Chang Chun Shi Jing Yue Kai Fa Qu Jing Yue Da Jie 5558 Hao
Changchun
China
130117

Sponsor information

Organisation
Jilin Heart Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Jilin Heart Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from (Vasile Sirbu, dr.sirbu74@gmal.com) as an Excel database, including OCT and Angio raw data, and will available for 5 years. Consent from participants was obtained, all data are anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/03/2022	26/10/2022	Yes	No