Study protocol:

BBK 3 –study

Randomised comparison of Culotte technique versus “Double Kissing” – Crush technique (DK-Crush) for the percutaneous treatment of de novo non-left main coronary bifurcation lesions with modern everolimus-eluting stents (DES) – European multicenter study

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BBK - 3 – study:

STUDY-SUMMARY

Background:
In percutaneous coronary intervention (PCI) of bifurcation lesions, the need for stenting of both, the main and side branch (double stenting), depends on lesion complexity. With high complexity (Medina classification 111, subtotal stenosis of both branches, severe calcified lesion, long lesions etc. or if dissection or abrupt occlusion during lesion preparation occurred) double stenting may be the treatment of choice. When double stenting is required, there are three major technical approaches: T-stenting (T- and Protrusion = TAP) technique, Culotte-stenting or “double kissing” Crush – technique (DK-Crush). Thus far, there is only limited evidence on the optimal technique, when double stenting is required. In the BBK 2 study, Culotte stenting demonstrated benefit over TAP stenting [1]. The DK-Crush 3 study [2] showed superiority for DK-crush technique as compared to Culotte technique, however only patients with distal left main stenosis were treated in this study. Both techniques are frequently used in daily routine. Yet, there is no randomized study, thus far, directly comparing the Culotte with the DK crush technique in coronary non-left main bifurcation lesions.
Aim:
This prospective randomized multicenter study will compare the long-term safety and efficacy of Culotte stenting versus DK-Crush stenting in the treatment of the de-novo non-left main coronary bifurcation lesions with new generation everolimus-eluting stents.
Methods:
Four-hundred patients, in whom a double-stenting technique is intended for the treatment of a non-left main de-novo coronary bifurcation lesion will be randomly assigned to Culotte stenting or to DK-crush stenting with an approved drug-eluting stent (SYNERGY-Stent). As a part of usual care, patients will undergo 9-month angiographic follow-up with quantitative coronary angiography. Clinical follow-up is planned at 30 days, 6 months, 1 year and 2 years. The primary study endpoint is the maximal percent diameter stenosis in the bifurcation lesion at 9 months. Secondary

endpoints include binary restenosis (estimated by Quantitative Coronary Angiography (QCA) analysis), Target Lesion Revascularisation (TLR), Freedom from Major Adverse Cardiac Events (MACE) and the rate of stent thrombosis according to the definition of the Academic Research Consortium (ARC definition). The study will have 80% power to detect a 25% decrease in the primary endpoint at $p < 0.05$ by Culotte stenting as compared with DK-Crush.

1. STUDY BACKGROUND:

Provisional side branch stenting is most frequently used type of treatment in coronary bifurcation lesions. When stenting of both the side branch and the main branch (double stenting) is needed, because of highly complex anatomy or if during lesion preparation dissection, TIMI flow < 2, high residual stenosis > 75% occurred, there is a variety of technical approaches, which have been proposed. The most common techniques in the daily routine are TAP stenting, Culotte stenting and “double kissing “-Crush stenting, if side branch stenting is needed.

Our recently published BBK 2 - study [1] demonstrated a benefit of the Culotte technique as compared to TAP technique during PCI of the de-novo coronary bifurcation lesions, with a significant reduction in in-stent restenosis (primary study endpoint). Moreover, BBK 2 - study showed a trend to better clinical outcomes after Culotte stenting during the first year of the clinical follow-up (secondary study endpoints). The difference was mainly driven by significant reduction for in-stent restenosis of the side branch stent.

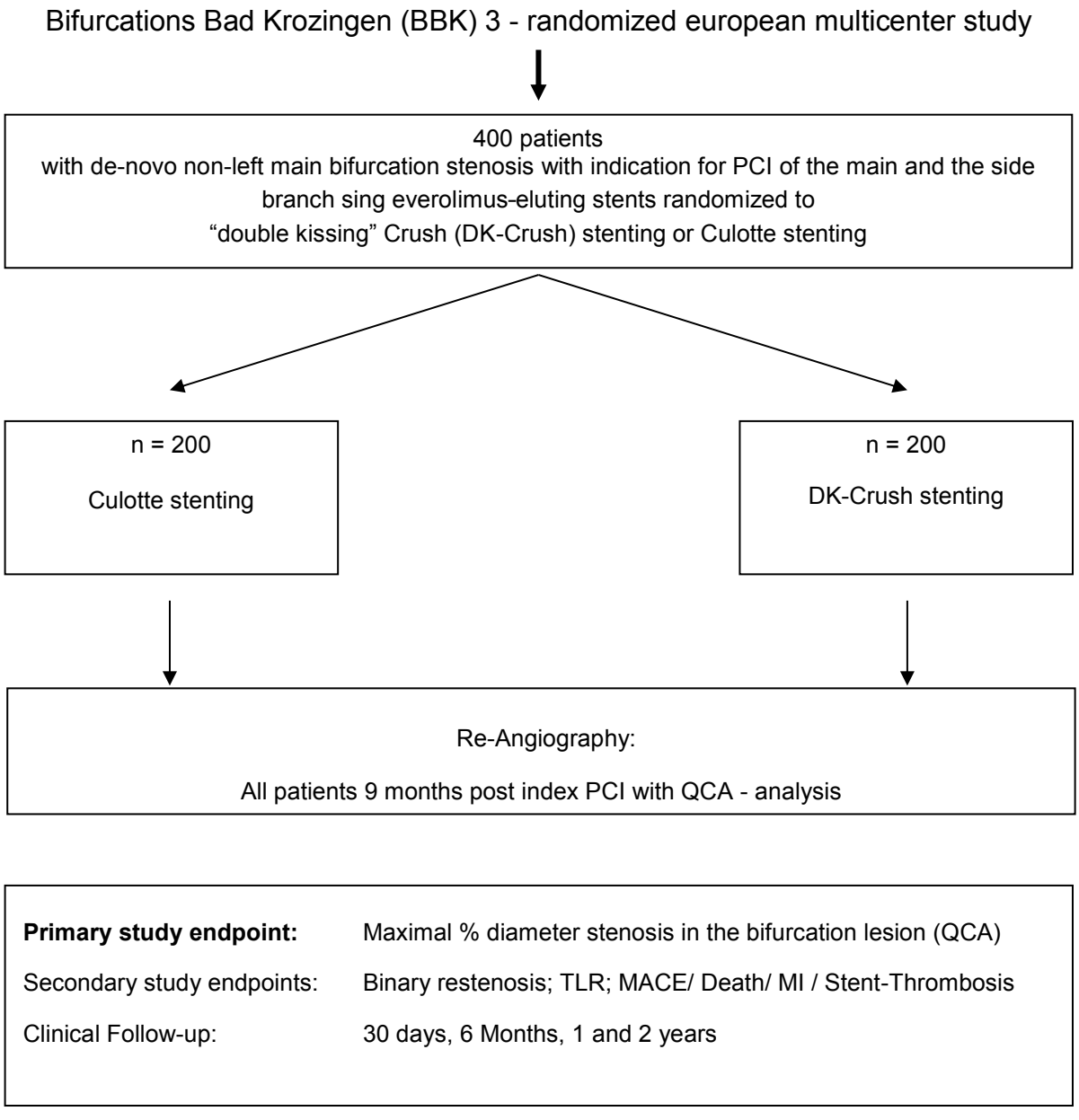
Interventional cardiologists from China, mainly Dr. Chen and his colleagues [2] modified the initially introduced classic crush technique to “double kissing“ -crush technique. DK-Crush technique is technically more challenging due to more procedural steps. The use of the DK-crush technique was assessed in randomized trials: comparison with classic crush techniques 3, provisional T-stenting 4 and with Culotte 2 (only for patients treated for distal left main stenosis). The DK-Crush technique was associated with lower angiographic restenosis rate and as well as with a lower reinterventions rates during long-term clinical follow-up.

The randomised multicenter Nordic II study 7 addressed the question whether classic Crush-stenting or Culotte-stenting achieves better angiographic and clinical outcome after PCI in bifurcation lesions. The results demonstrated no significant difference in respect to the primary study endpoint. Major adverse cardiac events (MACE) as primary study endpoint occurred in 3.7 % in the Culotte study arm as compared to 4.3 in the Crush study arm (p =0.87).

DK-Crush approach was tested in few randomized trials: DK-Crush I; DK II and DK III. The DK-Crush III study [2] focused to the comparison between DK-Crush and Culotte in patients with distal left main stenosis. Dr Chen et al. demonstrated lower stenosis rate and better clinical outcomes, if patients were treated using DK-Crush approach as compared to Culotte stenting.

All previous studies on the DK-Crush technique were performed using first generation drug-eluting stents (DES), which are not in use, any more. Currently, there is no randomized study available comparing DK-crush with Culotte techniques in patients with non-left main bifurcation lesions. From recent data it is known that the use of new-generation DES is associated with better clinical outcomes as compared to first-generation DES [5] [6].

Trial randomisation scheme:



Primary study endpoint:	Maximal % diameter stenosis in the bifurcation lesion (QCA)
Secondary study endpoints:	Binary restenosis; TLR; MACE/ Death/ MI / Stent-Thrombosis
Clinical Follow-up:	30 days, 6 Months, 1 and 2 years

Time and Event Schedule

Event	Screening	PCI	8-16-24 Hours	30 days	6 months	9 months	1 year	2 years
Inclusion/Exclusion criteria	X							
Informed consent signed	X							
Medical History	X			X	X	X	X	X
Angina pectoris status	X			X	X	X	X	X
Creatine kinase (CK) and hs-troponin	X		X					
Medication History	X	X		X	X	X	X	X
Adverse Event Monitoring		X	X	X	X	X	X	X
(PCI)		X						
Re – Angiography						X		

2. STUDY DESIGN

This study is a prospective, randomized, European multicenter evaluation of the treatment of de-novo bifurcated coronary lesions comparing a DK-crush stenting with Culotte stenting using approved modern third DES-generation.

The primary objective of this study is a comparison of DK-crush stenting with Culotte-stenting with respect to the maximal percent diameter stenosis within the bifurcation at 9 months. In addition, the study will assess various safety parameters.

Four-hundred patients will be enrolled in the study at European heart centers and will be randomly assigned to DK-crush stenting or to Culotte stenting of the non-left main bifurcation lesion. CE-certified everolimus-eluting Synergy - stents (third generation of the DES) can be used.

Sponsor of the study is the University Heart Center Freiburg · Bad Krozingen. Partial financial support is obtained by a scientific grant from Boston Scientific (BSI). Data from patients enrolled at participating study sites will be transferred in electronic form after pseudonymization to Dr. M. Ferenc at the University Heart Center Freiburg - Bad Krozingen to perform final data analysis and to publish the results of the study.

2.1 HYPOTHESIS

The hypothesis of this study is as follows:

In large coronary bifurcation lesions (main vessel ≥2.5mm, side branch ≥2.25mm) including significant ostial side branch disease, Culotte stenting compared with DK-crush stenting reduces maximal percent diameter stenosis at the bifurcation at 9-month follow-up by 25 %, relative.

3. STUDY ENDPOINTS

3.1. Primary study endpoint

The primary study endpoint is:

- Maximal percent diameter stenosis at the bifurcation at 9 months.

3.2. Secondary endpoints

The following secondary endpoints will be evaluated in this study:

- Binary restenosis (≥ 50% diameter stenosis) rate at any segment of the bifurcation at 9 months post procedure

- TLR of the main and side branch at 12 months post procedure.

- Binary restenosis (≥ 50% diameter stenosis) in the main and side branch at 9 months post procedure.

- MACE defined as death, Myocardial infarction (Q wave and Non-Q wave), emergent cardiac bypass surgery, or TLR at 30 days, 6 months, 1, 2years.

- Device success defined as attainment of < 30% residual stenosis of the target lesion using drug-eluting stent (DES) in the main and side branch

- Procedure time, radiation time and volume of used contrast medium

- Post-procedure thrombotic stent occlusion at 12 and 24 months according to the Academic Research Consortium-criteria:

- Stent thrombosis is classified by the ARC definition as definite, probable, or possible and as early (0 to 30 days), late (31 to 360 days), or very late (>360 days).

The definition of definite stent thrombosis requires the presence of an acute coronary syndrome with angiographic or autopsy evidence of thrombus or occlusion. Probable stent thrombosis includes unexplained deaths within 30 days after the procedure or acute myocardial infarction involving the target-vessel territory without angiographic confirmation. Possible stent thrombosis includes all unexplained deaths

occurring at least 30 days after the procedure. Intervening target-lesion revascularization is defined as any repeated percutaneous revascularization of the stented segment, including the 5-mm proximal and distal margins, that preceded stent thrombosis.

4 PATIENT SELECTION

This trial will include 400 patients with symptomatic de novo bifurcation lesion of a native coronary artery who meet eligibility criteria and provide written informed consent for participation in the study.
Eligible subjects will be informed about the scope and potential risks of the study verbally and in written form (ICF) the day before PCI. Informed consent will be obtained at the subsequent day before any study-related procedure and before start of the PCI.

4.1. Inclusion Criteria

Patients will be enrolled only, if all the following conditions are met:

1. Clinical indication (symptoms, ischemia documented or patients with acute coronary syndromes (NSTEMI) for interventional treatment of the bifurcation lesion.

2. Clinical indication to perform the double stenting as judged by the operator.

3. De-novo non-left main coronary bifurcation lesions according to the Medina classification of a native coronary artery with a reference vessel diameter: main branch >2,5 mm; side branch >2,25 mm (the difference between vessel diameter of the main and side branch should be ≤1 mm)

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4. Target lesion (main branch and / or side branch) with at least 50% diameter stenosis or FFR < 0.80.

5. The target lesion has not been previously treated with any interventional procedure.

6. The target vessel (main branch and side branch) must be feasible for stent implantation (successful passage with the guide wire; successful pre-dilatation with an appropriately sized balloon; lesion preparation, if needed

7. Patient has no other treatment planned within 30 days of the procedure.

8. Patient has been informed of the nature of the study and agrees to its

provisions and has written informed consent as approved by the Ethics Committee.

9. Patient is willing to comply all required post-procedure follow-up.

4.2. Exclusion Criteria

Patients are <u>not</u> eligible for enrollment into the study if any of the following conditions apply:

1. Patient had an acute myocardial infarction (> 3x normal CK) within 72 hours preceding the index procedure and CK has not returned to normal limits at the time of the procedure.

2. Patient with a known hypersensitivity or contraindication to aspirin, heparin, clopidogrel, prasugrel, ticagrelor, stainless steel, everolimus or contrast media that cannot be adequately pre-medicated.

3. Non successful treatment of other lesion during the same procedure

4. Patient with a platelet count of <100,000 cells/mm³ or >700,000 cells/mm³, white blood cells of <3,000 cells/mm³, or documented or liver disease.

5. Patient with a history of bleeding diathesis or coagulopathy.

6. Patient has suffered a stroke within the past six months.

7. Active peptic ulcer or upper gastrointestinal bleeding within the prior 6 months.

8. Patient has a co-morbidity (i.e. cancer or congestive heart failure) that may cause the patient to be non-compliant with the protocol, or is associated with limited life-expectancy (less than 2 years).

9. Patient must be excluded from the study if any of these angiographic criteria are met:
   a. The target vessel contains intraluminal thrombus.
   b. The patient has undergone previous PCI to the target vessel within 6 months.

4.3 Randomisation

Patients who fulfill inclusion and have no exclusion criteria and priovided written informed consent to the study will be randomised according to a standard random number generation method.
The study is designed as a non-blinded, randomized, European multi-center trial. Patients will be allocated to DK-Crush stenting or to Culotte-stenting using a computer-generated random sequence, set in blocks of 20 stratified to the type of

drug-eluting stent in clinical use. The size of the block and the random sequence will be select by the statistician and will be unknown to the investigators and medical staff caring for the patients. Randomization will be performed immediately before catheter treatment of the bifurcation lesion.

5. PROCEDURES BY VISIT

5.1. Patient Enrollment

All potential subjects should be consented prior to performing any study related procedures. The investigator or representative will explain the nature and scope of the study, potential risks and benefits of participation, and answer questions for the patient and/or legally authorized representative. If the patient agrees to participate, informed consent must be signed and dated; a copy must be provided to the patient or legally authorized representative.

Baseline data to be collected will include demographics, angiographic and clinical parameters.

5.2. Laboratory Assessments

- 12-leads ECG prior to procedure and between 12 hours and 24 hours post-procedure or before hospital discharge
- CK and CKMB and Troponin T prior to procedure and 8 hours, 16 hours and 24 hours post-procedure

5.3. Concomitant Medications

All subjects receive the medication regimen listed below. All medications administered should be recorded in the subjects medical record.

Prior to Procedure	Aspirin	At least 400 mg per os
	Clopidogrel	600 mg loading dose or
	Prasugrel	60 mg loading dose or
	Ticagrelor	180 mg loading dose
During Procedure	IV Heparin	For angioplasty bolus 100 I.U./ kg/ KG
	IC Glyceryl trinitrate	100 – 200 mcg prior to baseline and post intervention angiograms
Post-Procedure	Aspirin	At least 100 mg per day indefinitely
	Clopidogrel	75 mg per day for at least 6 months or
	Prasugrel	10 mg or 5 mg/day for at least 6 months as per drug label
	Ticagrelor	2 x 90 mg /day for at least 6 months as per drug label

Glycoprotein IIb/IIIa inhibitors can be used for bail out.

5.4. Coronary Angiography and Intervention

5.4.1. Angiography

Using standard procedures for angioplasty, an introducer sheath of at least 6 French will be introduced and the heparin bolus will be administered. After introduction of the guiding catheter and following intra-coronary injection of nitroglycerin, baseline angiography of the vessel will be performed in at least two best views that show the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter.

5.4.2. Lesion / Vessel Pre-treatment

For any patients with multiple lesions requiring treatment at the time of the index procedure, lesions outside the target vessel must be treated first successfully.

The target lesion in the main branch will be crossed with an intracoronary guide wire of 0.014 inch diameter and a second guide wire is passed into the side branch to protect the access. The choice of the appropriate guide wires is up to the discretion of the operator. After successful passage with the guide wires the lesion in the main branch should be pre-dilated with an appropriately sized balloon. Pre-dilatation of the side branch before stenting of the main branch is up to the discretion of the operator.

5.4.3. Stenting Procedure and Stenting Technique

Among the many approaches to bifurcation stenting, we chose techniques that avoid non-stented gaps at the orifice of the side branch with minimal stent distortion or stent overlap in the carina region or the proximal segment of the main branch. Both techniques the DK-Crush as well the Culotte-stenting provide complete coverage of the side branch ostium. Final ‘kissing balloon’ dilatation must be performed in all patients irrespective of whether they were assigned to DK-Crush or Culotte-stenting.

Stents should be selected long enough to cover the lesions completely. If more than one stent is needed to cover the lesion in the main or side branch completely, it is recommended to overlap the stents 1 – 2 mm. The aim should be to reach a diameter stenosis < 10% without proximal and distal dissections. Post dilatation may be performed at the discretion of the operator. Pre or post dilatation technique should avoid balloon injury to any segment of the vessel that will not be entirely covered by the drugeluting stent including the patients with provisional side branch stenting following an unsatisfactory result after balloon angioplasty. An additional use of the imaging techniques is up to the discretion of the operator.

DK-Crush:

Both vessels have to be wired first. Lesion preparation in the main vessel and side branch may be undertaken according to operator preference (rotablation, if needed). After lesion preparation, the side branch is stented first. Side branch stent should have a small protrusion into the main branch. Before stent implantation in the side branch, an adequately sized balloon should be placed in the main branch, just

opposite to the side branch ostium. After stent implantation in the side branch, stent balloon and wire are removed and the balloon in the main branch must be inflated, to crush the struts into the vessel wall. In next step, the new wire should be crossed into the ostium of the side branch and first kissing balloon dilatation will follow. The next step is to implant the second stent into the main branch, followed by a second kissing balloon-dilatation and final proximal optimisation (POT) procedure (single balloon inflation in proximal segment).

Culotte stent technique:
Both vessels have to be wired. Lesion preparation in the main vessel and side branch may be undertaken according to operator preference. After lesion preparation, the side branch has to be stented first.

The first stent is placed from main branch into the side branch side branch, covering the entire diseased segment with a wire jailed in the main vessel. The main vessel is rewired through the stent struts, and after removal of the jailed wire, is dilated with a balloon to separate stent struts. The side branch wire is then removed (to prevent metal-to-metal jail) and the main vessel is stented covering the proximal and distal segment. The side-branch is re-wired and high pressure (e.g. 20 atm) individual inflations are made in each vessel at the bifurcation point to ensure good stent strut separation. Finally, a lower pressure kissing inflation is made. For both the high pressure individual and lower pressure final kissing inflations, balloon sizing should be in accordance with the diameter of the vessel itself.

Further treatment to proximal or distal aspects of the main vessel or side branch can be continued at the discretion of the operator. At any stage, proximal or distal dissections may be treated as required with further stent implantations. At any stage, post-dilatations may be undertaken to optimize stent expansion.

Irrespective of the assigned treatment, glyceryl trinitrate is injected intra-coronary at the completion of the procedure and final angiography of the vessel is performed in the two optimal views that were chosen at baseline.
If needed, additional intravascular imaging should be used.

5.4.4. Stent type

Approved modern everolimus-eluting stent with biodegradable polymer will be used as study stent (Synergy-stent from Boston Scientific)

5.5. Follow-up Procedures

All patients enrolled in the study will be required to complete 30 days, 6 months, 1 and 2 years follow-up to evaluate long-term results.

5.5.1. 30 Days (± 5 days) Post Procedure (Telephone contact)

The assessment will include angina status (according to the Canadian Cardiovascular Society Classification of angina), all adverse events, all concomitant medications and any interventional treatment that occurred since the index procedure.

5.5.2. Angiographic Follow-Up 9 Months (± 30 days) Post Procedure

Irrespective of symptoms, current guidelines recommend considering routine follow-up angiography after treatment of complex lesions (such as bifurcation lesions). This is routine practice at our institution. Thus, as part of our clinical routine, all patients will undergo repeat angiography at 9 months after the index procedure.
Angiographies will be performed as described in Section 5.4.1.
All angiographies, including unscheduled angiograms, will be analysed by the angiographic core laboratory.

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5.5.3. At 30 days, 6,12 and 24 months (± 30 days) post Procedure (Telephone contact or contact with family doctor)

The assessment will include angina, all adverse events, all concomitant medications and any interventional treatment that occurred since the previous contact.

5.5.4 Quantitative coronary angiography:

For quantitative coronary angiography, angiograms obtained at baseline, at completion of the intervention and at 9 months follow-up will be analysed using a computer based system dedicated to bifurcation analysis (Qangio XA, version7.0, Medis, Leiden, Netherlands), according to the standard operating procedure of the angiographic core laboratory.
Quantitative angiographic measurements will be obtained of the three segments of the bifurcation lesion: the proximal and distal segment of the main branch and the side branch. We will perform measurements in the stented portion of the vessel (in-stent) and in the distal or proximal 5 mm margin (edge). In-segment analyses will comprise the in-stent and the edge area.
In addition, the bifurcation angle from the analysis system will be estimated.

6. SAFETY ISSUES

All serious adverse events must be reported for medical assessment and evaluation to the representative of the sponsor of the study: University Heart Center Freiburg – Bad Krozingen (Dr. M. Ferenc; PI of the BBK 3 study).

A Serious Adverse Event is defined as any untoward medical occurrence that meets at least 1 of the following serious criteria:

- Results in death (fatal)
- Immediately life-threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Other medically important serious event
- Medical or scientific judgment is to be exercised in deciding whether serious adverse event reporting is appropriate in other situations such as important medical events that may not be immediately life-threatening or result in death

or hospitalization but may jeopardize the subject or may require medical or surgical intervention to prevent 1 of the other outcomes listed in the above definition.
These events are typically to be considered serious.
Examples of such events include invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, or development of drug dependency or drug abuse.

7. SAMPLE SIZE ESTIMATION

The study is designed to have a 80% power to detect a 25% relative reduction of the primary endpoint by Culotte technique as compared with DK-crush stenting at a significance level of 0.05.
Based on our previous study we assume a maximum percent diameter stenosis of 20 % in the Culotte arm and a common standard deviation of 22%. We, thus, obtain a sample size of 172 patients in each arm to have an 80 % power to detect a reduction in maximum percent diameter stenosis from 26.7 % to 20 % by Culotte stenting as compared with DK- Crush stenting. The study will include 200 patients in each study arm, to allow for losses to angiographic follow-up.

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