Facilitated Culottes in Coronary artery bifurcation stenting using a dedicated side branch stent: Two years clinical outcome

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INTRODUCTION: Treatment of bifurcation coronary artery lesions with stenting has been associated with increased complication rate and remains a major challenge in intervention cardiology. Introduction of DES reduced restenosis in the main branch, however, restenosis at the ostium of the side branch remains a problem. Achieving permanent side branch (SB) access, stent delivery by simultaneous kissing balloon inflation and optimal main branch (MB) and SB ostium scaffolding are essential in stenting bifurcation lesion. A novel dedicated bifurcation stent may potentially overcome limitations of conventional stenting using the culottes technique.

OBJECTIVES: As part of an international registry we evaluated the clinical safety and efficacy of Tryton a dedicated side branch stent. In this study we sought to evaluate the immediate and two years clinical outcomes of facilitated culottes in coronary artery bifurcation stenting using Tryton.

METHODS: We prospectively followed 169 consecutive patients who had bifurcation coronary artery lesion treated with Tryton stents. Patients with bifurcation lesion and siutable for Tryton stent were eligible and the main exclusion criteria were chronic total occlusion, bypass graft lesions and instent restenosis. The primary clinical end point was the incidence of major adverse cardiac event (MACE) during the follow up period. Procedure outcome and/or complications were decumonted. Clinical follow up was complete for all patients and all subjects stayed on aspirin and clopidogrel over a follow up period of 6-24 months.

RESULT: 178 lesions in 169 patients treated with Tryton were included. Males were dominating the group (Table 1) and 33.7% were age >70 years. The common clinical presentation was NSTE-ACS followed by unstable angina. Bifurcation lesion involving the LAD/diagonal was the target in the majority of cases (Table 2). Mean clinical follow-up was 17.8 months and there was no cardiac death, emergency CABG or stent thrombosis (Table 3).

Table1: Base Line Clinical charecterstics

Patient Charecterstics	Frequency (n)	Percent (%)
Male	136	80.5
Age	Range 41-84	Mean 68
Hypertension	89	52.7
Diabetes	31	18.4
Chronic Renal Failure	7	4.1
Previous PCI	30	17.8
Total	169	100

Table 2: Target segment of Bifurcation lesion

Index Artery	Frequency (n)	Percent (%)
LMS	2	1.1
LAD/Diagonal	97	54.5
LCX/OM	54	30.3
RCA	25	14.1
Total	178	100

Table 3: Immediate Procedure outcome

Outcome	Frequency (n)	Percent (%)
Successful	177	99.4
SB Dissection**	6	3.4
Stent Embolisation	1	1.3
Emergency CABG	0	0

** **Dissection that needs stenting with DES**

Successful completion of the procedure with final 'systematic four step kissing balloon' was achieved in 99.4% (Table 3). Over all MACE rate was low and few cases of TVR/TLR were encountered (Table 4). There were 11 admissions for non-related medical conditions, 5 admissions for non-specific chest complaint and five more for elective PCI to a different coronary artery.

Table 4: 17.8 months Clinical outcome

Clinical Event	Frequency (n)	Percent (%)
Over all MACE	17	10.1
TVR	10	5.6
TLR	4	2.3
All cause deaths	1	1.8
Stent Thrombosis	0	0
MI	9	5.1

CONCLUSIONS: Facilitated culottes stenting using Tryton side branch dedicated stent combined with a 'workhorse DES' is feasible and safe in a broad spectrum of unselected bifurcation lesions.
This technique, completed with 'four step kissing' balloon dilatation is associated with favourable clinical outcomes, with low rate of MACE and TLR, comparable with our prior experience with 'conventional culottes' stenting using DES.
A multicentre randomised trial (TRYTON _ IDE) is currently in recruitment phase , comparing this strategy with 'Provisional' bifurcation stenting, results of which will be eagerly awaited.
Use of OCT, IVUS or FFR may have a positive effect and perhaps should be used more often.