

Title: "Indirect meta-analysis of Tryton side branch® stent versus a provisional single stent technique for patients with a bifurcation coronary lesion ".

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Abstract.

Background. Several trials and meta-analysis have addressed whether bifurcations lesions require stenting of both the main vessel and side branch. The Tryton side brach stent is a bifurcation system that secures the side branch and provides ostial protection. Uncertainty remains on the benefits of such Tryton Stent versus a single (provisional) stenting with regards to the occurrence of periprocedural myocardial infarction (periMI).

Methods. Studies treating bifurcation lesions were searched in Pubmed. The primary end-point was the occurrence of peri-MI. Crude and weighted by the inverse of variance method risks (R) and 95% Confidence Intervals (CI) were computed.

Results. Seventeen studies (n=2924) for the comparison of Tryton stent vs. single stent. The crude risk of peri-MI among patients treated with a single technique and Tryton Stent were 4.42 % (95% CI 3.98-4.86%) and 3.45 % (95% CI 2.79-4.12%), respectively. The risk estimation weighted by inverse variance yield 1.48% (95%CI 1.00-1.98) and 2.78% (95% CI 1.61-3.95%), respectively.

Conclusions. Stenting of both the side branch with a Tryton stent and the main vessel in bifurcation lesions may not reduce the rate of periprocedural myocardial infarction as compared to a provisional one-stent technique.

Table 1. Studies using a provisional stent technique, included in the meta-analysis.

Studies	Reference	Periprocedural MI definition	Periprocedural MI incidence (provisional stent)
BBC-ONE	Heart 2012;98:1431-35 Circulation. 2010;121:1235-1243	CK \geq 3 fold or rise > 50% above previous values	4 / 233
NORDIC	Circulation. 2006;114:1955-1961	Biomarkers (Troponin/CKMB \geq 3 fold)	12 / 153
BBC-ONE & NORDIC pooled analysis	Circ Cardiovasc Interv. 2011;4:57-64	Biomarkers (Troponin/CKMB \geq 3 fold)	16 / 457
ARTS II	Eur H J 2007;28:433-42	non Q MI: CK > 3 fold; Q MI: Q+CK>reference	15 / 263
Galassi	J Am Coll Cardiol Intv 2009;2:185-94	non Q wave MI: CK \geq 3 fold CK-MB; Q MI: Q+CK-MB \geq 3	2 / 170
DK-CRUSH II	J Am Coll Cardiol 2011;57:914-20	Biomarkers (Troponin/CKMB \geq 3 fold)	7 / 185
Pan	Am J Cardiol 2011;107:1460 -1465	CK > 3 fold	4 / 293
NORDIC- BALTIC III	Circulation. 2011;123:79-86	Biomarkers (Troponin/CKMB \geq 3 fold)	22 /350
Pan	Am Heart J 2004;148:857- 64	CK > 3 fold	2 /47
Bifurcations Bad Krozingen registry	Am Heart J 2010;159:454-61	CK or CKMB \geq 3 fold	0 / 202
DEBIUT	<u>Catheter Cardiovasc Interv</u> 2012;80:1138-46.	CKMB \geq 3 fold	5 / 77
SMART- STRATEGY	JACC Cardiovasc Interv. 2012 Nov;5(11):1133-4	CK-MB \geq 3	7 / 128
		Procedural MI = 96 / 2172 = 4.42% 95% CI 3.98 - 4.86	

Table 2. Excluded studies and reasons for such a decision.

Study name	Reference	Reason for no inclusion	Periprocedural MI incidence (provisional stent)
CACTUS	Circulation 2009;119:71-8	Deviation of periprocedural MI definition	12 / 173
Colombo	Circulation. 2004;109:1244-9	Periprocedural MI not defined	2 / 22
Collins	Am J Cardiol 2008;102:404-410	Deviation of periprocedural MI definition	7 / 266

Table 3. Meta-analysis of studies with provisional stent technique, applying an inverse-variance weighting method and a classical coefficient correction ($\Omega= 0.5$) for studies with zero risk.

Studies	Risk	Variance	W (1/variance)	Risk x w product
BBC-ONE & NORDIC pooled analysis	16 /457	7.39×10^{-5}	13526.6	473.6
ARTS II	15 /263	2.04×10^{-4}	4890.2	278.9
Galassi	2 /170	6.84×10^{-5}	14622.0	172.0
DK-Crush II	7 /185	1.97×10^{-4}	5081.6	192.3
Pan	4 /293	4.60×10^{-5}	21759.3	297.0
NORDIC-BALTIC III	22 /350	1.68×10^{-4}	5941.6	373.5
Pan	2 / 47	8.67×10^{-4}	1153.6	49.1
Bad Krozingen	0 / 202	1.22×10^{-5}	82215.5	203.0
Debiut	5 / 77	7.88×10^{-4}	1268.1	82.3
SMART-STRATEGY	7 / 128	4.04×10^{-4}	2476.0	135.4
			$\Sigma=152934.6$	$\Sigma= 2257.2$

Risk (weighted by inverse-variance method) = = 1.48%

Standard error (risk) = 0.00255

$1.96 \times SE \times 100 = 0.5$

95% Confidence interval (risk) = 0.98-1.98 %

Table 4. Global findings.

Procedural MI	Weighted risk	Weighted 95% Confidence Interval
Provisional Stent	1.48	0.98 - 1.98
Tryton stent technique	2.78	1.61 - 3.95