Angiographic dissection pattern post balloon angioplasty in SFA lesions

-a retrospective multi center analysis-

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Disclosure

Speaker name :

Mashiko Fujihara

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ■ I do not have any potential conflict of interest

Background

- Nitinol stent has been mainly used for the endovascular therapy (EVT) for superficial femoral artery disease (SFA)
- The pivotal clinical trials of SFA stent revealed higher patency rate over **balloon angioplasty including bailout stent**
- Since the approval of drug-coated balloon (DCB), nothing left behind approach is being advocated
- However, in DCB studies, **definition of optimal balloon angioplasty** are **not clear** and **dissection pattern** post balloon angioplasty are not reported

Aim

- **Angiographic dissection pattern** post balloon angioplasty in SFA lesions were evaluated
- The clinical outcome of **balloon alone procedure** based on dissection pattern were examined

Material and Method

Study Design and Patients

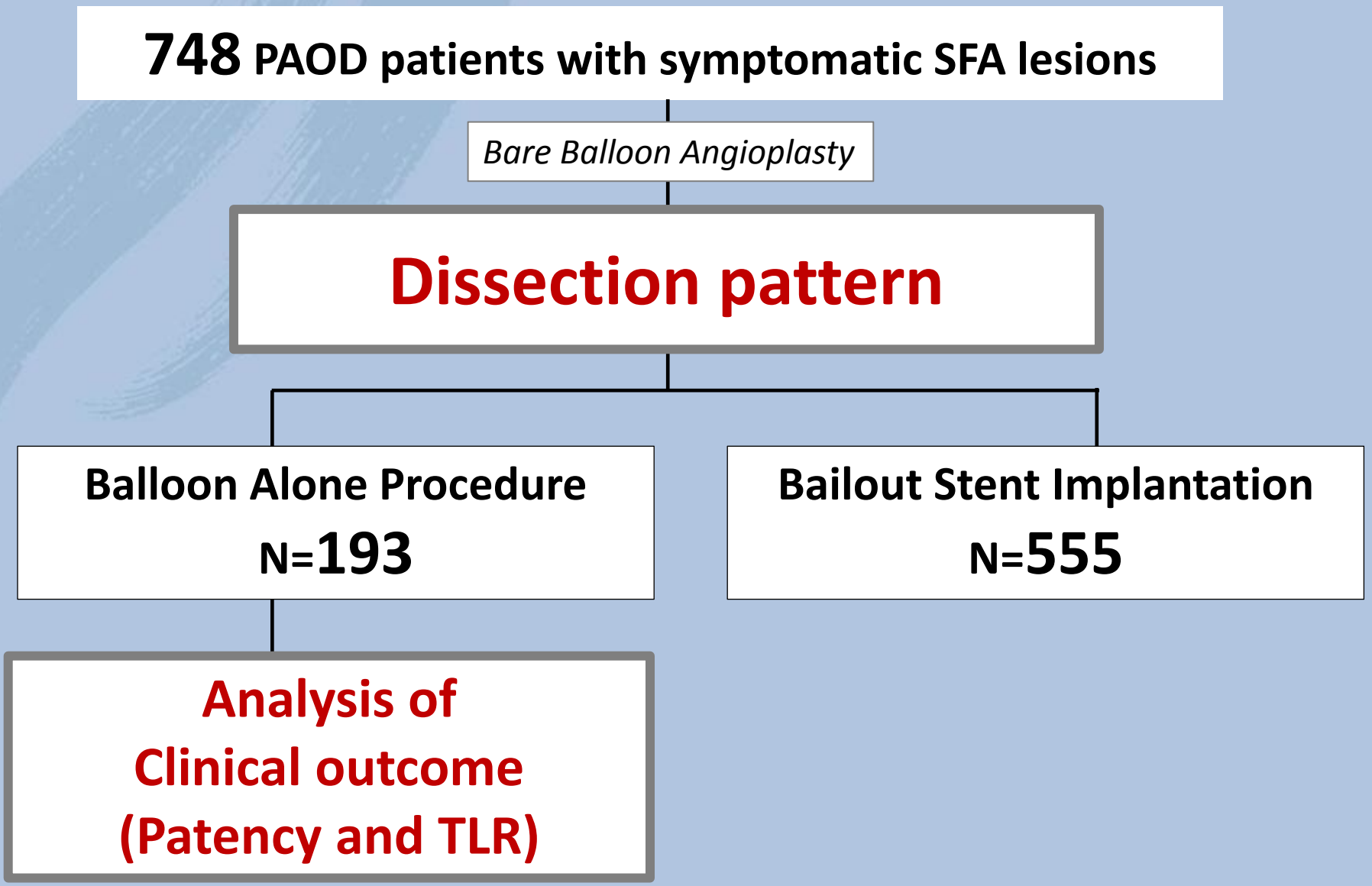
A retrospective, multicenter, non randomized investigation at 4 cardiovascular centers.

Inclusion and Exclusion Criteria

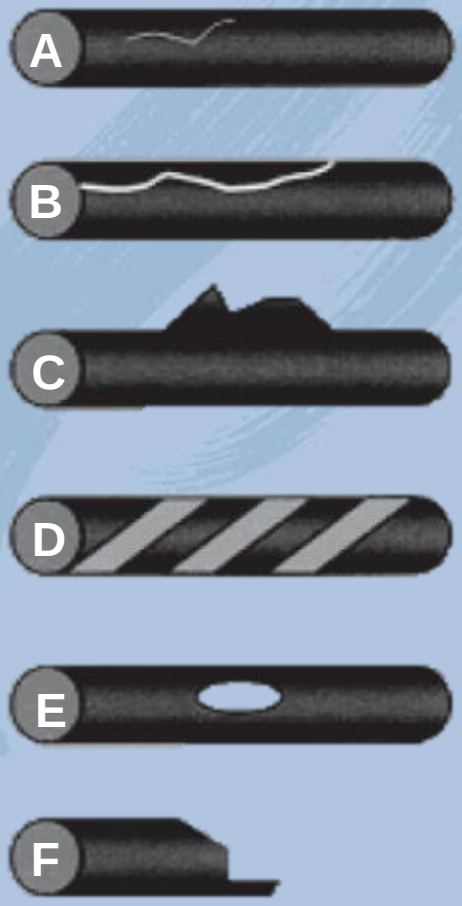
Inclusion criteria	Exclusion Criteria
• Age >20 years old • Rutherford category class (RCC) 2–6 • Angiographic evaluation was performed post balloon angioplasty	• In SFA stent restenosis • Direct SFA stent • CO2 Angiography • Drug coated balloon

Participated Hospital	
• Kishiwada Tokushukai Hospital • Kansai Rosai Hospital	• Saka General Hospital • Tokyo Rosai Hospital

STUDY Scheme and Endpoints



Definition of Vessel Dissection modified from coronary artery' classification



A) minor radiolucent areas

B) dissections are parallel tracts

C) contrast outside the lumen

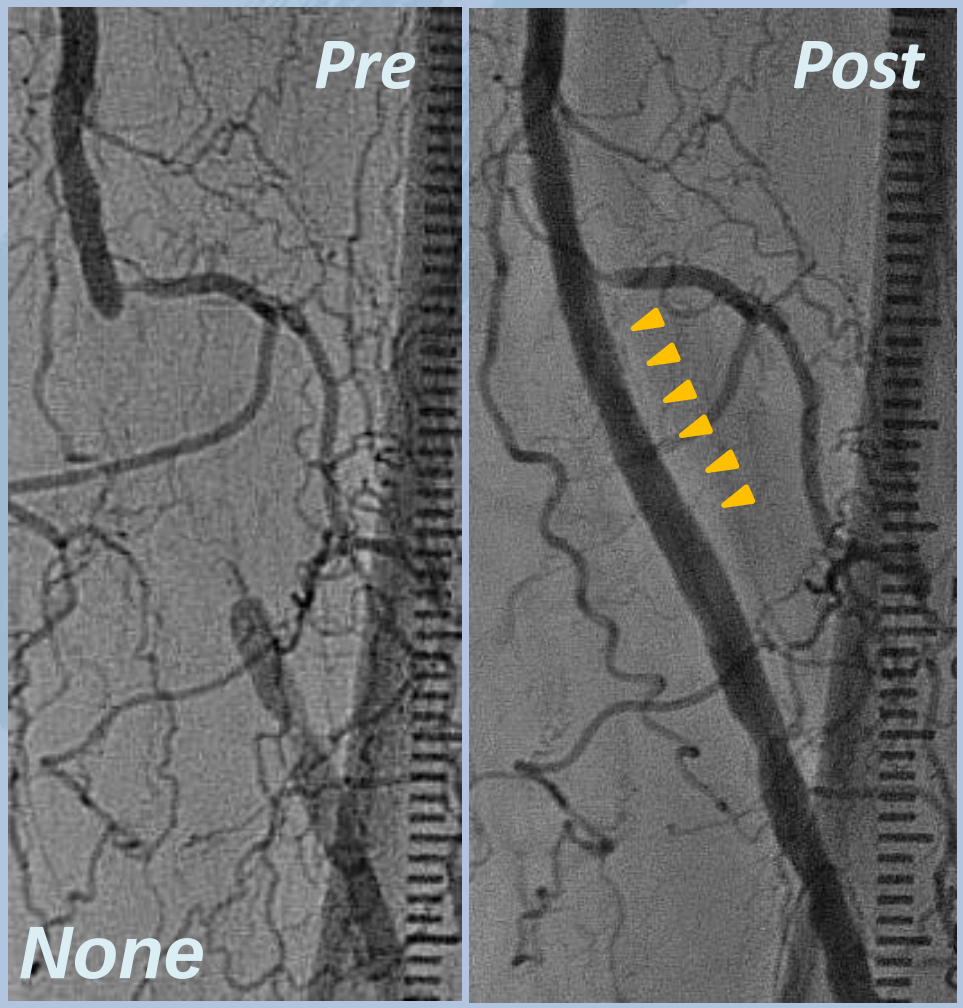
D) Spiral luminal filling defects

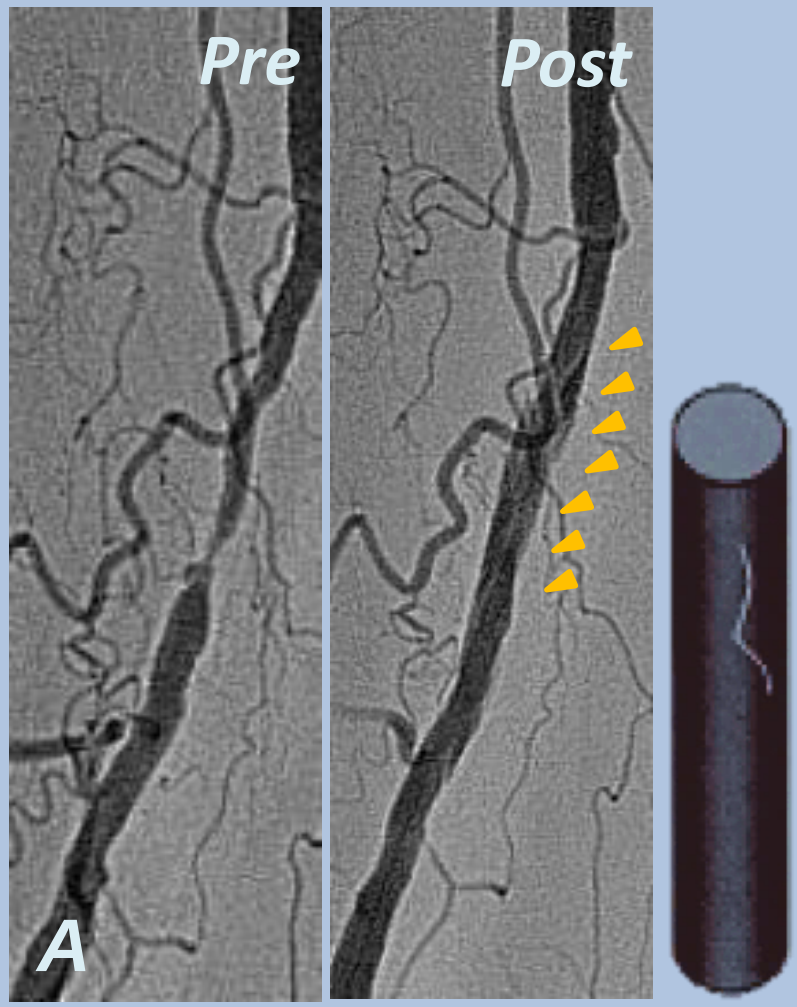
E) persistent filling defects

F) total occlusion without distal antegrade flow.

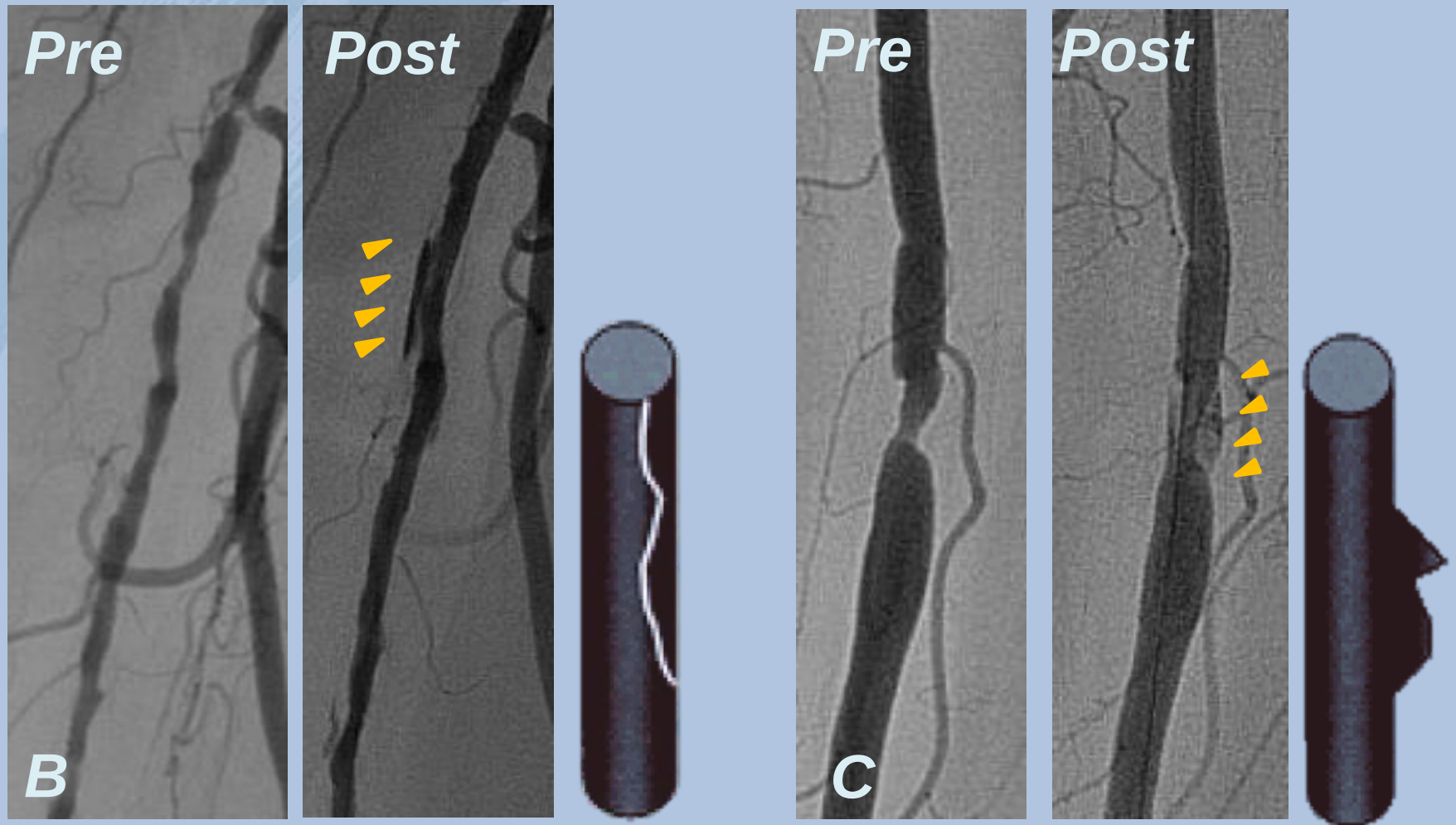
National Heart, Lung and Blood Institute classification system for coronary artery dissection types. Cardiovasc. j. 2011

None & Type A Dissection Pattern

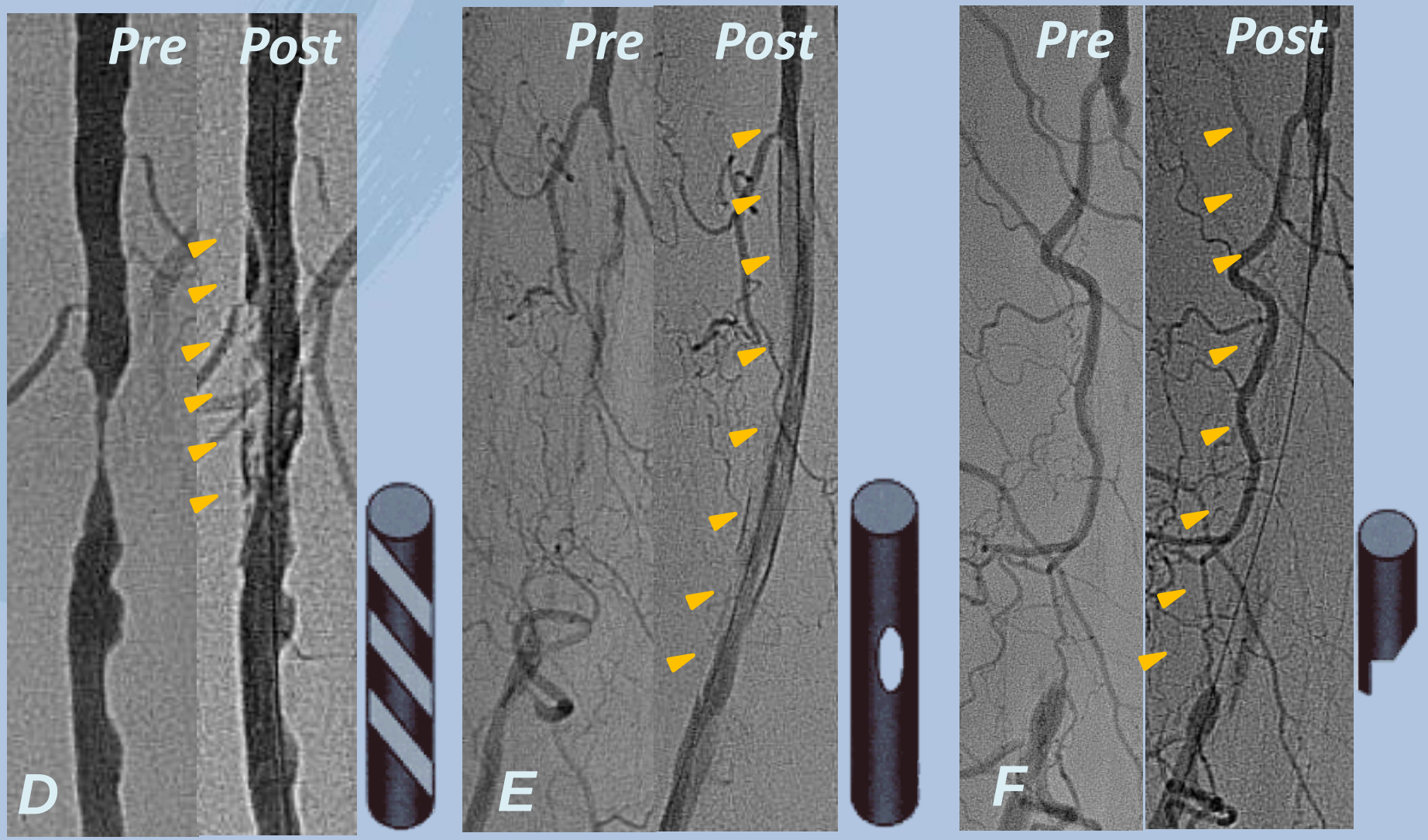




Type B & C Dissection Pattern



Type D,E&F Dissection Pattern



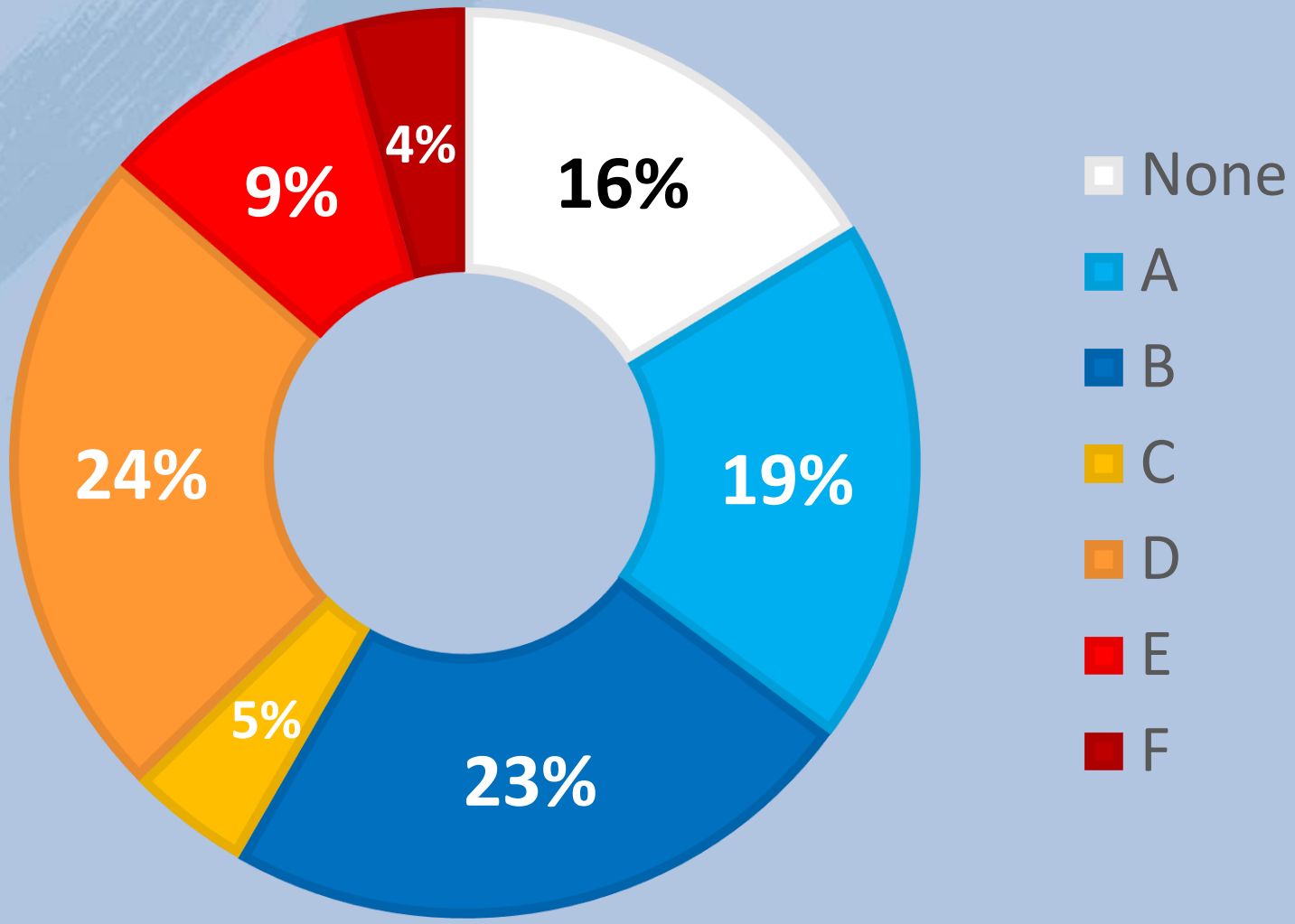
Patient and Lesion Characteristics

	All N=748		All N=748
Age (years old)	**72**.6± 9.5	Lesion Length (mm)	**148**.1±92.4
Male (%)	66.8	Ref vessel size (mm)	5.4±1.0
Hypertension(%)	88.2	TASC CD (%)	**46.5**
Diabetes (%)	**58.4**	CTO (%)	**40.2**
Dyslipidemia (%)	52.6	***Calcification***	
Obesity(%)	14.0	*None*	34.8
Regular Hemodialysis (%)	**32.7**	*Moderate*	**26.6**
Coronary Artery Disease (%)	63.2	*Severe*	**38.6**
Critical Limb Ischemia (%)	35.0	Non BTK run-off	15.8
Rutherford Classification	3.50±1.2		

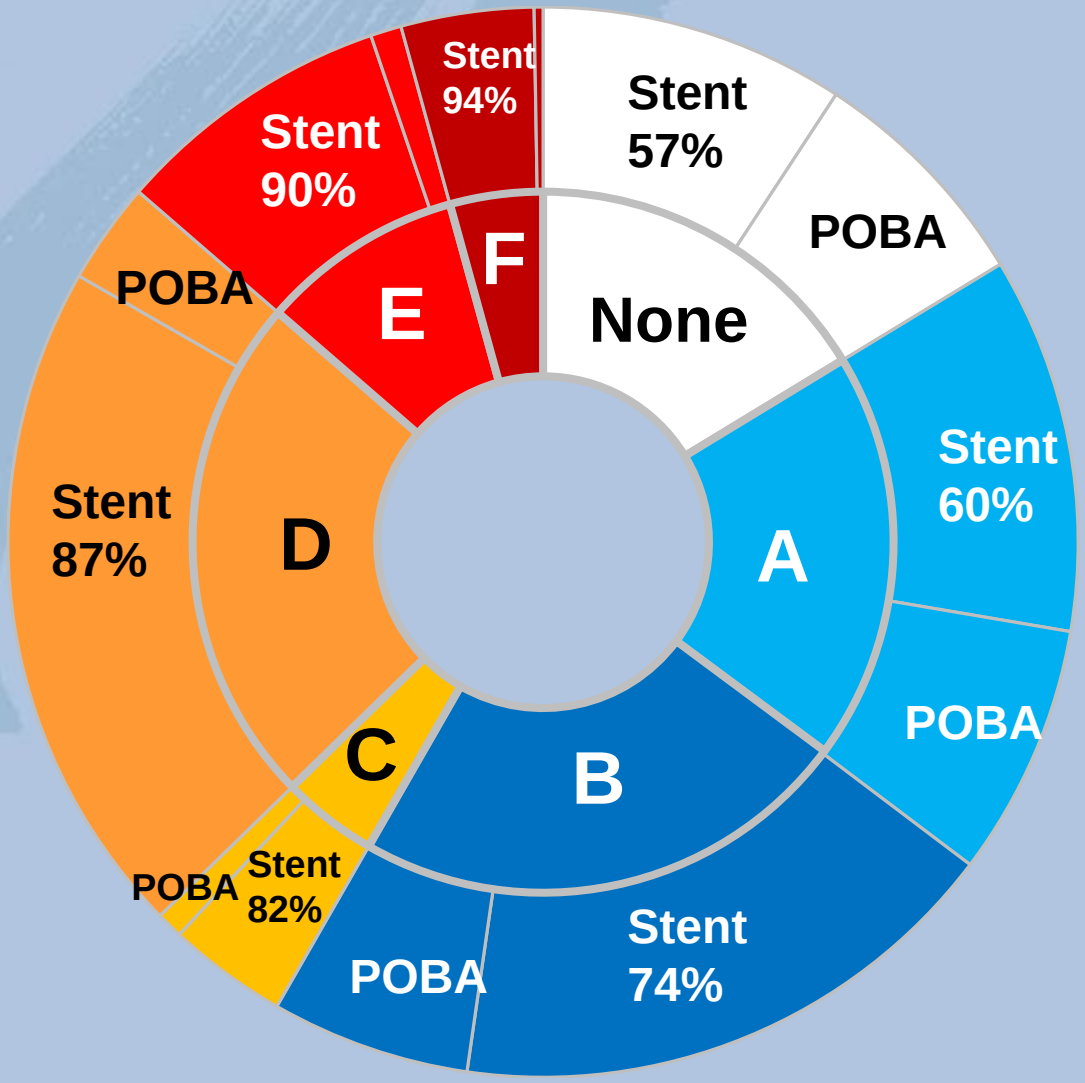
Procedure Characteristics

	All N=748
Bare Balloon (%)	97.6
Cutting Balloon (%)	2.4
Balloon Type	
0.014 inch (%)	21.2
0.018 inch (%)	63.1
0.035 inch (%)	15.6
Balloon Size	
Average Balloon size	4.7±0.8
Balloon size≥ 5mm (%)	62.7
Average Inflation time (sec)	80.7±88
Inflation Time≥ 2minutes (%)	30.7
IVUS use (%)	27.8

Dissection Pattern of Post Balloon Angioplasty



Stent Implantation rate between Dissection Pattern



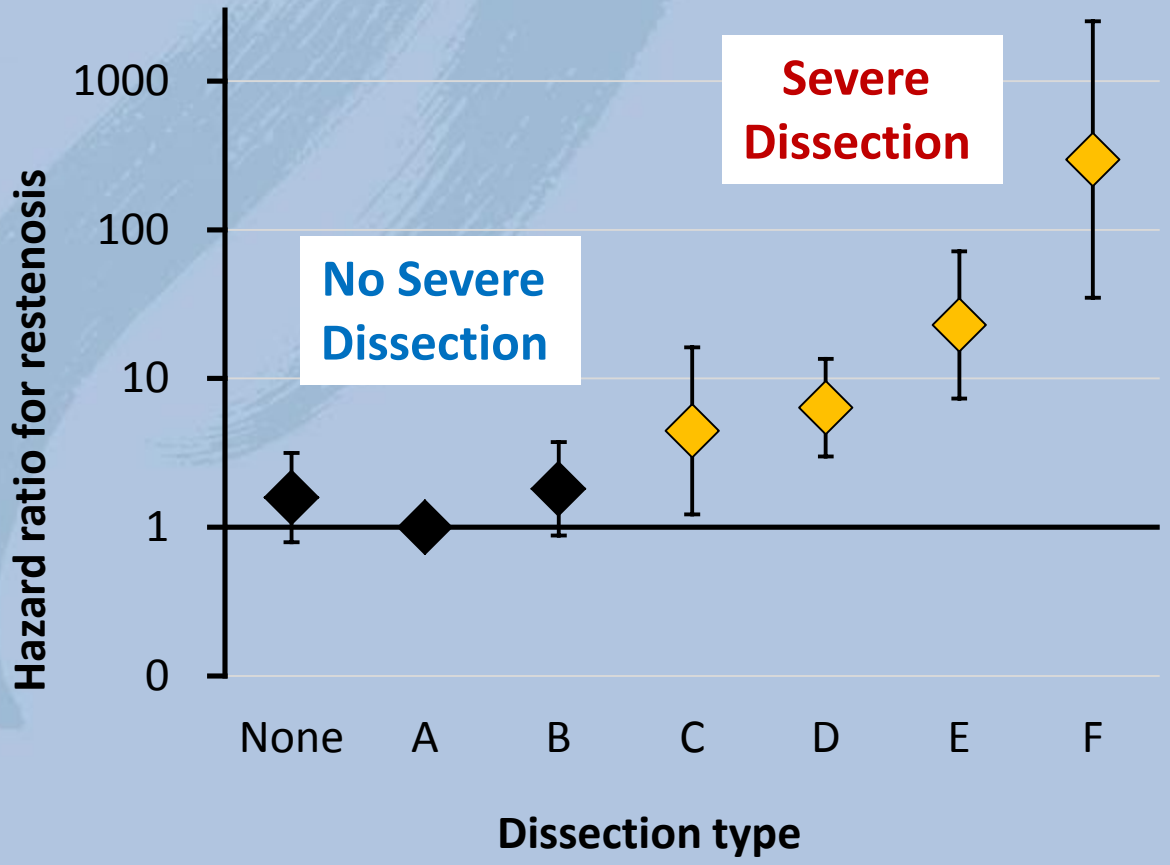
Primary or Bailout Stent Implantation rate

74.1%

Balloon Alone Procedure

25.8%

Hazard Ratio of restenosis comparison with dissection pattern

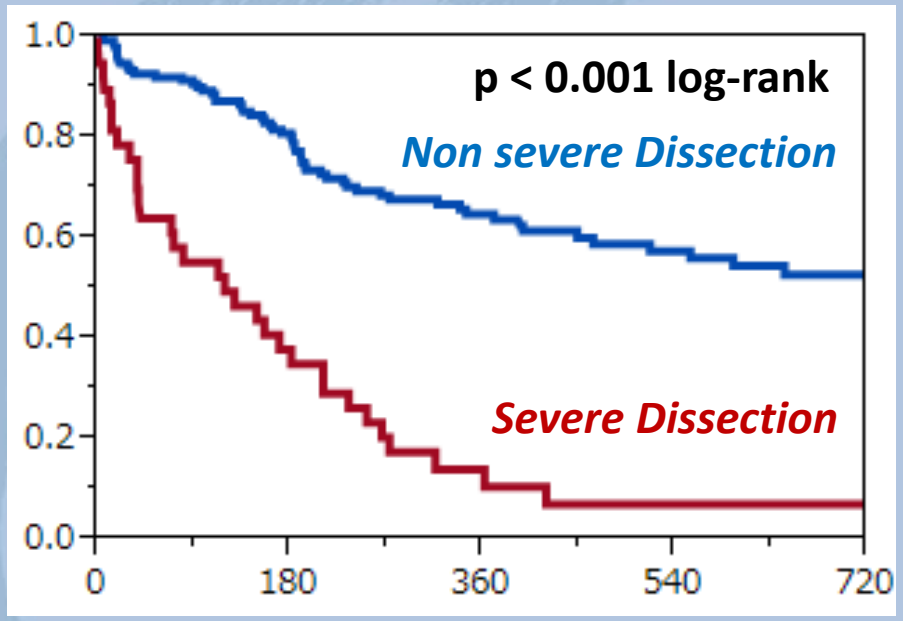


	HR [95% CI] (p value)
None	1.58 [0.79, 3.16] (p = 0.193)
A	1.00 (Ref)
B	**1.81** [0.88, 3.73] (p = 0.108)
C	**4.45** [1.22, 16.2] (p = 0.024)
D	**6.37** [2.99, 13.6] (p< 0.001)
E	**22.9** [7.33, 71.6] (p< 0.001)
F	**297** [34.9, 2527] (p< 0.001)

Data are unadjusted hazard ratios for restenosis relative to type A dissection, obtained from the Cox regression model with mixed effects, in which inter-subject variability was treated as random effects. Error bars indicate 95% confidence intervals. *Statistical analysis was performed by R version 3.1.0 (R Core Team, Vienna, Austria).

Clinical Outcomes of Balloon Alone Procedure

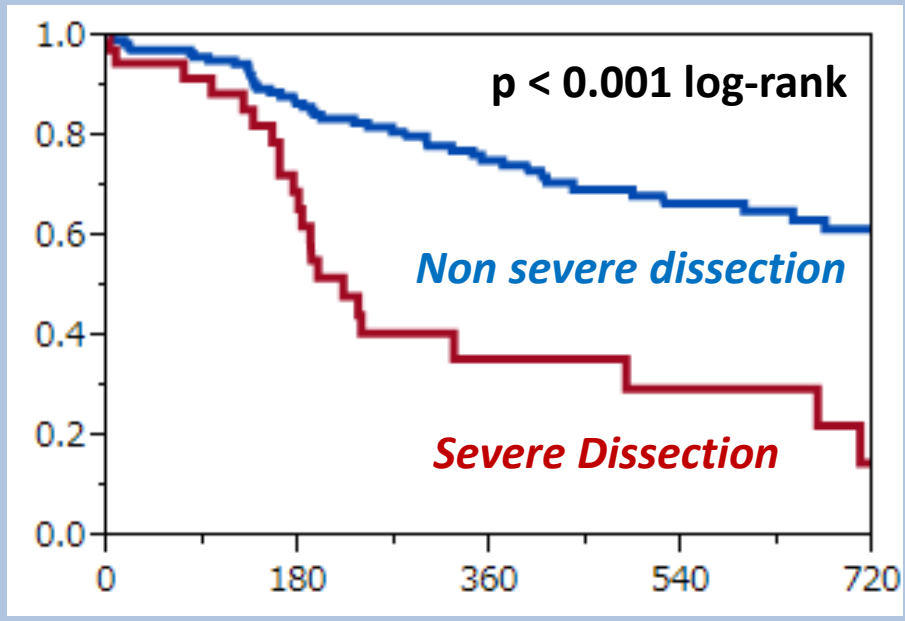
Primary Patency (PSVR<2.5)



Follow up period (days)

Days	0	180	360	540	720
at risks (Category-1)	155	113	67	41	30
%	100	81	65	58	53
at risks (Category-2)	38	14	5	2	2
%	100	38	11	7	7

Free from Clinically Driven TLR



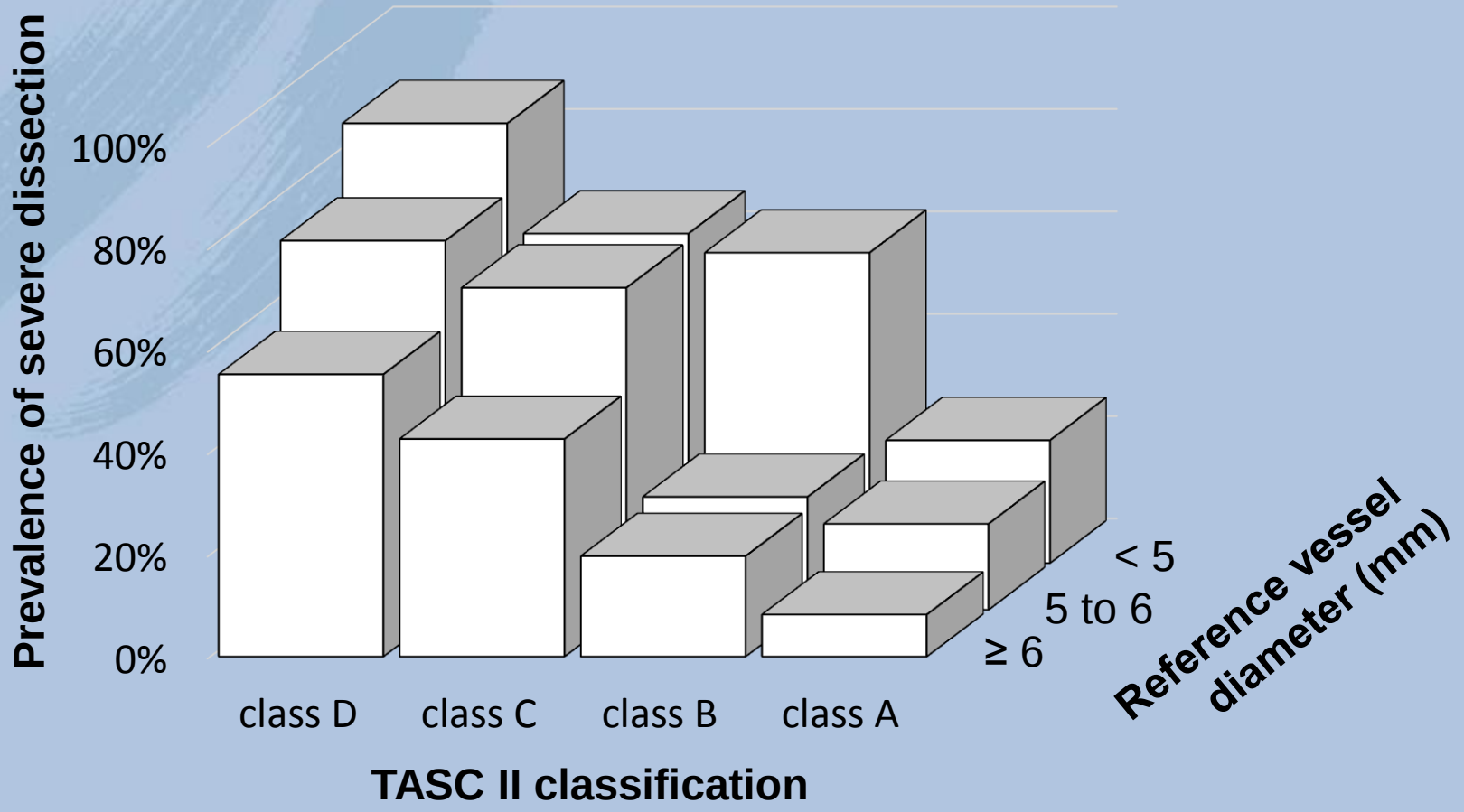
Follow up period (days)

Days	0	180	360	540	720
at risks (Category-1)	155	118	78	47	33
%	100	86	75	67	62
at risks (Category-2)	38	20	8	6	3
%	100	66	34	30	15

Predictive factors for Severe dissection - Multivariate analysis

	Severe Dissection (Type C,D and F)			
	Uni-	Multivariate		
	P value	HR	95%CI	P Value
Non Hemodialysis	0.0159	1.09	0.74-1.63	0.64
CTO	<0.0001	4.3	3.02-6.4	**<0.001***
TASC CD	<0.0001	2.1	1.46-3.06	**<0.001***
Reference vessel diameter<5mm	<0.0001	1.94	1.25-3.04	**0.0032***
Non Severe Calc	0.0308	1.38	0.95-2.02	0.08
Large inch system balloon (0.035inch)	0.0080	1.60	0.97-2.67	0.06
Vessel/balloon size<1.0	0.0004	1.28	0.76-2.15	0.34
IVUS usage	0.013	1.55	1.06-2.27	**0.021***

TASC CD and small vessel were strong predictor of severe dissection



Data are prevalence of severe dissection in subgroups, calculated from the generalized linear mixed model with logit-link function, in which inter-subject variability was treated as random effects. *Statistical analysis was performed by R version 3.1.0 (R Core Team, Vienna, Austria).

Conclusions

- Angiographic dissection pattern post balloon angioplasty in SFA lesions were analyzed
- **42%** of cases resulted in C, D, E and F type **severe dissection.**
- Primary patency rate and freedom from clinically driven TLR rate were significantly lower in severe dissection
- The predictive factors of severe dissection were found in **TASC(II) CD, small vessel and total occlusion.** Calcified lesion was not predictive factor.
- In case of severe dissection, **balloon alone procedure has the limitation** and stent implantation is recommended

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