Optimal PCI Strategy in True Coronary Bifurcation Lesion

Minimal Crush Technique with Optimal Kissing Ballooning

Balloon Size, Pressure, and Dilation Force

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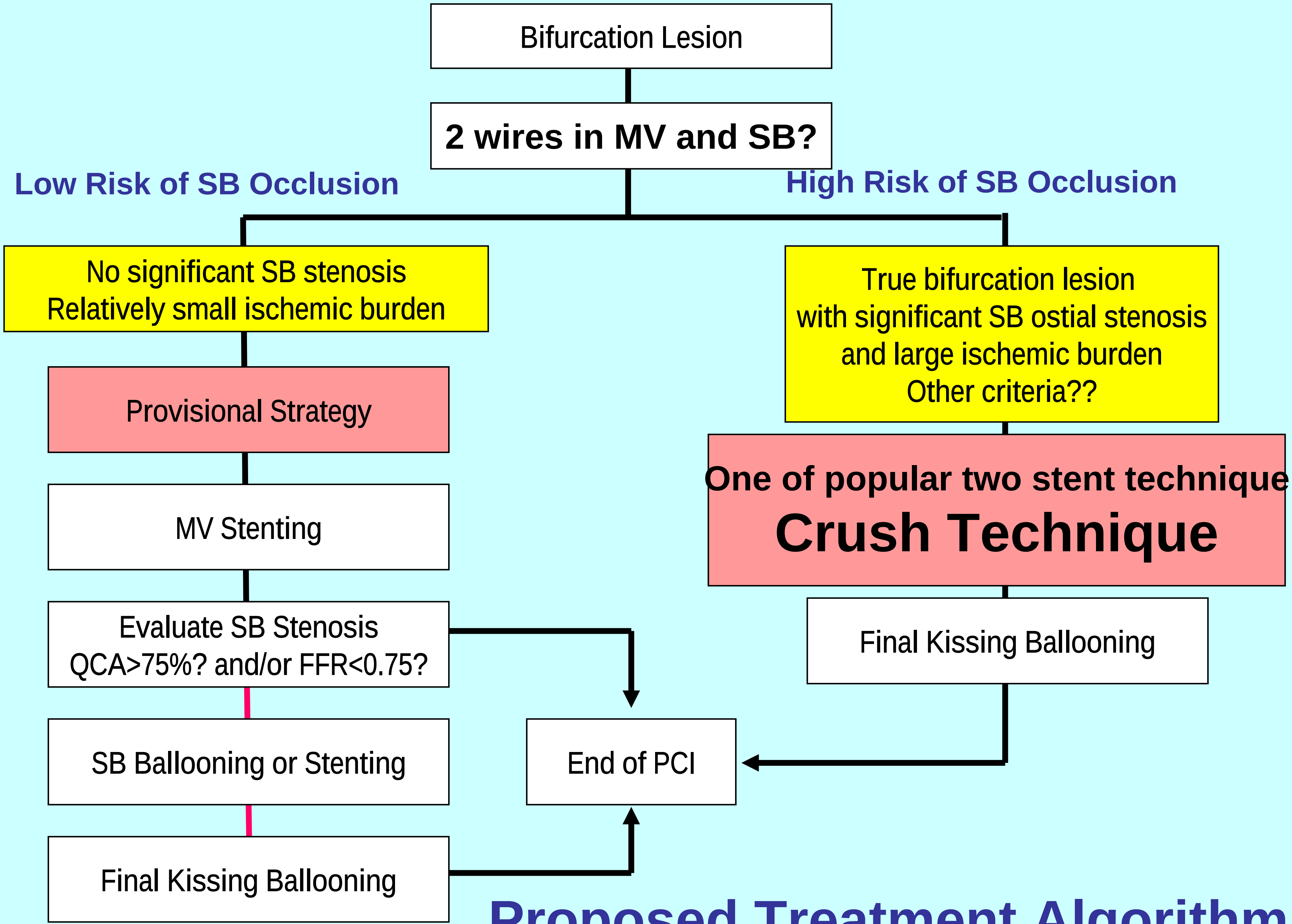
13th Angioplasty Summit TCT Asia Pacific
Seoul Korea, April 23-25, 2008

Bifurcation lesion and revascularization

- Bifurcation PCI is more than 15-20% of revascularization procedures, and increasing with use of DES …

- Bifurcation PCI remains a challenge in terms of procedural success rate as well as long term MACE, especially restenosis in SB ostium.

- However, previous studies are often small scale and display methodological flaws and other shortcomings such as inaccurate designation of lesions, heterogeneity, and inadequate description of techniques implemented.



Proposed Treatment Algorithm

Technical issues in crush technique
How to improve clinical outcome of two stent technique

- Attain consistent and definite DES coverage of SB ostium with minimal length of multiple overlapped stent layers
- Avoid stent distortion
- <u>Acquisition of optimal lumen area at SB ostium and excellent apposition of DES with SB wall</u>

Impact of FKB on SB restenosis in crush technique

SES(n=130)/PES(n=101); 9 month follow-up

	Kissing Balloon(94)	No Kissing Balloon(92)	P value
Main Vessel			
Late lumen loss	0.26 ± 0.65	0.35 ± 0.64	0.3
Restenosis rate	6.4%	12.0%	0.2
Side branch			
Late lumen loss	0.24 ± 0.50	0.58 ± 0.77	< 0.001
Restenosis rate	9.6%	41.3%	< 0.000001

A Hoye, A Colombo, et al. J Am Coll Cardiol 2006;47:1949-58

Minimal Crushing Technique with Final Kissing Ballooning - Immediate and 8 months follow up results-

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Study Population

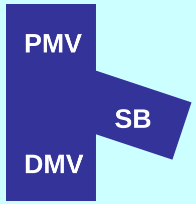
From July 2006 to July 2007

MV and SB Diameter Stenosis >50% within 5mm to carina on visual estimation
SB Vessel Size>2.25mm, treated with CYPER stent

56 bifurcation lesions of 51 patients	N = 51
Age (years)	61.5 ± 10.5
Male	32 (63%)
Clinical Diagnosis	
Stable angina	6 (11.8%)
Unstable angina	40 (78.4%)
STEMI / NSTEMI	5 (9.8%)
LV EF (%)	64.6 ± 7.6

Characteristics of Bifurcation Lesion

	N = 56
Medina Classification	
PMV DMV SB	
1 1 1	50 (89.2%)
0 1 1	5 (8.9%)
1 1 0	1(1.9%)
Location (MV/SB)	
LM/LCX	16 (28.6%)
LAD/Diagonal	34 (60.7%)
LCX/OM	5 (8.9%)
PDA/PLB	1 (1.8%)



Quantitative Angiography Findings

Variable	MV	SB	P value
Baseline			
Reference diameter (mm)	3.50 ± 0.58	2.79 ± 0.38	< 0.01
Lesion length (mm)	24.7 ± 6.4	19.4 ± 7.2	< 0.01
MLD (mm)	1.40 ± 0.65	0.97 ± 0.65	< 0.01
Diameter stenosis (%)	64.1 ± 13.2	65.9 ± 18.8	0.726
After Crushing			
MLD (mm)	2.80 ± 0.43	2.21 ± 0.49	< 0.01
Diameter stenosis (%)	19.0 ± 8.8	21.6 ± 11.0	0.126
After Final Kissing			
MLD (mm)	3.13 ± 0.39	2.54 ± 0.38	< 0.01
Diameter stenosis (%)	10.5 ± 5.5	10.4 ± 5.6	0.903

Quantitative Angiography Findings

Variable	After Crushing	After Kissing	P value
Main vessel			
Under side branch origin			
MLD (mm)	2.82 ± 0.43	3.15 ±0.37	< 0.01
Diameter stenosis (%)	19.2 ± 8.8	10.0 ± 5.4	< 0.01
Side branch ostium			
MLD (mm)	2.23 ± 0.49	2.55 ± 0.38	< 0.01
Diameter stenosis (%)	21.4 ± 10.8	10.1 ± 5.5	< 0.01

8 month Angiographic Follow-Up (n=47)

Variable	Post-PCI	Follow-up	P value
Main vessel			
Lesion			
MLD (mm)	3.12 ± 0.36	2.87 ± 0.41	0.000
Diameter stenosis (%)	9.41 ± 4.43	15.03 ± 8.46	0.000
Late loss		0.24 ± 0.39	
Under side branch origin			
MLD (mm)	3.11 ± 0.36	2.92 ± 0.34	0.000
Diameter stenosis (%)	9.45 ± 4.37	15.12 ± 8.32	0.000
Late loss		0.19 ± 0.31	
Side branch-Ostium			
MLD (mm)	2.49 ± 0.42	2.06 ± 0.59	0.000
Diameter stenosis (%)	11.63 ± 7.25	25.39 ± 21.25	0.000
Late loss		0.44 ± 0.67	

Procedural Data and Complications

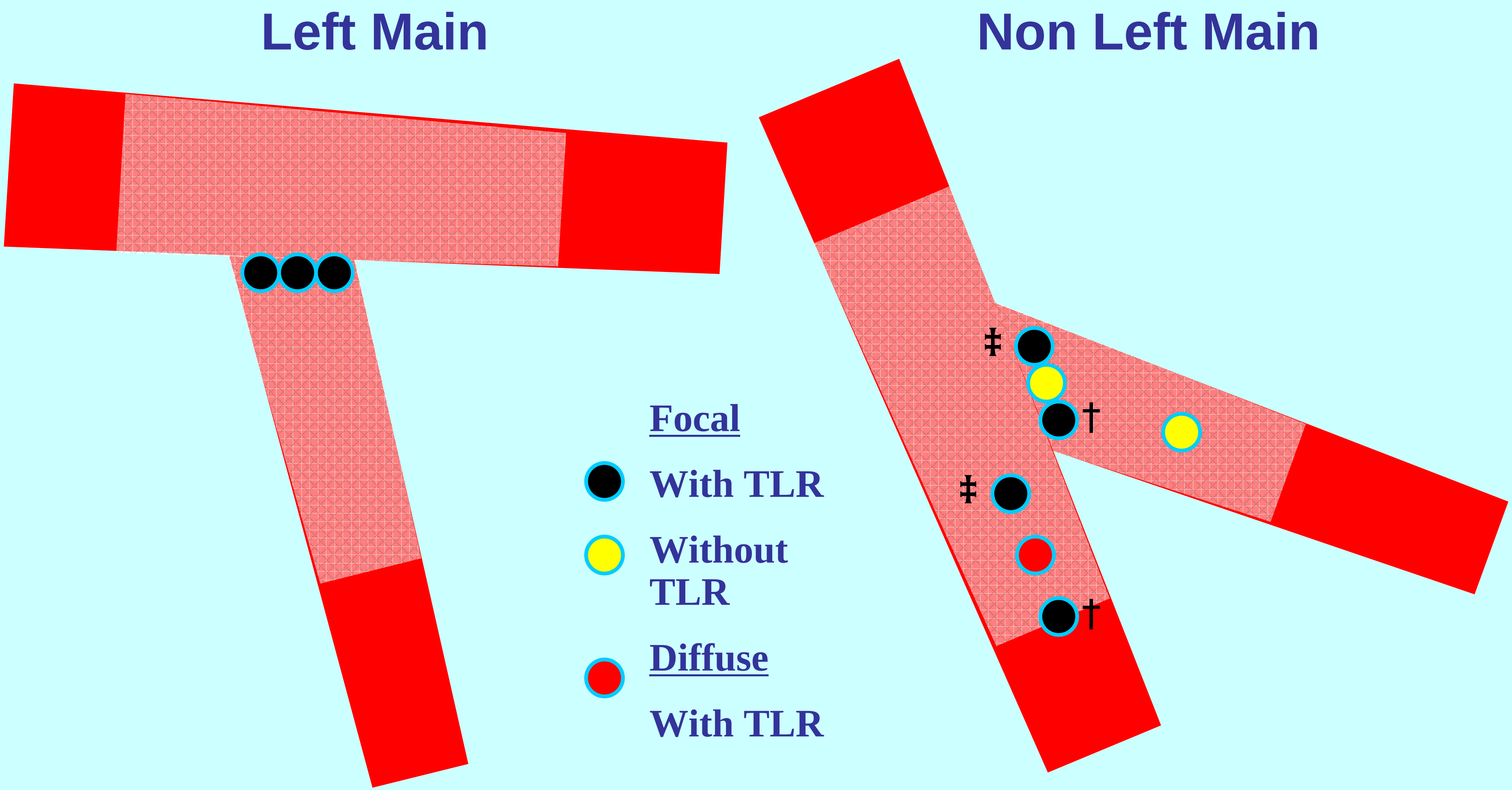
	(%)
DES coverage of SB ostium	54 (96.4%)*
Final kissing ballooning	54 (96.4%)
SB wire recross failure	0 (0.0%)
SB balloon recross failure	2 (3.6%)
MV complication	
Minor Dissection	2 (3.6%)
Transient slow flow	3 (5.4%)
SB complication	0 (0.0%)
CK-MB >x3 of upper normal value	9/51 (17.6%)

* IVUS and/or Angiographic Stent View

Follow-Up Results: Interim Outcomes

	(%)
Mean follow-up periods	7.6 ± 2.9 month
Major adverse clinical events	6 (11.8%)
Death	0
Non fatal myocardial infarction	0
Repeat revascularization	6 (11.8%)
SB ostium	5
MV non-bifurcation site	3
Stent thrombosis	1 (1.9%)
Cerebrovascular accident	0
8 month F/U coronary angiography	44/51 (86.3%)

Restenosis of stented bifurcation

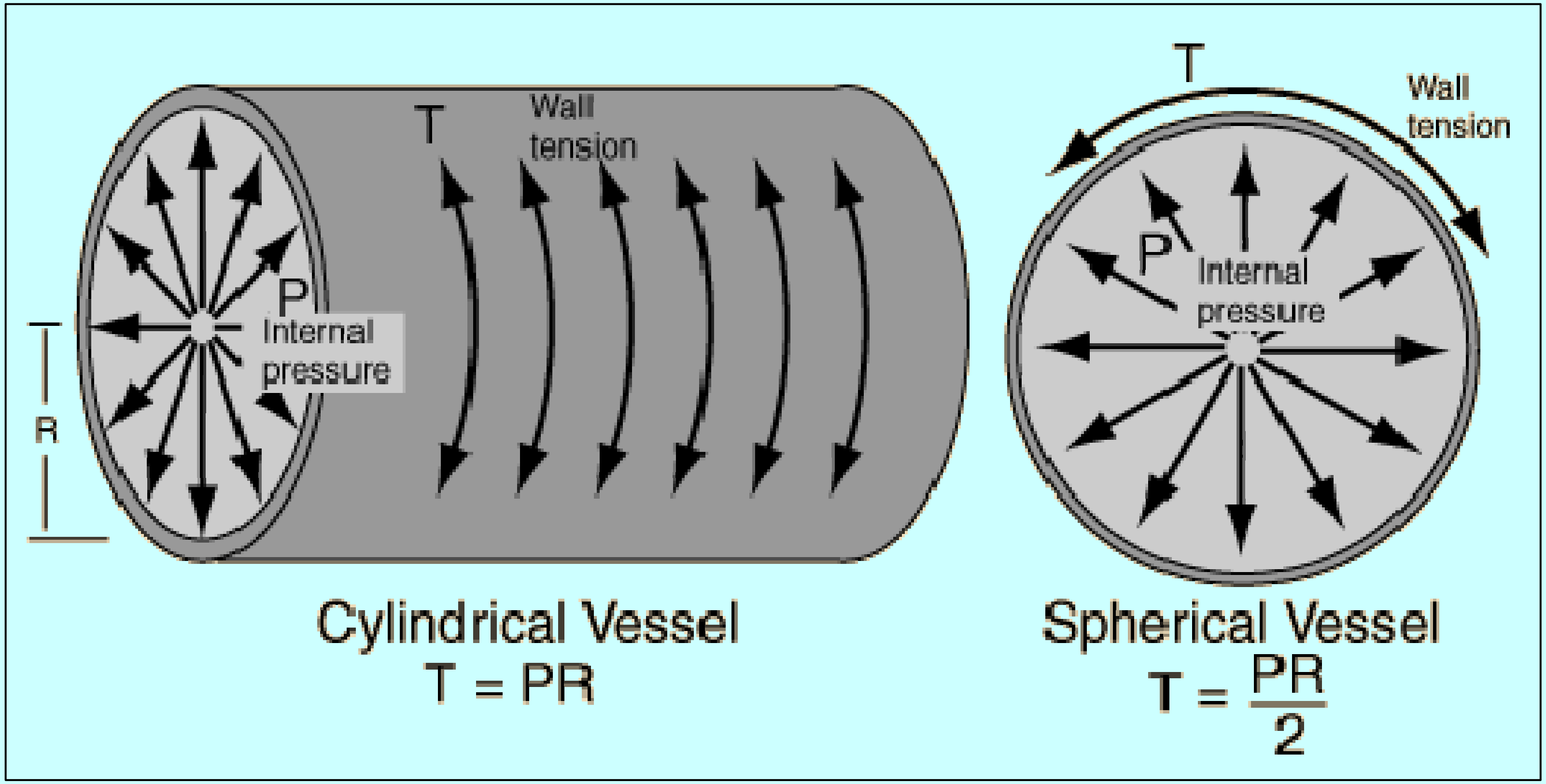


TLR: Left Main: 3/16(18.7%), Non Left Main 3/35 (8.6%)

60%(6/10) of restenosis occurred in SB ostium

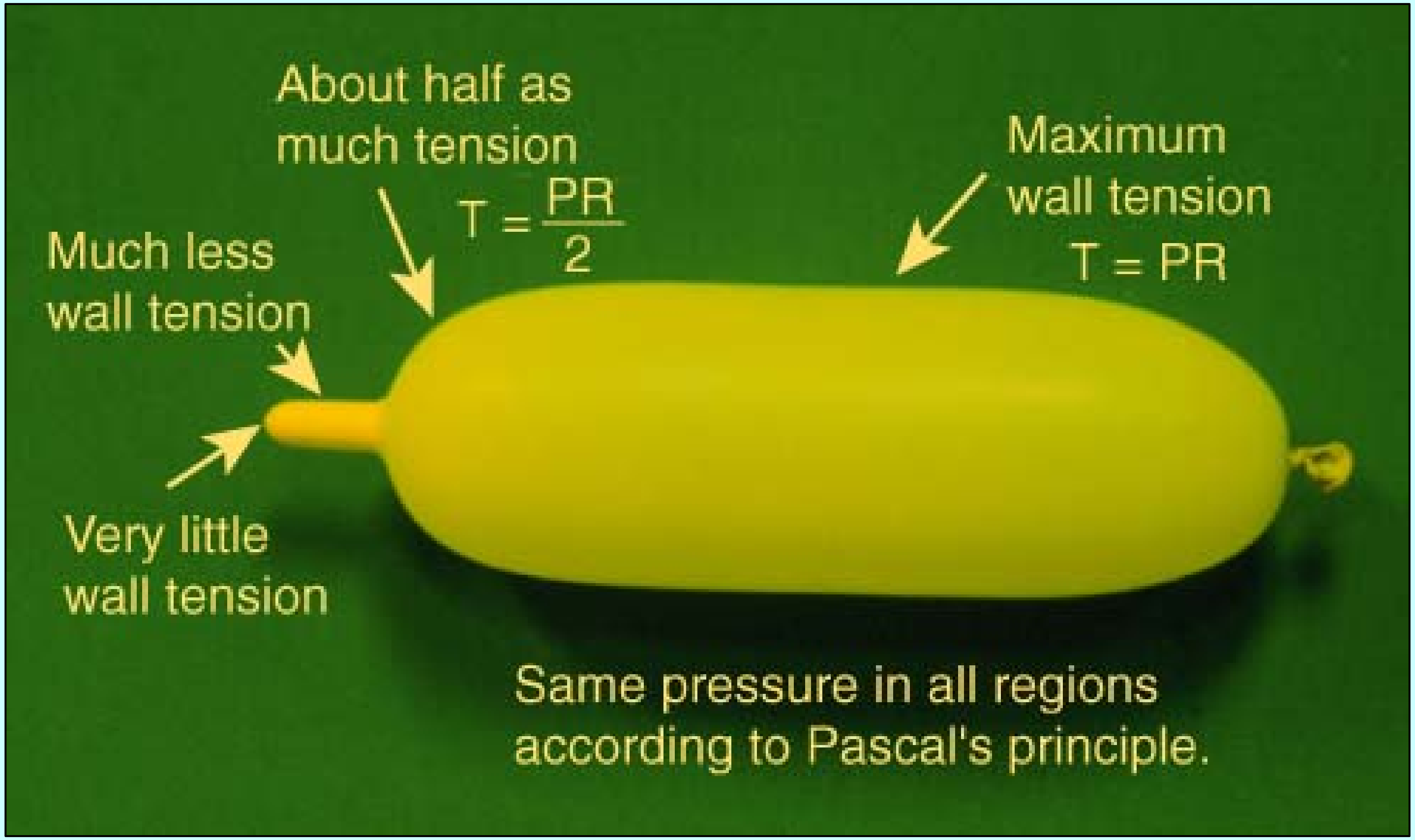
Can we improve the performance of final kissing ballooning in crush technique?

LaPlace's law



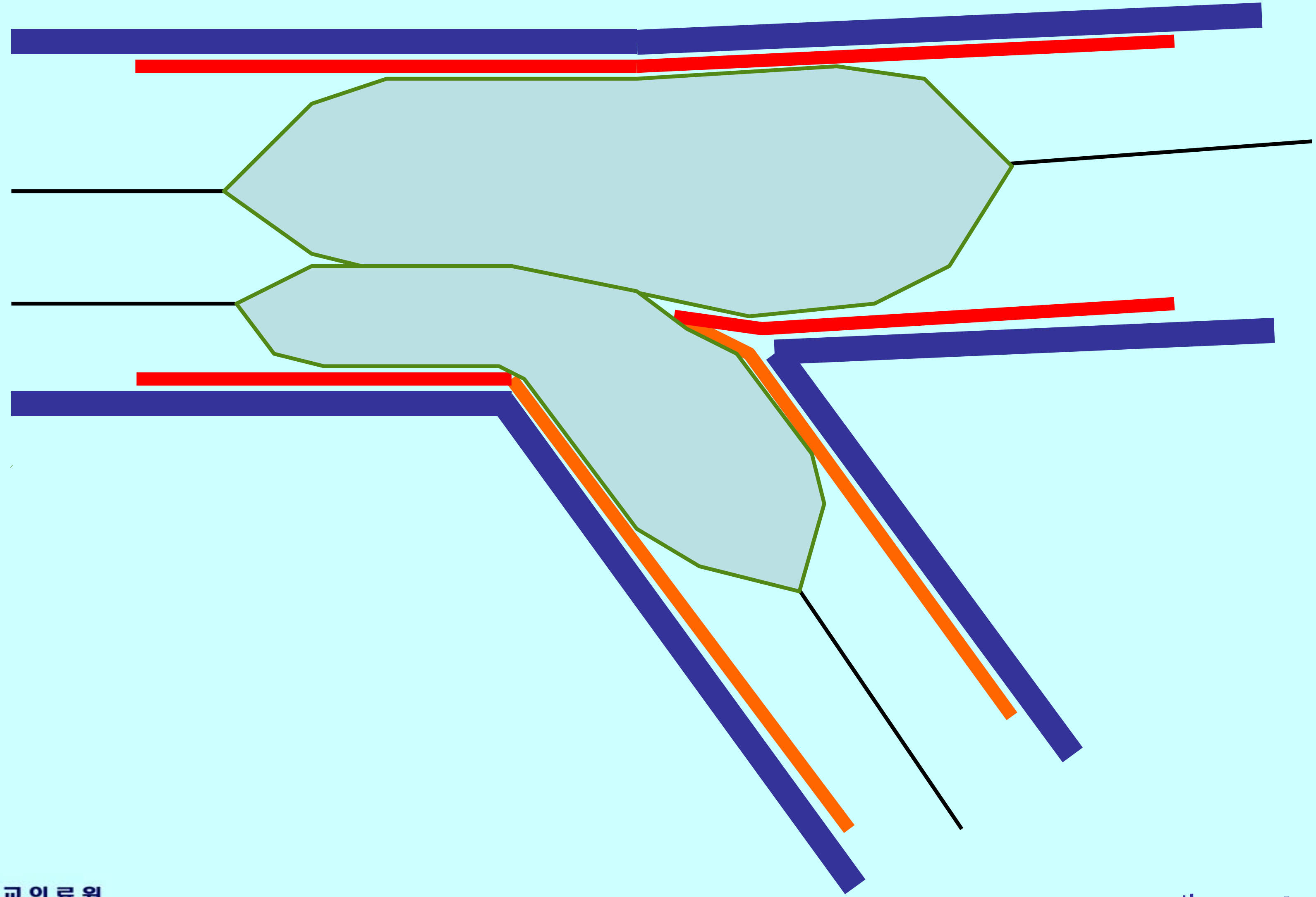
The larger the vessel radius, the larger the wall tension required to withstand a given internal fluid pressure. For a given vessel radius and internal pressure, a spherical vessel will have half the wall tension of a cylindrical vessel.

Pascal's principle and LaPlace's law



Pascal's principle requires that the pressure is everywhere the same inside the balloon at equilibrium. But there are great differences in wall tension on different parts of the balloon. The variation is described by Laplace's Law.

Mechanism of SB osteal lumen enlargement during kissing ballooning



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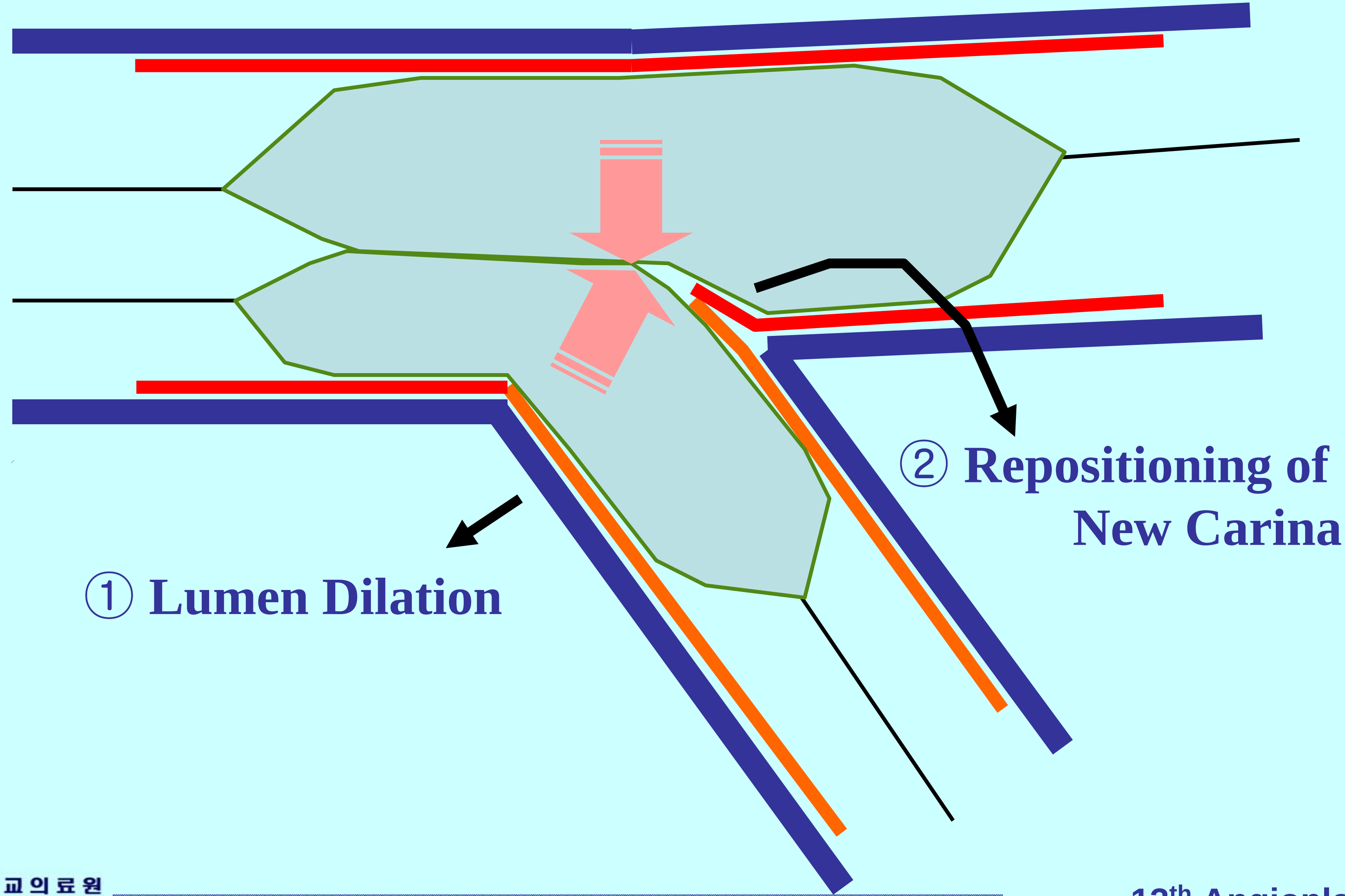
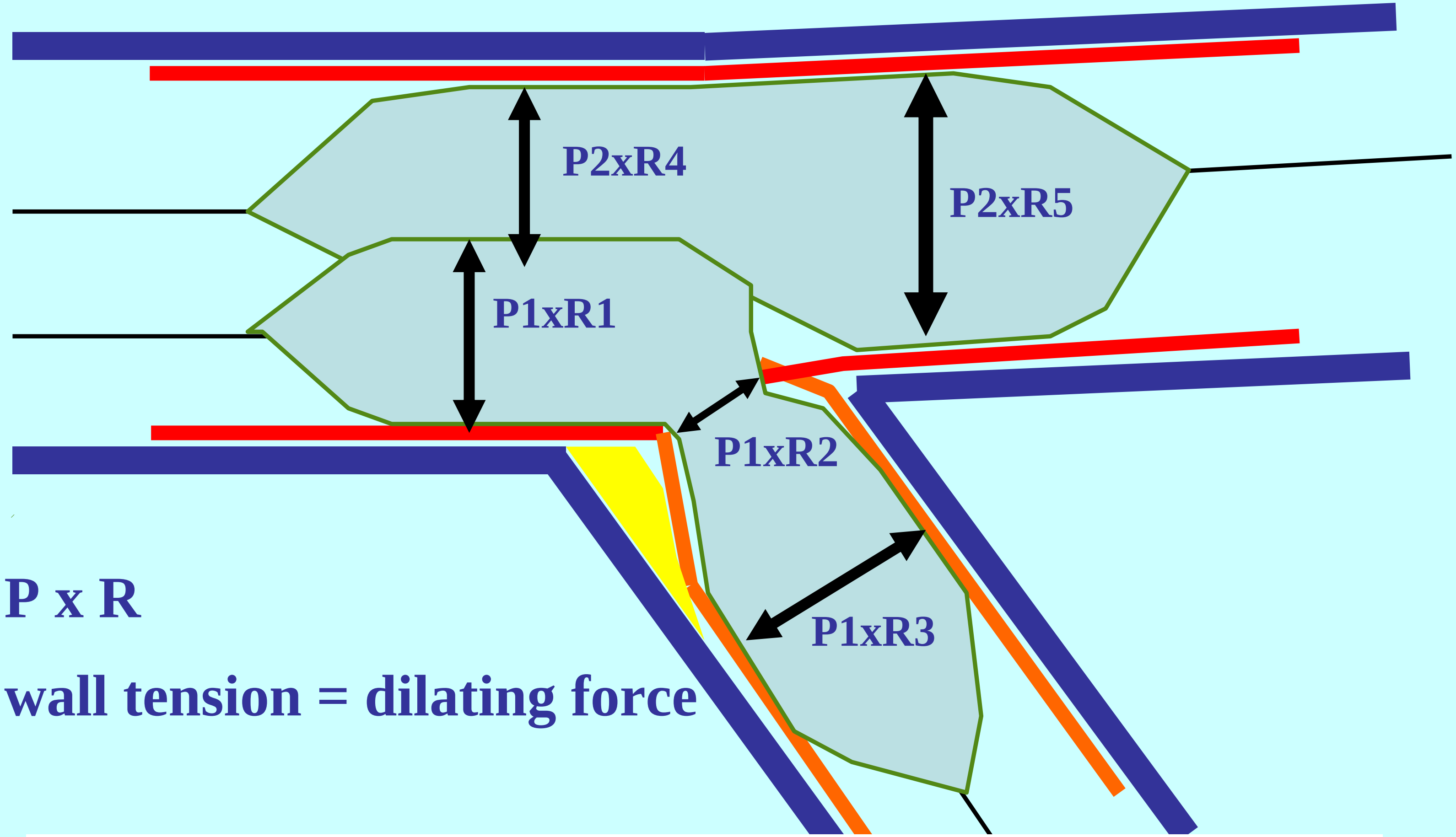


Inflation pressure, diameter, and dilating force

Importance of lesion preparation/predilation



F = P x R

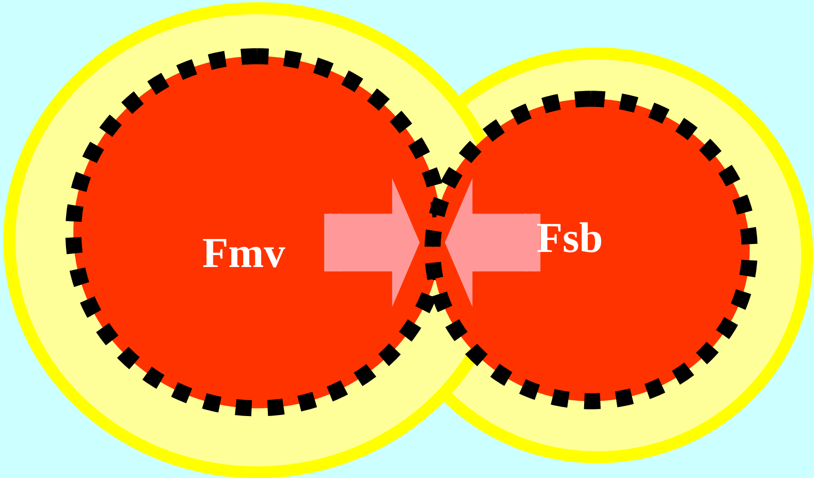
F = wall tension = dilating force

Pascal's principle requires that the pressure is everywhere the same inside the balloon at equilibrium. But there are great differences in wall tension on different parts of the balloon. The variation is described by Laplace's Law.

What we should consider during kissing ballooning after crushing

- Before Crushing
  - Lesion preparation and modification
- After Crushing
  - Separate high pressure dilation of MV and SB
  - Maintain same dilating force during kissing ballooning to obtain optimal stent expansion at SB ostium
    - Balloon size, compliance, and length
    - Inflation pressure

Final kissing ballooning
Balloon size, inflation pressure and dilation force



$$F = \frac{\text{Pressure x Diameter}}{\text{2 x Wall Thickness}}$$

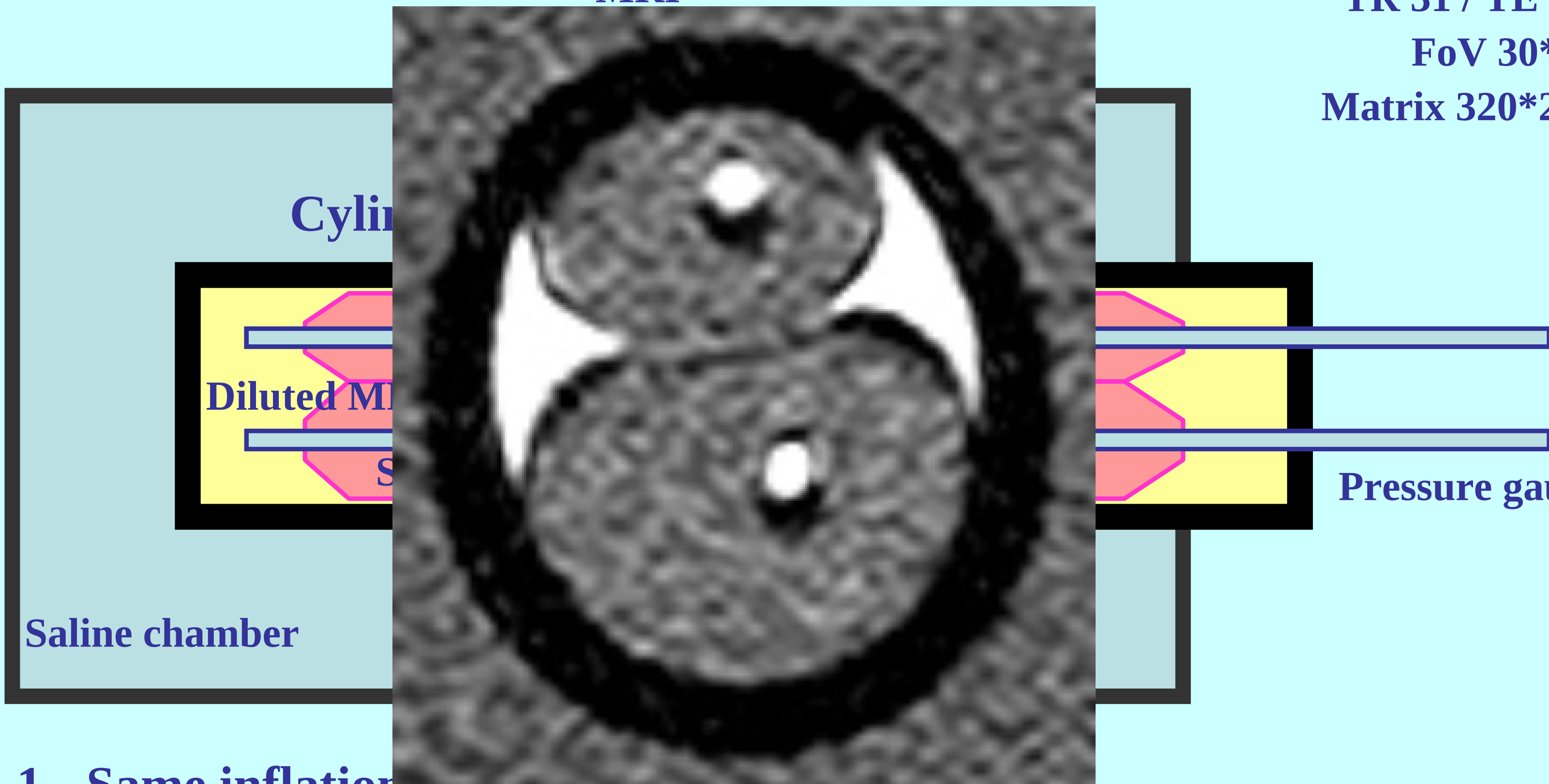
Fmv = Fsb

<u>Suggestions based on logical thinking</u>

- **Smaller lumen/balloon may need more higher inflation pressure to equalize dilation force**
- **Should consider compliance and length of balloon**
- **Acquisition of optimal lumen of MV and SB ostium before final kissing balloon is very important especially in hard/calcified lesion and heavy plaque burden**

In vitro observation
Balloon size, pressure, and dilating force

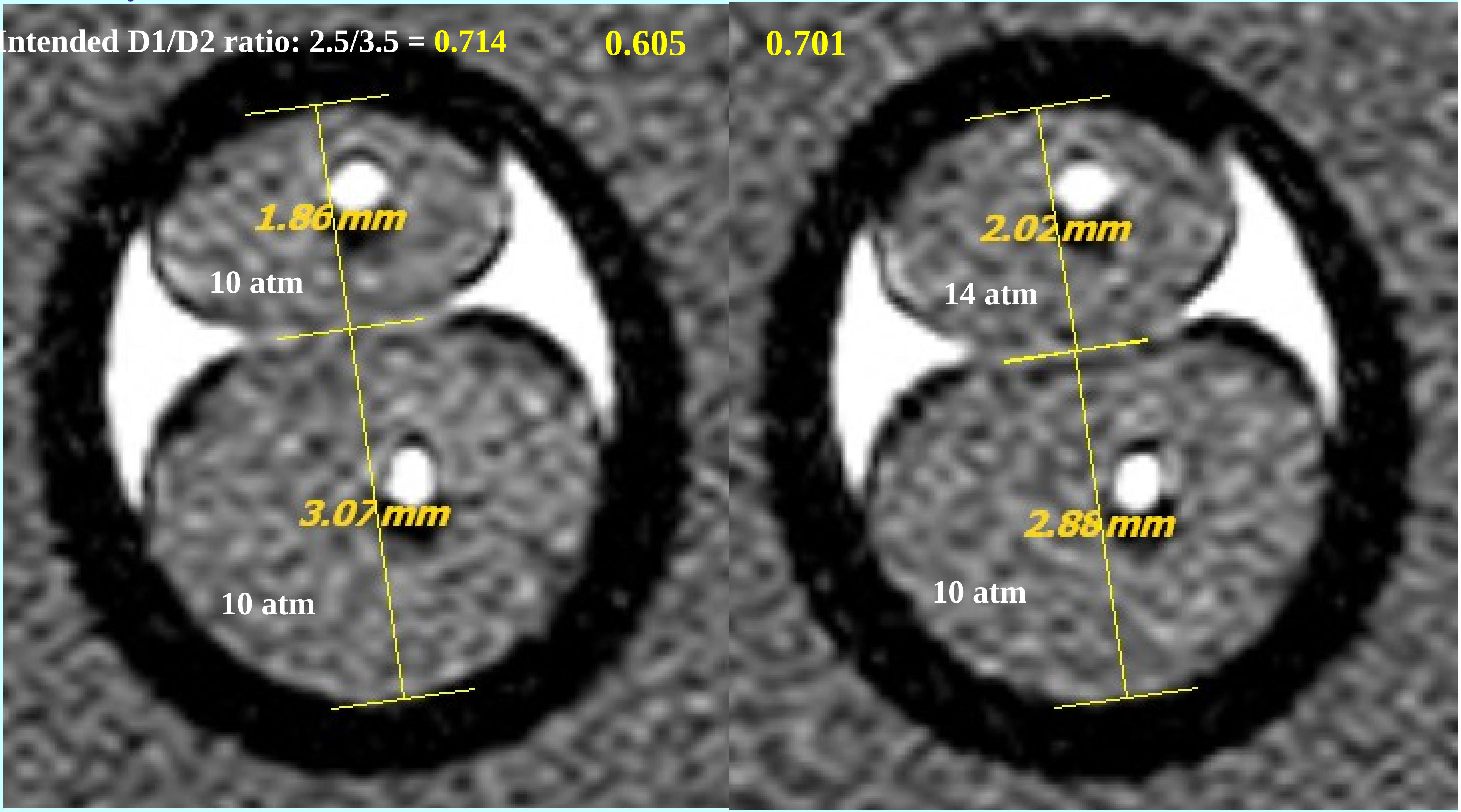
Philips Achieva 3.0T
Setting: 3D Fast Turbo Echo
TR 31 / TE 9.2
FoV 30*30
Matrix 320*258



1. Same inflation pressure: 10 atm each
2. Same dilating force: 14 x 2.5 atm.cm, 10 x 3.5 atm.cm

In vitro observation
Balloon size, pressure, and dilating force

Thick Cylindrical Vessel Phantom

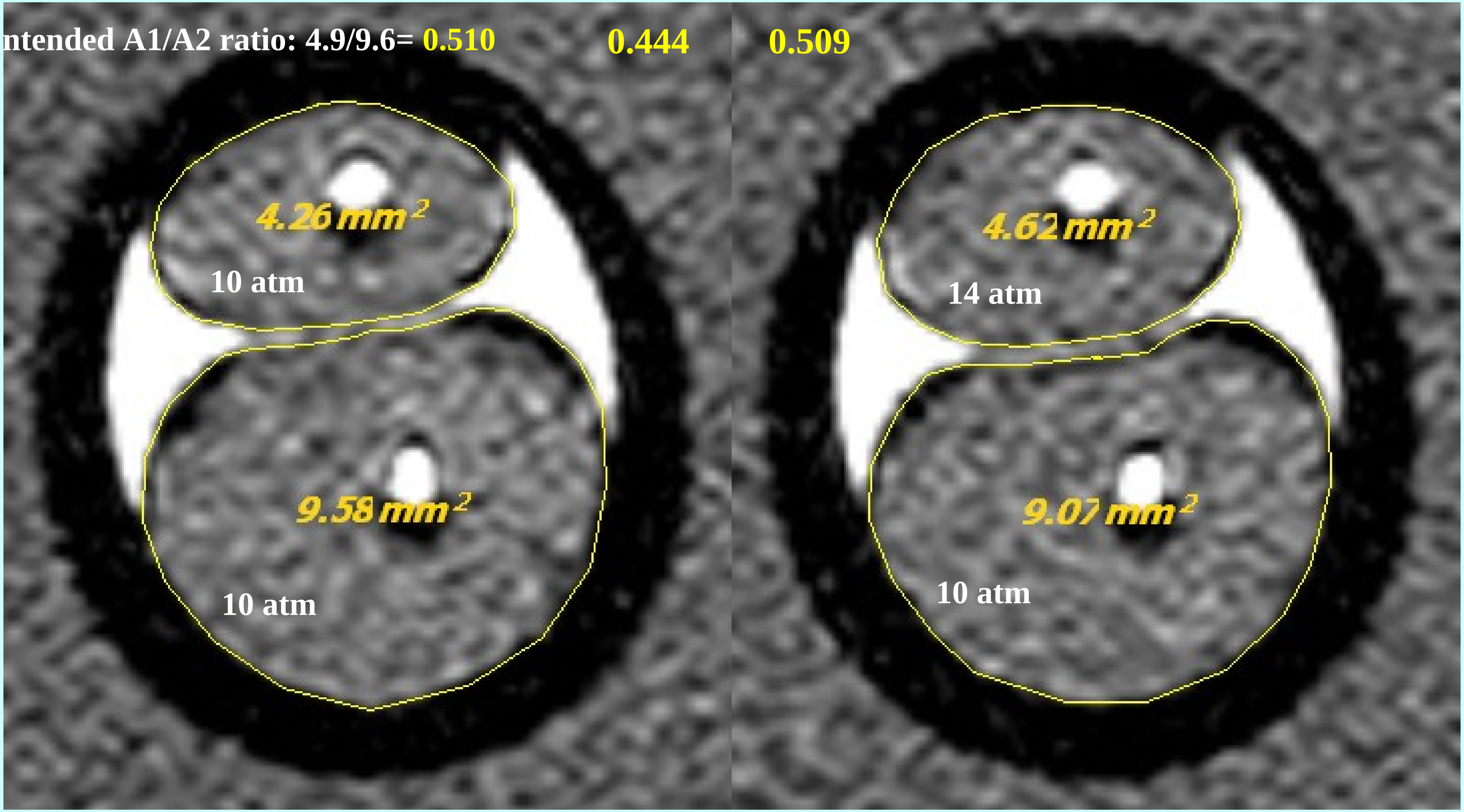


Same inflation pressure

Same dilating force

In vitro observation
Balloon size, pressure, and dilating force

Thick Cylindrical Vessel Phantom

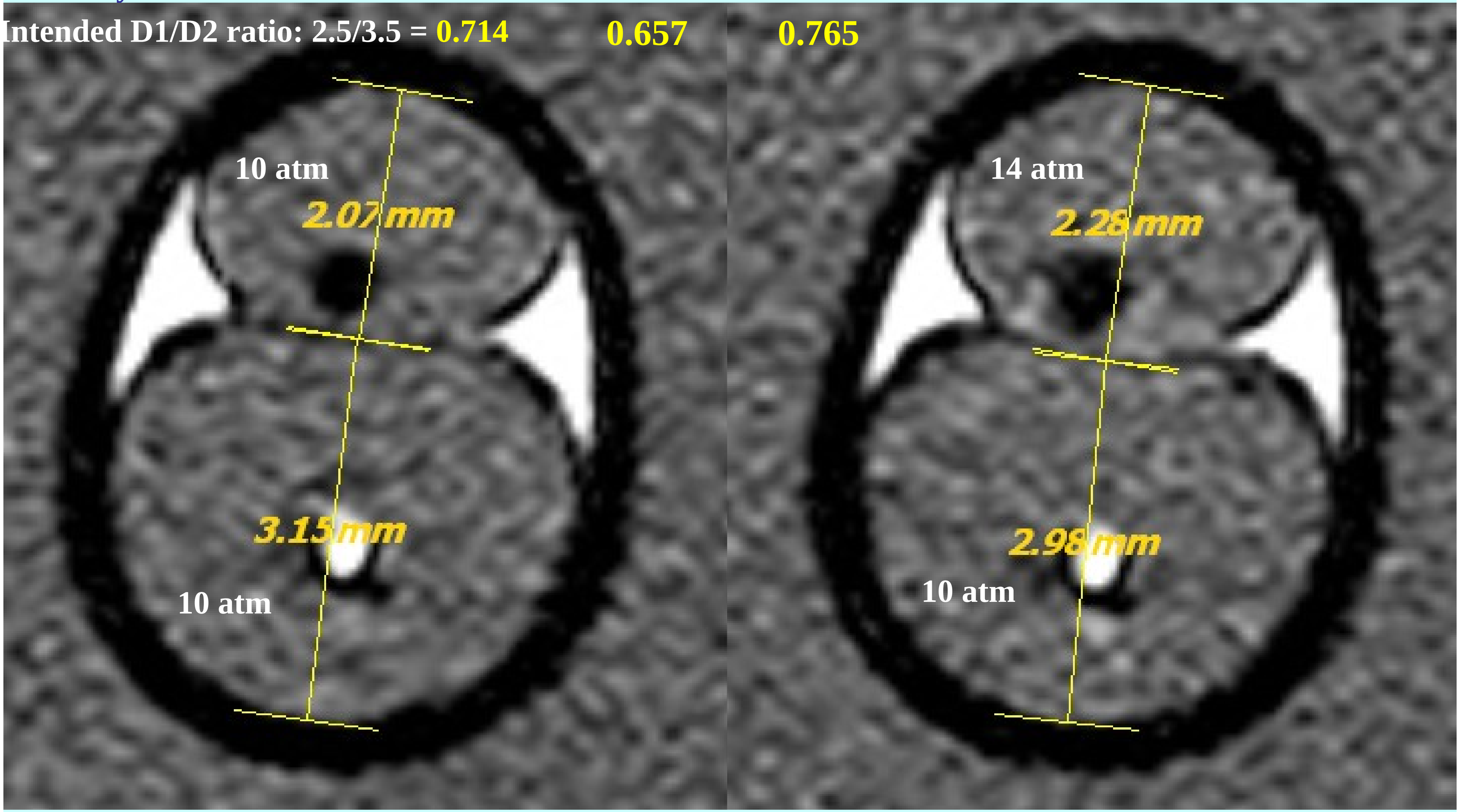


Same inflation pressure

Same dilating force

In vitro observation
Balloon size, pressure, and dilating force

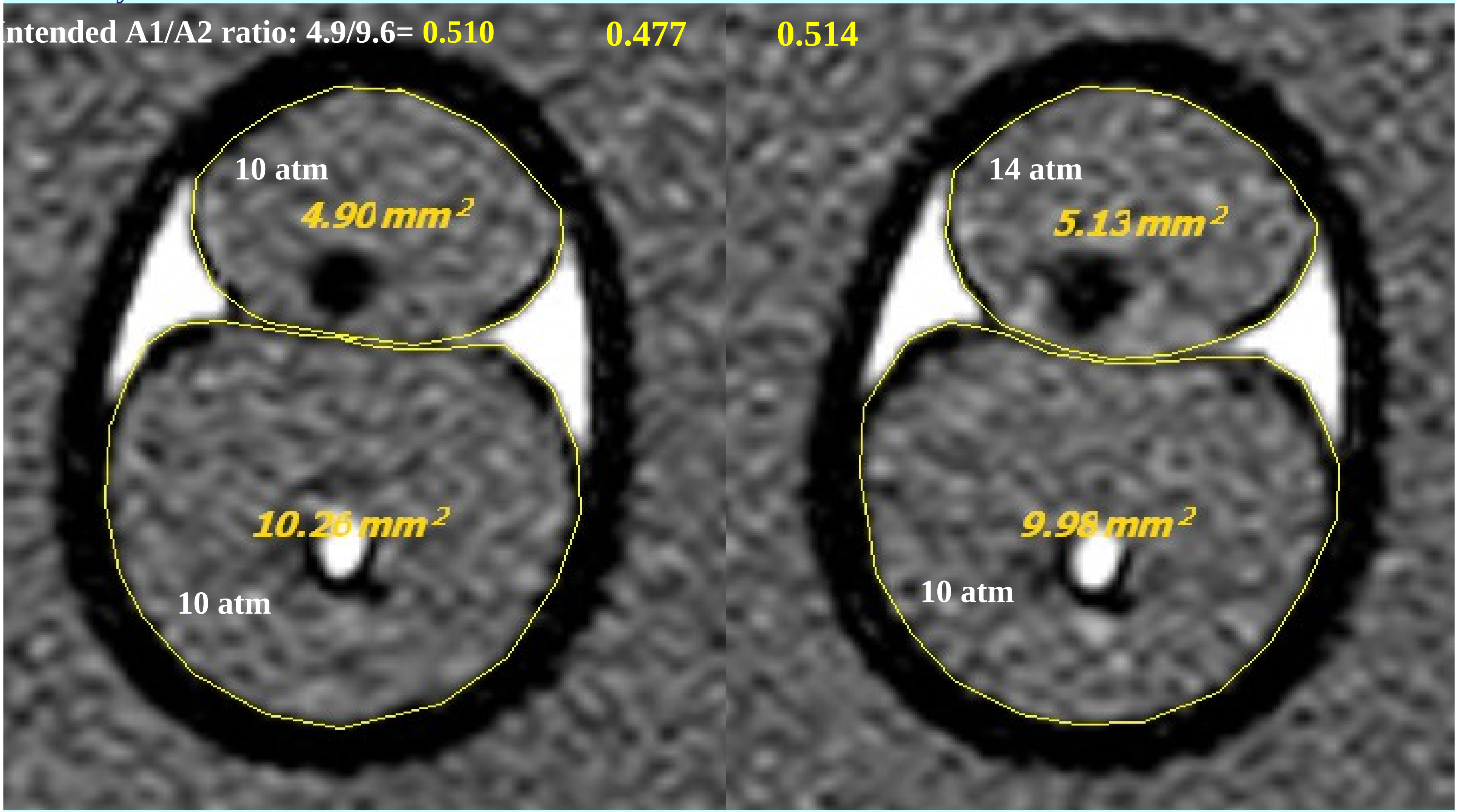
Thin Cylindrical Vessel Phantom



Same inflation pressure **Same dilating force**

In vitro observation
Balloon size, pressure, and dilating force

Thin Cylindrical Vessel Phantom



Same inflation pressure **Same dilating force**

In vivo observation

- 5 unstable angina patients with LAD/DIG bifurcation lesion, after informed consent
- Age: 59.6±12.8 yrs, LVEF: 63±13%
- Medina classification: 111:(4), 110:(1)
- Mini-crush technique with Cypher stents
- Kissing balloon dilation
  - 1st : Same inflation pressure (8-10 atm)
  - 2nd: Same dilating force (Pmv x Rmv = Psb x Rsb)
- IVUS pullback in both LAD and DIG after each kissing ballooning

In vivo observation: pre-PCI QCA

Variable	
Main Vessel	
Reference vessel diameter (mm)	3.65 ±0.07
MLD (mm)	0.63 ± 0.43
Diameter stenosis (%)	82.27 ± 11.72
Under side branch origin	
MLD (mm)	1.07 ± 0.55
Diameter stenosis (%)	70.09 ± 15.61
Side Branch	
Reference vessel diameter (mm)	2.64 ±0.06
MLD (mm)	0.59 ± 0.28
Diameter stenosis (%)	77.21 ± 10.54
Ostium	
MLD (mm)	1.00 ± 0.75
Diameter stenosis (%)	61.41 ± 29.26

In vivo observation: procedural data

	Main Vessel	Side Branch
Balloon predilatation		
Diameter (mm)	2.40±0.22	2.40±0.22
Pressure (atm)	12.8±1.1	10.0±4.9
Stent deployment		
Diameter (mm)	3.50±0.00	2.55±0.11
Length (mm)	23.0±3.5	19.0±4.2
Pressure (atm)	11.6±3.8	16.8±1.1
Kissing ballooning		
Diameter (mm)	3.20±0.27	2.45±0.27
Length (mm)	17.4±7.7	19.2±3.7
Pressure (atm)		
1st Equal Pressure	9.6±0.9	9.6±0.9
2nd Equal Dilating Force	9.6±0.9	13.2±1.1

In vivo observation: post-PCI QCA

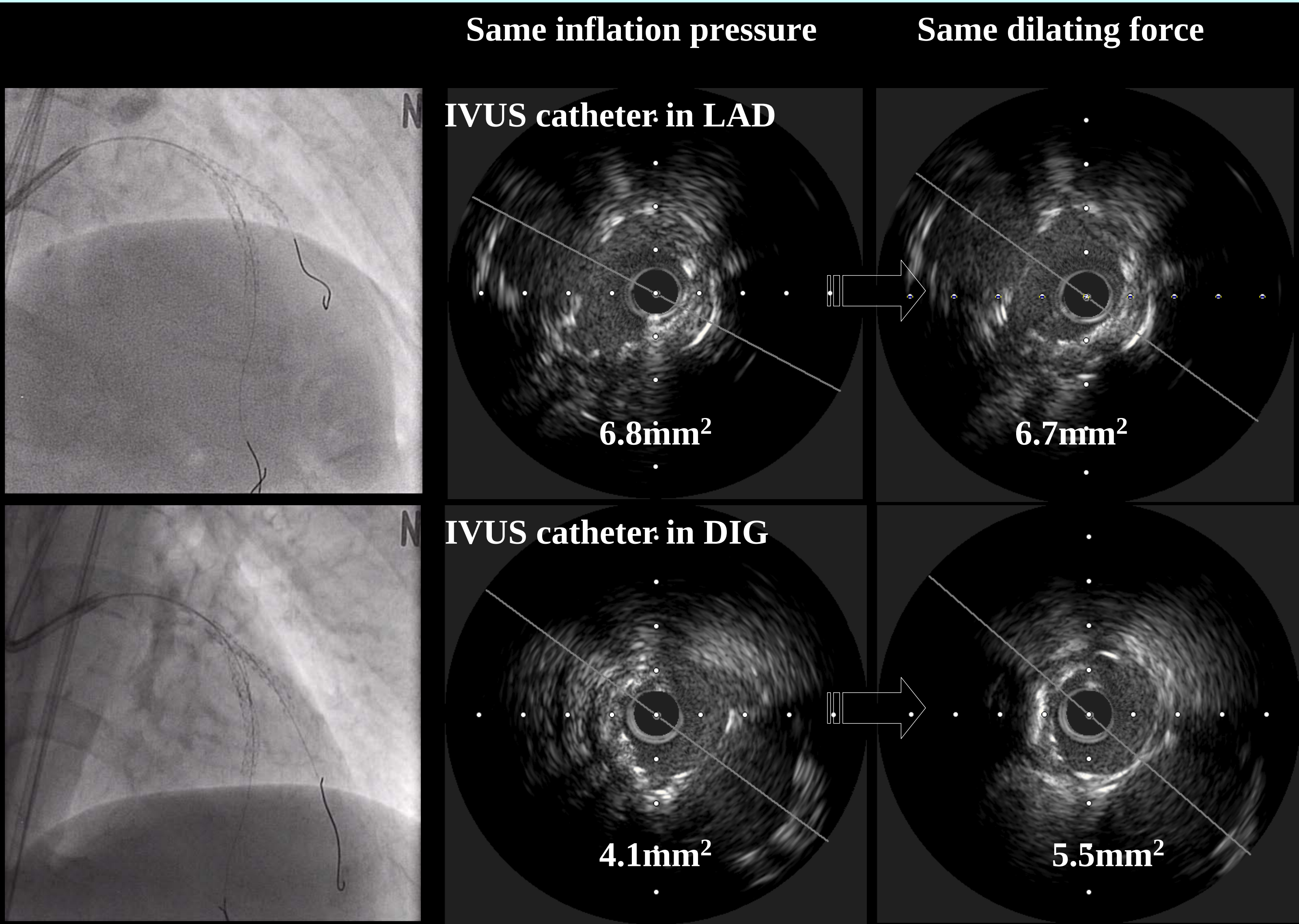
Variable	Same Pressure	Same Dilating Force	P value
Main Vessel			
MLD (mm)	3.02 ± 0.11	3.26 ± 0.09	0.049
Diameter stenosis (%)	16.98 ± 3.42	10.30 ± 2.72	0.028
Under side branch origin *			
MLD (mm)	3.02 ± 0.11	3.26 ± 0.09	0.049
Diameter stenosis (%)	16.98 ± 3.42	10.30 ± 2.72	0.028
Side Branch			
MLD (mm)	2.17 ± 0.19	2.32 ± 0.09	0.100
Diameter stenosis (%)	17.01 ± 7.07	12.72 ± 5.30	0.297
Ostium			
MLD (mm)	2.30 ± 0.21	2.41 ±0.16	0.069
Diameter stenosis (%)	15.26 ± 6.20	9.92 ± 4.57	0.043

* All 5 patients have the narrowest segment in MV under SB ostium.

In vivo observation: post-PCI IVUS

Variable	Same Pressure	Same Dilating Force	P value
Main Vessel			
Carina			
MSA (mm^2)	8.38±1.50	8.64±1.67	0.357
EEM CSA (mm^2)	15.86±3.57	15.76±3.57	0.828
Under bifurcation			
MSA (mm^2)	6.16±1.08	6.18±1.05	0.721
EEM CSA (mm^2)	11.88±1.79	11.88±2.37	1.000
Side branch ostium			
MSA (mm^2)	3.98±0.29	4.48±0.67	0.182
Delta Increase in MSA (mm^2)		0.50±0.69	

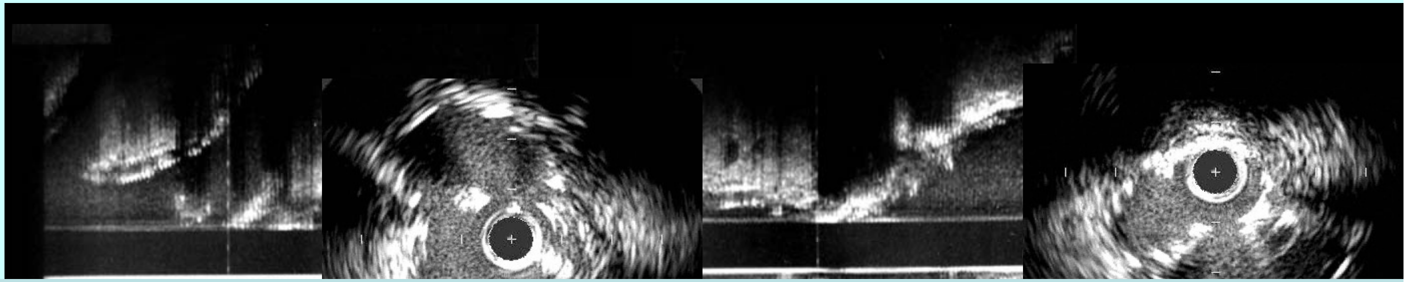
In vivo observation: Case



Final kissing balloon

Balloon size, length, compliance, inflation pressure, and dilating force

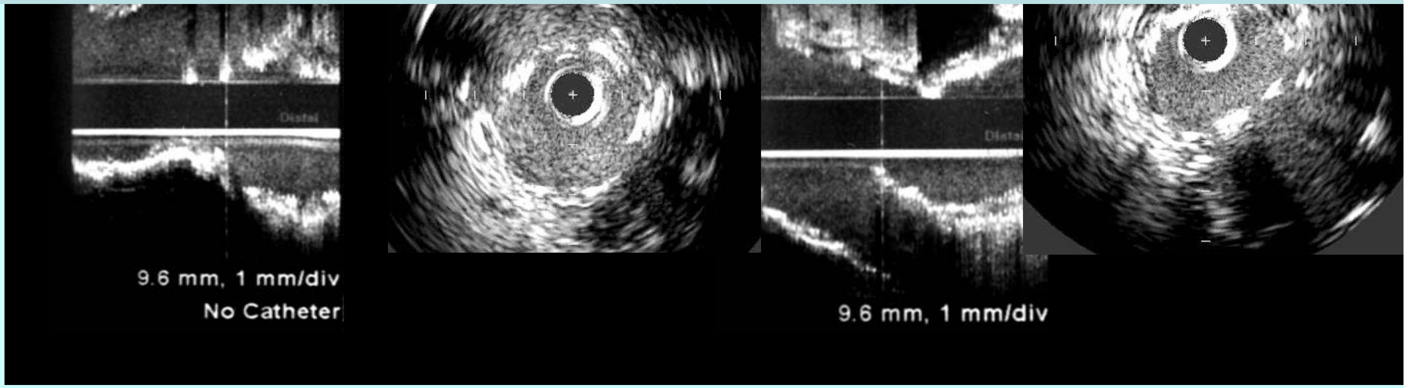
Kissing #1
LAD 3.0x20mm   8atm



❋ Further experiments should be necessary to clarify the requirements for optimal kissing balloon technique.

Kissing #2
LAD 3.0x20mm   14atm
DIG* 3.0x13mm   8atm

* non-compliant high pressure balloon



Conclusions

- To improve the performance of kissing ballooning after crushing …
  - Adequate lesion preparation before crushing
  - Appropriate balloon size and compliance
  - Separate high pressure dilation of MV and SB before kissing
  - Maintain same dilating force (based on LaPlace's law) during kissing
- Techniques and devices for bifurcation PCI is under developing and not standardized.
- We need more experimental studies and prospective randomized trials comparing well defined and refined techniques in well defined lesions which will provide optimal treatment algorithm and technique in patients with true bifurcation lesion.

Impact of elaborate techniques on clinical outcome
Mini-crush technique/Balloon crush

- 52 bifurcation lesions (45 consecutive patients)
- Minicrush with final kissing ballooning
- Procedural success: 100%
- Angiographic success: MV 96.1%, SB 98.1%

- Overall TLR: 12.2%
- Side branch stent thrombosis: 1(2.2%)
- 8 month angiographic F/U: 41/45 (93.3%)
- Restenosis: MV 12.2%, SB 2.0%

AR Galassi, A Colombo, et al. Catheter Cardiovasc Interv 69:976-983, 2007