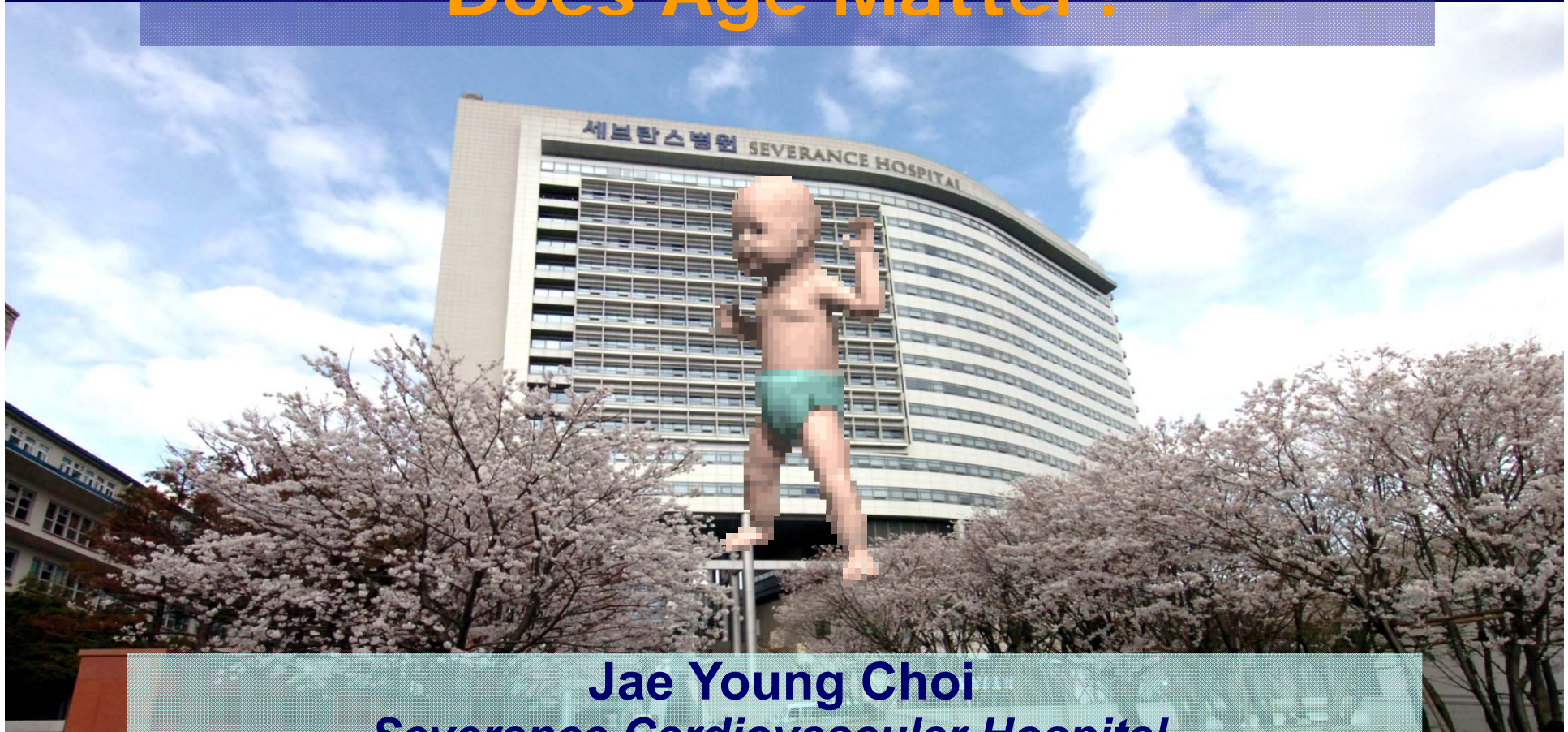




ANGIOPLASTY SUMMIT
TCTAP 2012

Transcatheter Closure of ASD: Does Age Matter?



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- Introduction -

- Transcatheter closure of secundum ASD has been accepted as an attractive option of standard Tx.
- There may be a substantial resistance against a clinical decision for device closure in either very young or old patients,
probably because of the paucity of data and/or lacking of individual experience in this extreme age group of patients.
 - *Is device closure safe and effective in very young or very old patients?*



ASD closure in small children

- Optimal timing of known ASD closure: 1~5yrs
- The need for early intervention in small children
 - ; special clinical setting for an early closure;**
 - Chronic lung disease in premature infants
 - Chr'some anomaly with compromised CPF
 - Recurrent resp. problem +/- airway anomaly

; secundun ASD may "outgrow"

→ *"suitable" ASD for device closure may be changed to an "unsuitable" ASD*

McMahon et al. Heart 2002, Tortoriello et al. Pediatr Cardiol 2002, Holzer R and Hijazi ZM. Curr Opin Cardiol 2004

→ **Timing of treatment in the era of device closure :
How small is too small? & How early is too early?**



What's been revealed so far?

- Surgery -

Surgical ASD closure in young children

- **1996 J Card Surgery, Mainwairung RD et al**
 - **5 of 6 infants; little or no benefit in symptom**

but contradictory results reported by
- **1981 Arch Dis Child, Bull C et al.**
 - **some of the infants c ASD requires early surgery**
- **2004 Asian Cardiovasc Thorac Ann, Parvathy U et al.**
 - **18pts < 2yrs; early surgery in symptomatic pts**
- **2005 JTCS, Lammers A et al. - 24 symptomatic infants**
 - **early surgery should be performed in symptomatic infants with compromised lungs**



What's been revealed so far?

- Device Closure -

Recent literatures for transcatheter ASD closure in young children

- 2003 JACC, Butera et al : 48pts < 5yrs
→ **100% closure without complication, Sx relieved**
- 2007 CCI, Cardenas et al. : 52pts < 15kg, 70% symptomatic infants
→ **device closure is a safe and effective alternative**
- 2007 JTCS, Diab et al : 15 infants, 11 percutaneous, 3 peratrial
(3.0~8.3kg, median 5.6kg, mean<5.5kg)
→ **device closure is a safe and effective alternative**
- 2008 PICS, Choi et al : 24 device vs 16 surgery < 10kg
→ **device closure is a safe and effective alternative, The advantage over surgery is valid in small children**
- 2011 CHD, Wood et al : 9 ASD infants c BPD (+ 6 other LR shunt dis.)
→ **device closure is a safe and effective**



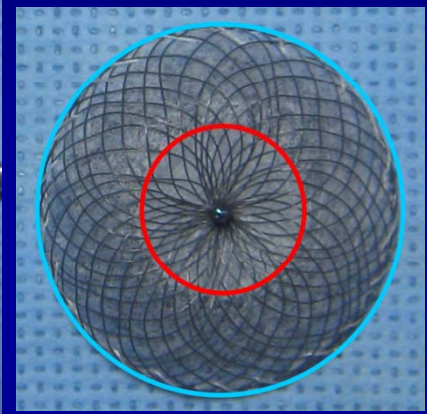
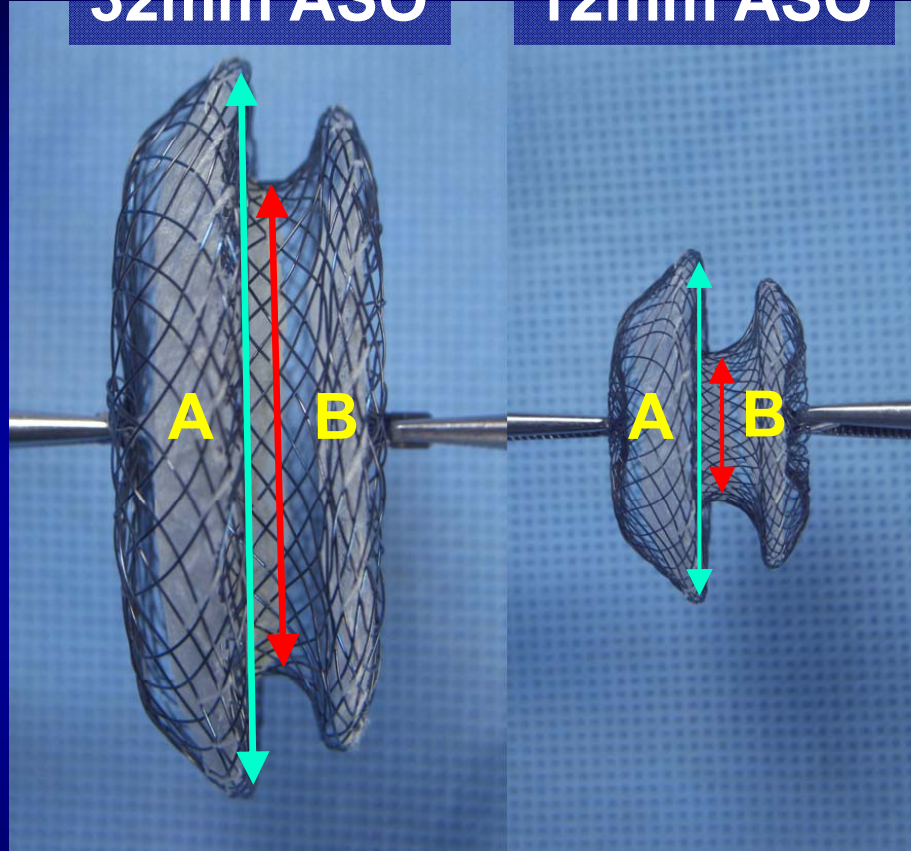
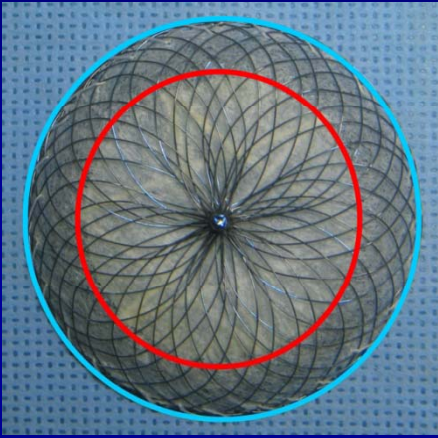
Problems encountered during the device closure in small children

- **Large delivery system / small vascular access**
→ *damage to vascular access*
- **Rigid coupling of device-delivery cable & relatively stiff delivery system**
→ *damage to the cardiac structure*
→ *difficulty in checking the proper device position*
- **Excessive rim width of atrial discs in small devices**
→ *device contact to adjacent structures, esp. mitral valve (potential abandonment of the procedure)*
→ *small total septal length preclude implantation of a larger device*
- **Small LA : insufficient space for opening of the LA disc**
- **Lack of long-term data in small children**



32mm ASO

12mm ASO



A/B = 1.5

A/B = 2.4

38mm ASO
A/B = 1.4

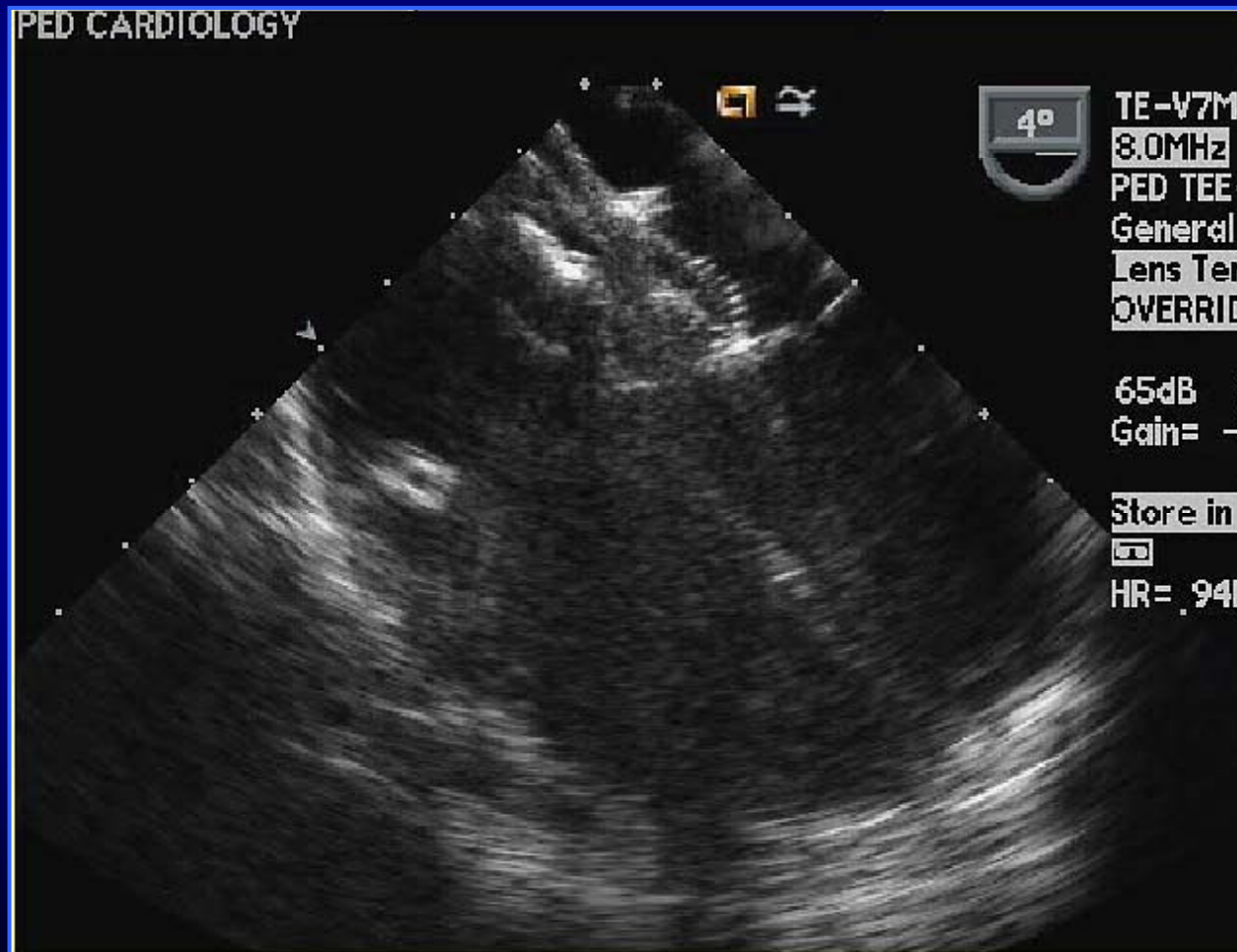


5mm ASO
A/B = 3.4



LA disc encroaching to MV :

- often $>5\text{mm}$ rim is not sufficient
- more common problem in small children !





Solutions for problems encountered during the device closure in small children

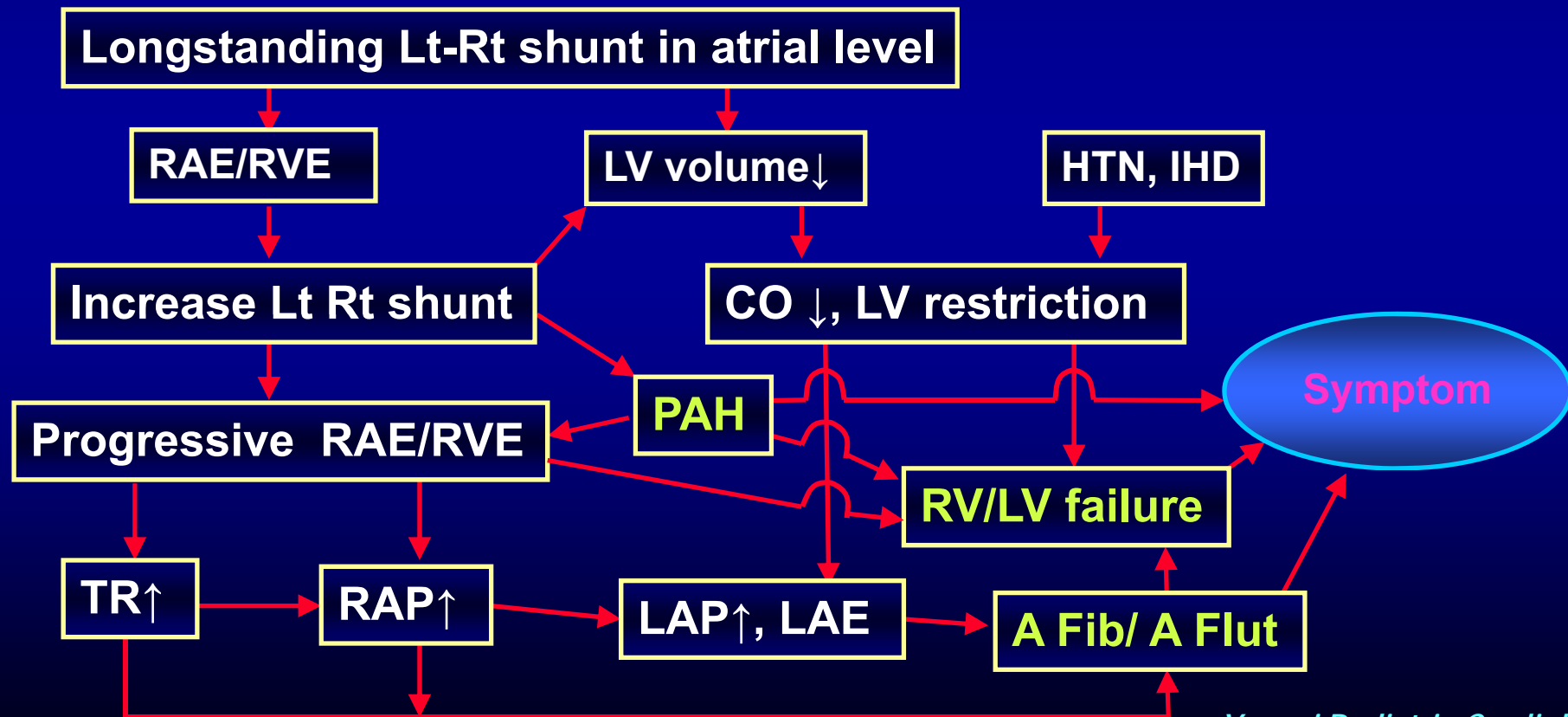
- **Damage to vascular access & cardiac structure**
: sophisticated technique & meticulous approach are needed
- **Excessive rim width of atrial discs in small devices**
: need further device modification
: “stopgap” technique
 - *choose a device acc. to the total septal length (=LA disc diameter)* *Amin Z. CCI 2006;68:778*
Fischer G et al. CCI 2009;73:949
- **Technical modifications such as BAT are also useful in small children** *Dalvi BV et al. CCI 2008;71:679*



- ASD closure in the elderly -

- little basis for **survival benefit**; lack of study in long-term base
- sufficient data for improvement of **symptom, exercise tolerance, dysrhythmia & QOL**, + **reverse remodelling** of heart

Pathophysiology





What's been revealed so far?

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- Surgery -

Literatures for surgical ASD closure in the elderly

- 1996 *ATS, Shibata Y et al.* : 49pts > 50yrs
 - **satisfactory long-term results, improves QOL: ASD repair in elderly pts without severe PVD should not be delayed**
- 1997 *Jpn Heart J, Miyaji K et al.* : comparing 40~69yrs vs >70yrs
 - **functional class & TR improved. to prevent progressive TV annular dilatation, surgical closure should be performed.**
- 2001 *JACC, Attie F et al.* : 521 pts > 40yrs, randomized study
 - **anatomic closure is superior to medical tx in preventing major event. Operation must be performed as soon as possible, even if symptom seems to be minimal.**
 - pros - Konstantinides et al. (N Engl J Med, 1995), Steele et al. (Circulation, 1987) : nonrandomized*
 - cons - Shah et al. (Br Heart J, 1994) : nonrandomized*
- 2001 *Heart, Jemielity M et al.* : 76 pts > 40yrs
 - **improve clinical status / prevent RV dilation & insufficiency.**



What's been revealed so far?

- Device Closure -

Literatures for ASD device closure in the elderly (>60 yrs)

- 2005 CCI, Schubert s. et al. : 59pts > 60yrs, 25% LV restriction
 - no complication in non-restrictive LV, pre-medication required in restrictive LV(25%), fenestrated device needed in 2pts(3.4%).
- 2006 IJC, Swan L et al : 50pts > 60yrs
 - device closure is safe in elderly. Rt. heart shows remodeling. post-closure pulm edema in 1 pt. - resolved by diuretics.
- 2009 Korean Circ J, Spies C et al : 55pts > 60yrs
 - safe & effective; 100% success, no major complication. functional status improved, RV remodeling occurred.
- 2009 CCI, Taniguchi M et al : 9pts > 60yrs with chr. A Fib
 - improved functional class in all patients, geometric remodeling occurs.



Problems in device closure for the elderly

- **More complex clinical presentation:**
frequent comorbid cardiac +/- systemic diseases
 - Atrial arrhythmia
 - LV diastolic failure and/or restriction
(LV dysfunction after closure)
 - Pulmonary hypertension
 - Decompensated RV failure
 - Paradoxical embolism, etc

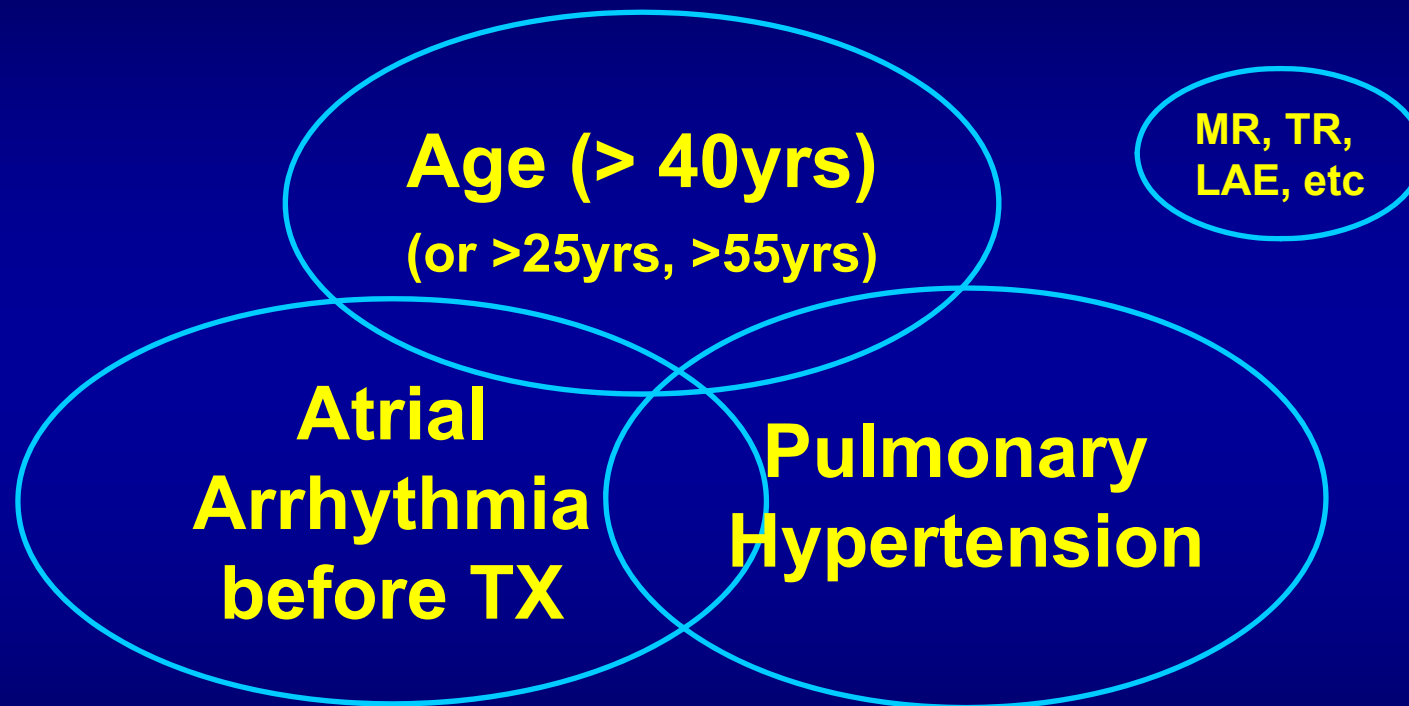


Incidence of Co-morbid Cardiac & Systemic Diseases among Elderly Patients > 60 yrs

	<i>Schubert (2006) (Berlin, 59pts)</i>	<i>Swan (2005) (Toronto, 50pts)</i>	<i>Spies (2009) (Chicago, 55pts)</i>
Systemic disease			
Hypertension (%)	42.4	34	?
DM (%)	?	6	?
Lung Disease (%)	?	4	?
Cerebral insult (%)	13.6	?	?
Cardiac comorbidity			
Pulm Hypertension (%)	49	?	42
A Fib +/- A Flutt (%)	40	20	24
Coronary HD (%)	13.6	16	?
LV dysfunction (%)	-	8	-
or LV restriction (%)	25	-	-
Pulm edema or (%)	-	2	-
Fenestrated device (%)	3.4	-	3.6



Risk factors of persistent or newly-developed atrial fibrillation / flutter



- Gatzoulis MA et al, N Engl J Med, 1999,
- Oliver JM et al. Am J Cardiol 2002,
- Silversides CK et al, Heart 2004



CCI 2009 73:682 – rationale based on “AFFIRM study”

Transcatheter Closure of Atrial Septal Defect in Elderly Patients With Permanent Atrial Fibrillation

Manabu Taniguchi,^{1*} MD, Teiji Akagi,¹ MD, Shinichi Ohtsuki,² MD, Yoshio Okamoto,² MD, Yasuharu Tanabe,³ RDCS, Nobuhisa Watanabe,³ RDCS, Koji Nakagawa,⁴ MD, Norihisa Toh,⁴ MD, Kengo Kusano,⁴ MD, and Shunji Sano,¹ MD

Sup

Device + Catheter Ablation

Medical Treatment



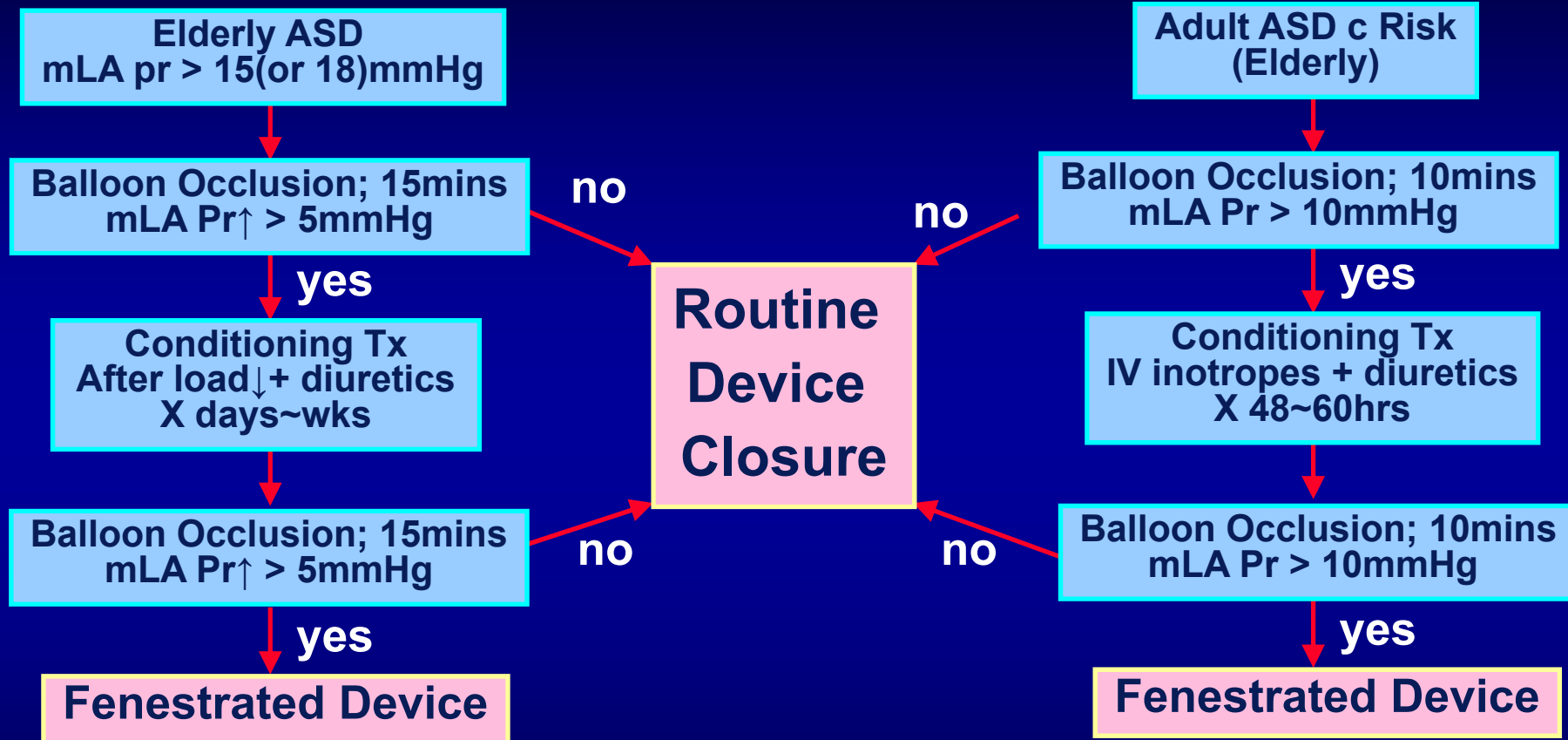
Rhythm Control

Rate Control





"Masked LV Restriction" or "LV Dysfunction after ASD Closure"



From Chicago,

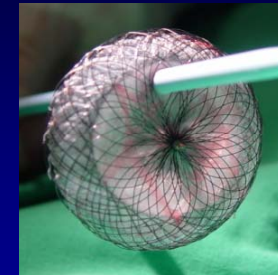
2005 CCI, Holzer R et al,
2008 J Invasive Cardiol, Elshershari H et al,
2009 J Invasive Cardiol, Al-Hindi A et al,
2009 Korean Circ J, Spies C et al

From Berlin,

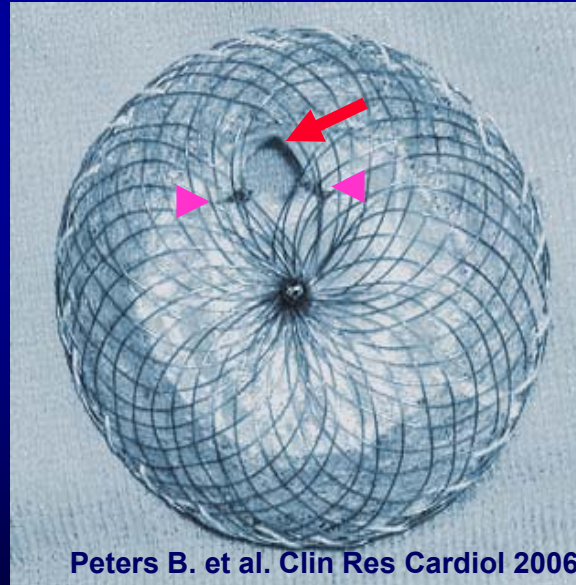
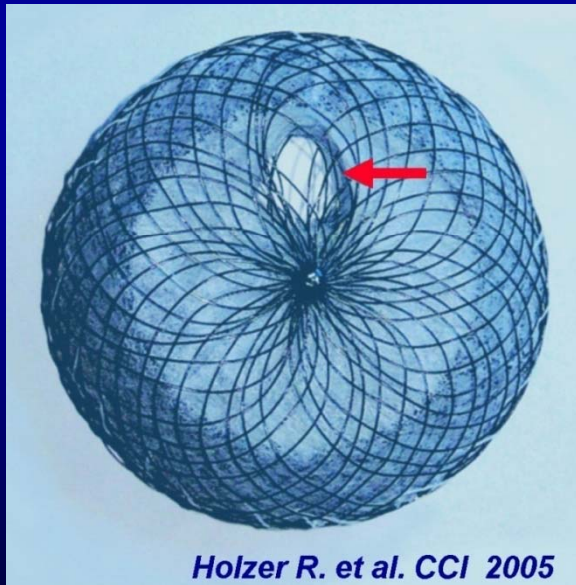
2001 Z Kardiol, Ewert P. et al,
2001 CCI, Ewert P. et al,
2005 CCI, Schubert s. et al.



- Patients c severe pulm. HiBP
- Elderly patients at high risk of post-procedural LV dysfunction



→ Self-fabricated fenestrated device





Experience of Severance Cardiovascular Hospital

Subjects & Method

- **977 patients with ASD secundum**
: 7-year period - 2004. 04 ~ 2011. 03
- **Device closure : 754 pts**
 - group 1 : 79 small children wt 10kg or less
 - group 2 : 627 patients wt>10kg & age<60yrs
 - group 3 : 48p elderly pts age 60yrs or more: comparison of hemodynamic & clinical parameters
- **Surgical closure : 223 pts**
: factors prevent device closure*
*: *except for personal reasons; financial problem, etc*



Demographic & Hemodynamic Data of Device Group

ASO group	Group 1 (n=79)	Group 2 (n=627)	Group 3 (n=48)	P-value
Age (year)	1.2±0.4	26.3±18.3	63.9±5.9	<0.001
Weight (kg)	9.1±1.1	46.3±11.4	60.8±9.8	<0.001, 0.002
Female (%)	57 (72%)	433 (69%)	38 (79%)	n/s
Qp/Qs	2.5±0.9	2.5±0.7	2.9±2.9	n/s
Defect size (mm)	14.4±3.0	23.0±7.5	25.0±6.0	<0.001
Device size (mm)	13.9±3.4	23.2±7.4	24.7±6.1	<0.001
Multiple defect (%)	26 (33%)	100 (16%)	10 (21%)	0.015
PAP (mmHg)	27.1±6.2	31.7±11.3	37.7±10.1	0.035, 0.023, 0.001
PAH (%)	4 (5%)	94 (15%)	19 (39%)	<0.001
Arrhythmia (%)	0 (0%)	19 (3%)	10 (21%)	<0.001

- Statistics; One-way ANOVA, Kruskal-Wallis test



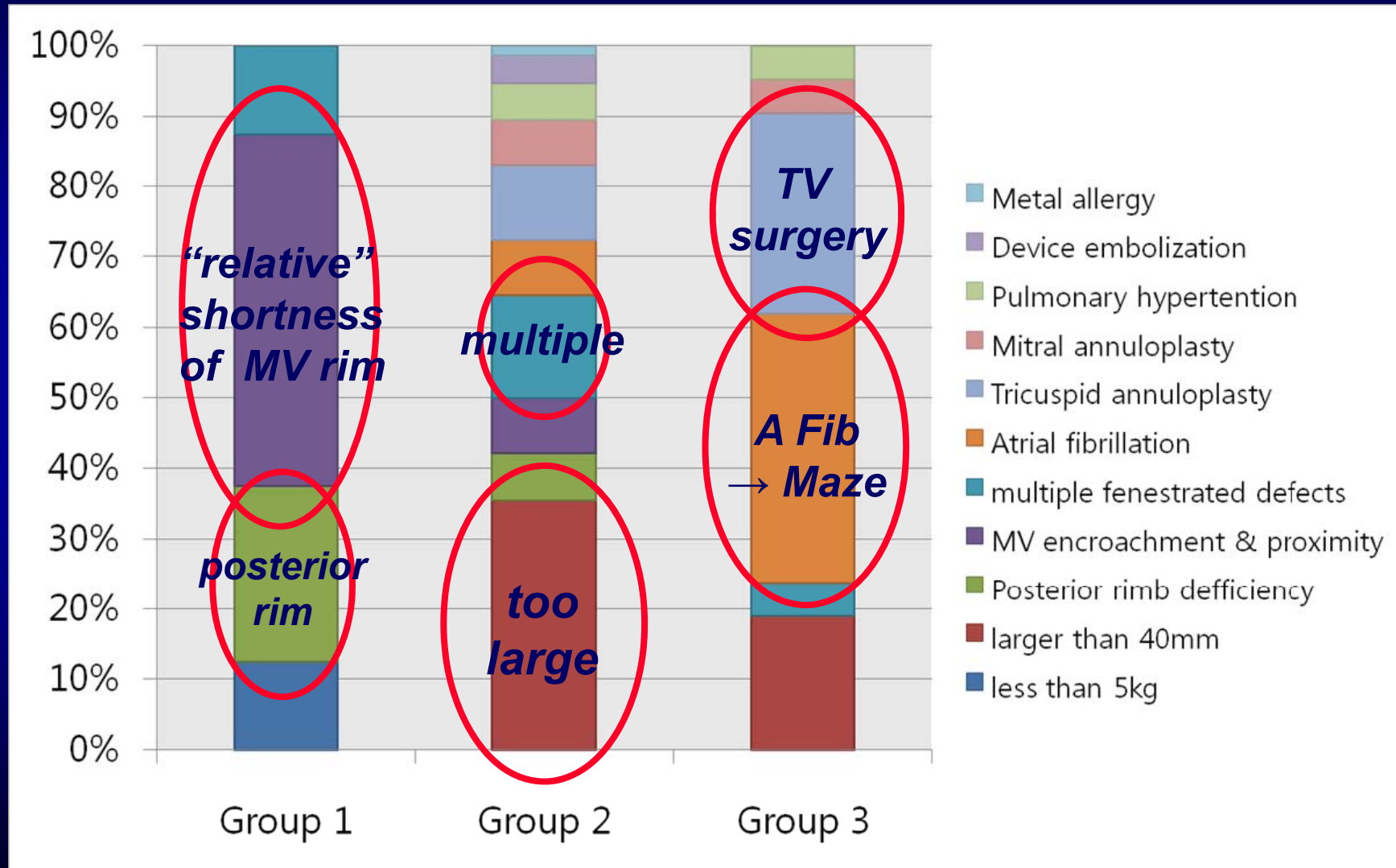
Comparison of Immediate and F/U Results among Each Subgroups

ASO group	Group 1 (n=79)	Group 2 (n=627)	Group 3 (n=48)	P-value
PSR* (%)	79/82 (96%)	627/645 (97%)	48/48 (100%)	n/s
RSR** (%)	2 (2.6%)	6 (1%)	1 (2%)	n/s
Complication rate (%)	1 [#] (1.3%)	12 ^{\$} (1.9%)	1 [†] (2.0%)	n/s
Procedure time (min)	67.8±19.6	65.1±17.9	66.8±16.8	n/s
Fluoroscopy time (min)	13.8±7.2	14.2±9.6	18.5±8.4	0.001

* : Procedural Success Rate, ** : Residual Shunt Rate, # : 1 minimal pericardial effusion, \$: 4 minimal pericardial effusion, 3 groin hematoma, 2 transient neurologic abnormality, 3 transient arrhythmia, † : 1 atrial fibrillation



Interfering Factors Preventing from Device Closure in Surgery Group





Take Home Message (I)

For small children,

- More sophisticated technical approach and decision is needed with regard to the fact that the closure system haven't specifically designed for small and fragile heart and vessel of very young children.
- Further modification of device toward decreased rim to waist diameter ratio is warranted to extend the applicability of this versatile treatment modality



Take Home Message (II)

For elderly patients,

- Thorough evaluation of co-morbidity and risk factors is important to predict post-procedural complication and to plan treatment strategy.
- The physician must let their patients know about serious complications such as chronic atrial arrhythmia and PAH which may persist after the ASD closure so that they can make right decision in choosing the treatment modality and promote compliance to further medical treatment.
- LV dysfunction (LV restriction) after device closure is rare, but potentially fatal outcome may be prevented by meticulous evaluation and appropriate treatment plan.



Conclusion

- ✓ **Transcatheter closure of secundum ASD with ASO is technically feasible, safe and effective in a wide range of age.**
- ✓ **Meticulous approach and individualized strategy for each patient are mandatory to maximize the efficacy and safety of this versatile therapy.**