

Progress and challenges in pediatric medical device development

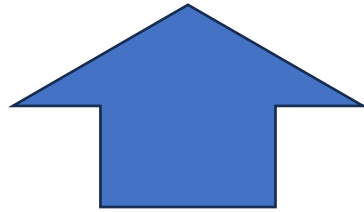
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Environment of pediatric medical device development

Device-lag Off-label use



Barriers for pediatric medical device development

1. **Universal problems specific to children**
 - Small market size
 - Rare disease
 - Wide variety in body and lesion size (Somatic growth of children)
2. **High cost for device development**

HBD for children



PAS-ARC

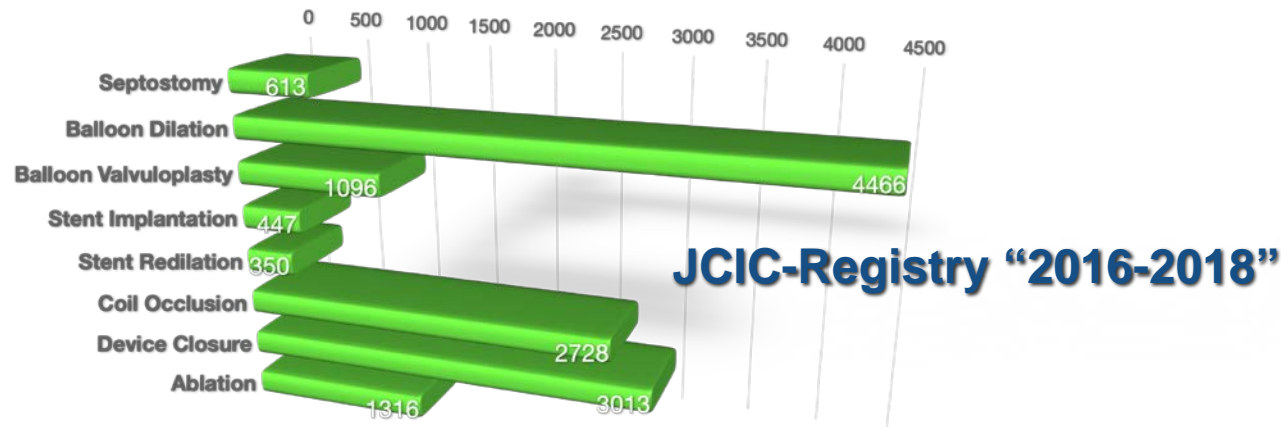


PAS = Pulmonary Artery Stenosis

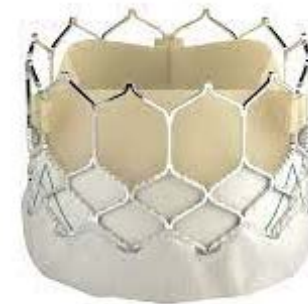
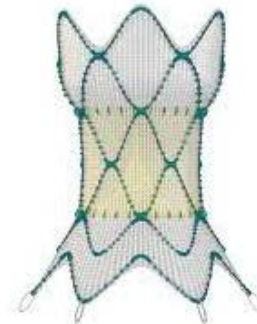
JCIC Registry



- ✓ Conducted by National Clinical Database (NCD) and JCIC
- ✓ High completeness (>90% of procedures in Japan)



- ✓ Previously used for post-marketing database surveys in some devices

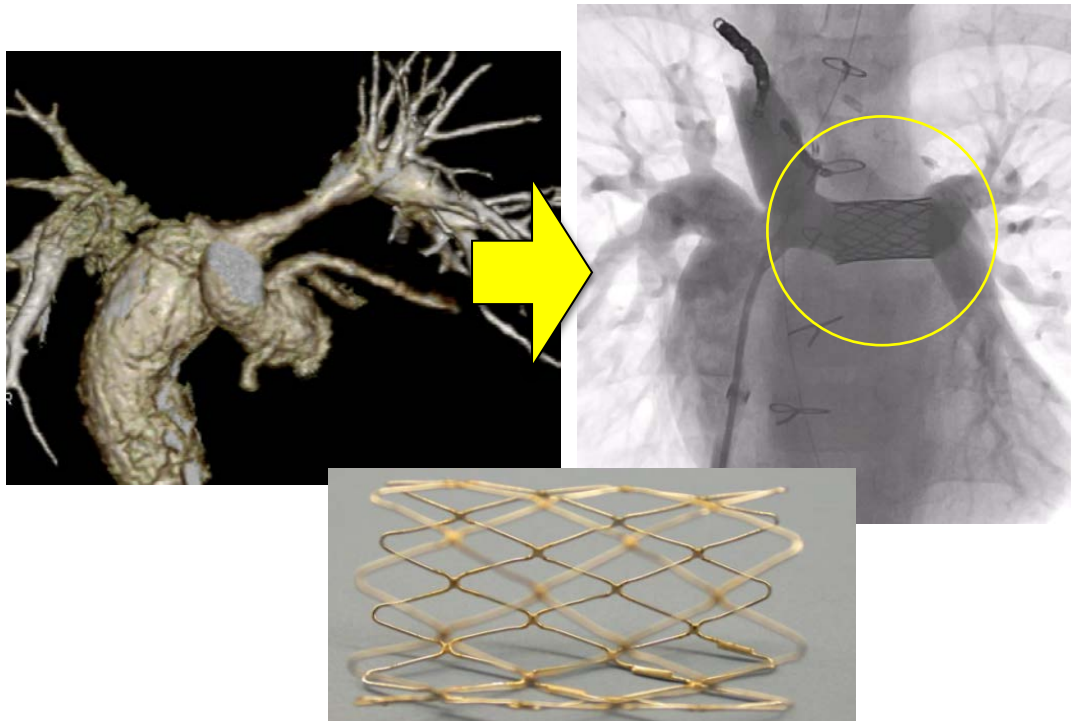


Standardization of definitions and endpoints (PAS-ARC project)

PAS-ARC



“PAS” Pulmonary Artery Stenosis



Contents

- Step 1) The definition of classification of the lesions
 - (Biventricular physiology)
 - 1-1) Etiology and Mechanism
 - 1-2) Physiology and Lesion location
 - 1-3) Definable metrics
- Step 2) Apply the definition to Single ventricular physiology
 - 1-1) Etiology and Mechanism
 - 1-2) Physiology and Lesion location
- Step 3) Outcome and AE
 - 3-1) Efficacy Endpoints
 - 3-2) Safety Endpoints
- Step 4) Overall integration
- Step 5) Discussion with other professions, government and industry

Update - AMED research

Japan Agency for Medical Research and Development

Research on the Improvement of the Environment to Promote Pediatric Medical Device Development

HBD for children



PAS-ARC



July 2023 – March 2026

Budget approved for 2023-2024
9100,000 USD

Objectives

- ✓ To reconstruct the JCIC-R database to be able to applicate effective PMS of the different types of devices and reduce the time/cost of PMS while securing the quality of surveillance.
- ✓ To improve the environment of pediatric medical devices development by strengthen the global collaboration of the stakeholders.

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Projects

- #1 Reconstitution of the JCIC-R database to facilitate device development
- #2 Standardization of definitions and endpoints (PAS-ARC project)
- #3 Quality Improvement of the JCIC-R dataset
- #4 Research of the clinical needs based on the RWD on the JCIC-R

#1 Reconstitution of the JCIC-R database to facilitate device development

“Minimum data set” project

The new concept to minimize the number of data-set while ensuring effectiveness and safety evaluation in PMS using JCIC-R.

Heart and Vessels
<https://doi.org/10.1007/s00380-020-01691-0>

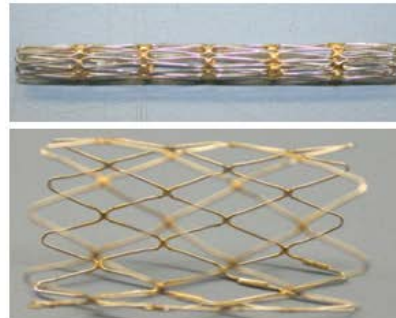
ORIGINAL ARTICLE



Clinical trial of the CP stent for pulmonary artery stenosis: the first investigator-initiated clinical trial for pediatric interventional cardiology in Japan

Takanari Fujii¹ · Hideshi Tomita¹ · Toshiki Kobayashi² · Hitoshi Kato³ · Hisashi Sugiyama⁴ · Ayumi Mizukami⁵ · Hideaki Ueda⁶

PMS of CP stent



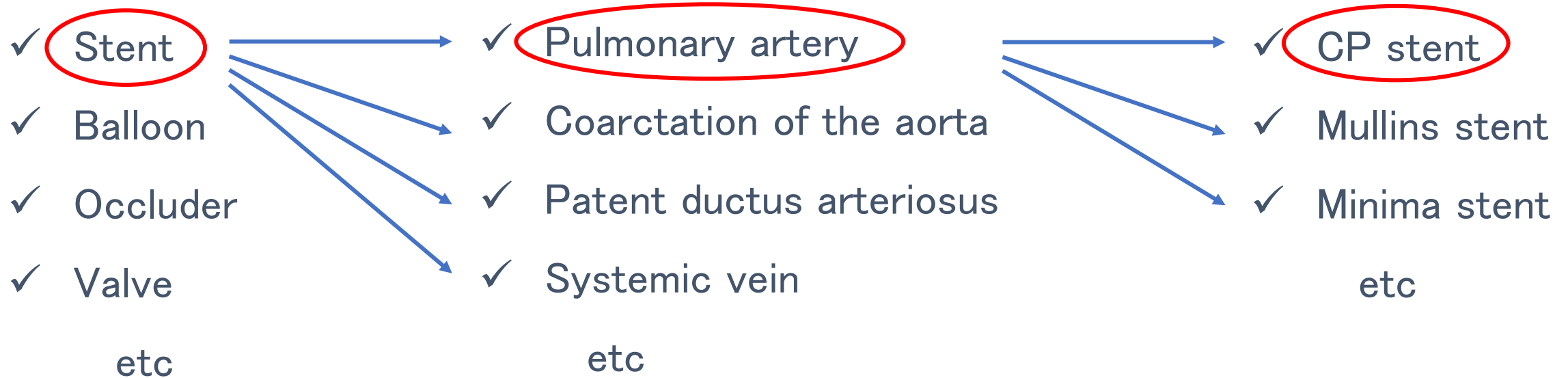
CP Stent™ Specifications

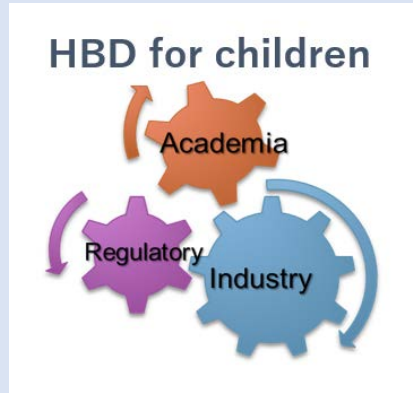
Stent Length (CM)	Configuration (Number of Zigs)	Platinum Wire (Inches)	Bare Stent Catalog No.	Covered Stent Catalog No.
1.6	8	0.013	CP8Z16	Cvrd. CP8Z16
2.2	8	0.013	CP8Z22	Cvrd. CP8Z22
2.8	8	0.013	CP8Z28	Cvrd. CP8Z28
3.4	8	0.013	CP8Z34	Cvrd. CP8Z34
3.9	8	0.013	CP8Z39	Cvrd. CP8Z39
4.5	8	0.013	CP8Z45	Cvrd. CP8Z45

#1 Reconstitution of the JCIC-R database to facilitate device development

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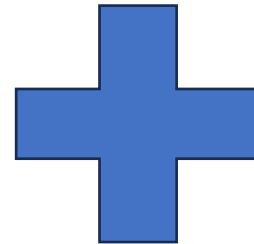
JSPCCS
HBD for children



JCIC-R WG



JSPCCS
JCIC



**Research on the Improvement of the Environment
to Promote Pediatric Medical Device Development**