

Progress and challenges in pediatric medical device development

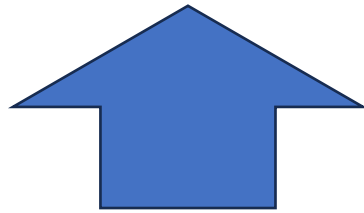
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Showa University Hospital

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
 - Somatic growth of patients
 - Large size variation in body and lesion size
- 2. High cost for device development**

HBD for children



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

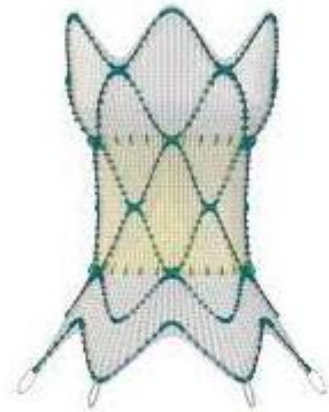
Objectives

- ✓ 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.

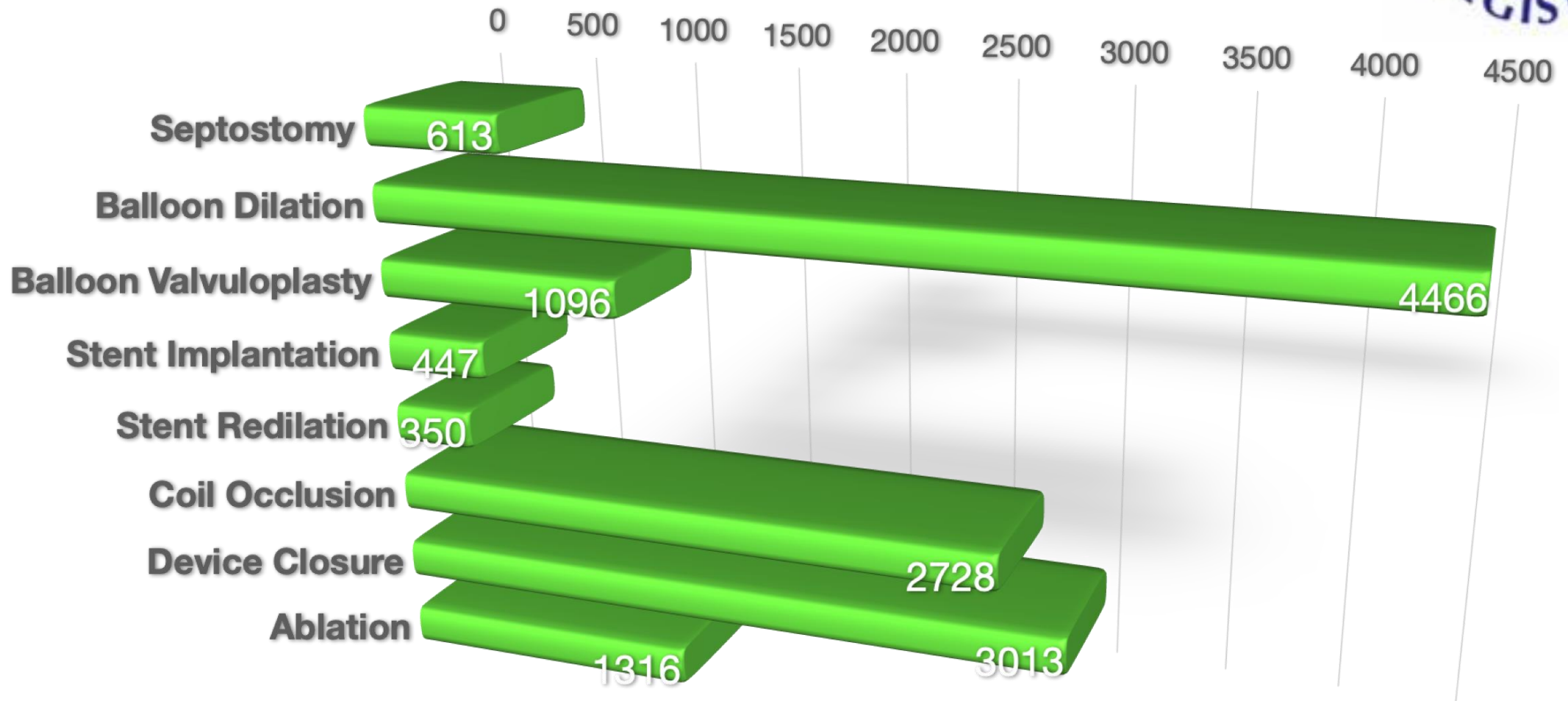
JCIC Registry



- ✓ 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



JCIC-Registry “2016-2018”



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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

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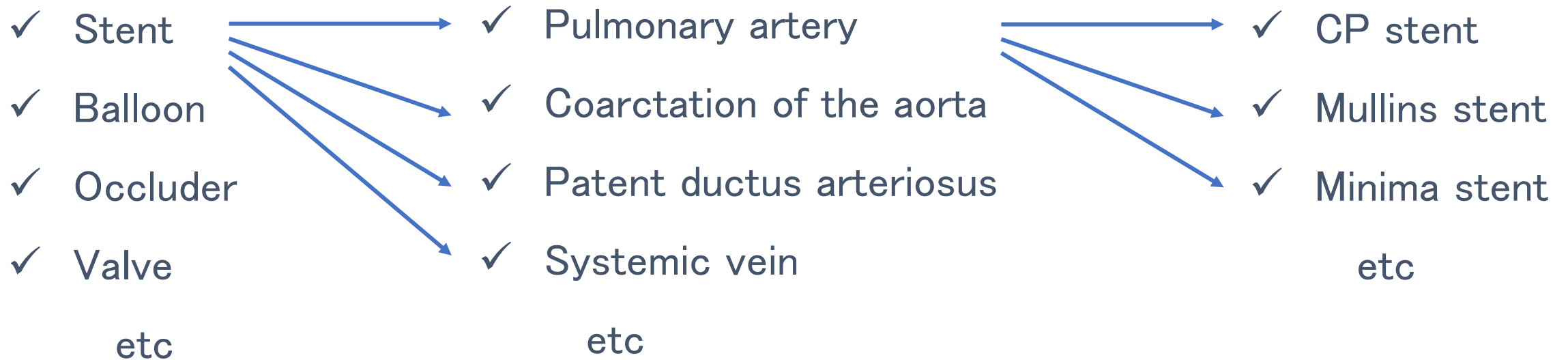
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#1 Reconstitution of the JCIC-R database to facilitate device development

“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.



PMS of CP stent

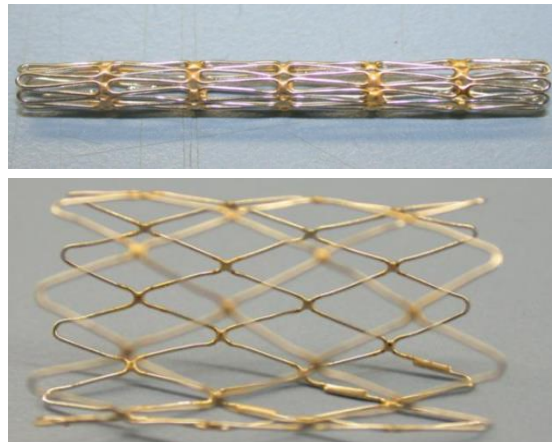
Heart and Vessels
<https://doi.org/10.1007/s00380-020-01691-0>

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



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

#2 Standardization of definitions and endpoints (PAS-ARC project)

Update PAS-ARC group

Contents

- Step 1) The definition of classification of the lesions (Biventricular physiology)
 - 1-1) Etiology and Mechanism
 - 1-1-1) Etiology
 - 1-1-2) Mechanism
 - 1-2) Physiology and Lesion location
 - 1-2-1) Physiology
 - 1-2-2) Lesion location
 - 1-3) Definable metrics
 - 1-3-1) Angiographic vessel diameter
 - 1-3-2) Systolic pressure gradient across the stenosis
 - 1-3-3) Ratio of RV systolic pressure/ arterial systolic pressure
 - 1-3-4) % flow distribution
 - 1-3-5) Lesion morphology

#2 Standardization of definitions and endpoints (PAS-ARC project)

Update PAS-ARC group

Contents (continue)

Step 2) Apply the definition to Single ventricular physiology

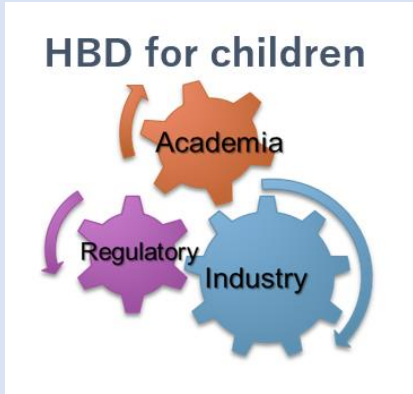
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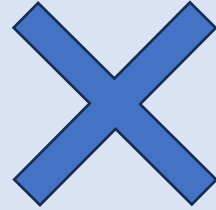
Step 3) Outcome and AE

Step 4) Overall integration

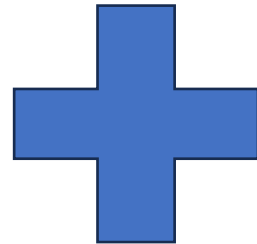
Step 5) Discussion with other professions, government and industry



JSPCCS
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JCIC-R WG



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