Impact of repeat percutaneous coronary interventions for chronic total occlusion following previously failed attempts from the analysis of the Japanese CTO Expert Registry

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Disclosure Statement of Financial Interest

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Introduction / Aim

- Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) can be challenging to perform with variable success rates, depending on operator experience and expertise.
- Previous failed attempt of CTO-PCI has been associated with lower procedural success rates and is part of the Japanese Chronic Total Occlusion (J-CTO) score that was developed to predict the likelihood of successful guidewire crossing within 30 minutes.
- The aim of this study is to investigate the impact of repeat CTO-PCI by highly skilled operators following previous failed attempt.

Methods

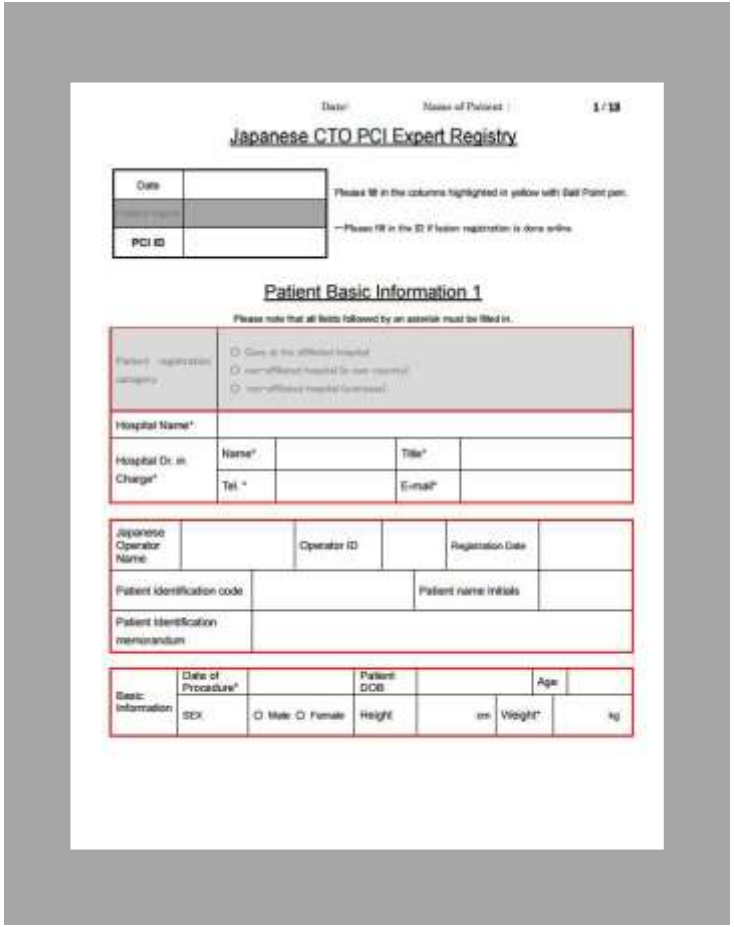
- The Japanese Board of CTO Interventional Specialists has develop a prospective, nonrandomized registry of patients undergoing CTO-PCI performed selected highly experienced Japanese specialists.
- From 2014 to 2016, the registry included 4177 consecutive CTO-PCI cases. The overall procedure success rate of CTO-PCI was 88.9%. A previous failed attempt had been performed in 844 patients (20.2%).
- We compared the baseline patient and angiographic characteristics, procedural and clinical results between first-attempt PCI and re-attempt PCI. In addition, we analyzed unsuccessful factors of re-attempt CTO-PCI with univariate and multivariate analysis.

Japanese CTO PCI Expert Registry

- The Japanese Board of CTO Interventional Specialists was established in 2013 to accumulate quantitative and reliable data to identify issues such as stagnation in the development of CTO-PCI techniques and to compare with other databases of foreign countries.
- Japanese CTO PCI Expert Registry started a database of CTO-PCI performed by certified expert physicians who have a certain level of CTO-PCI skills from JAN/2014
- Patients are enrolled by certified expert operators.
- Procedure success is adjudicated by a Core-lab

Japanese CTO PCI Expert Registry Overview

Pts. Enrollment	Jan.2014~
Participants as of JUN.2016	45 of Japanese Expert physicians
Criteria for Participants	・More than 300 cases of experience of CTO-PCI ・More than 50 cases of CTO PCI per year ・Recommendation from two steering committee member
Core lab.	Adjudication of Indication and Procedure Success
Organization	Japanese Board of CTO interventional specialist
Chairman	Etsuo Tsuchikane (initiated by Osamu Katoh and Kazuaki Mitsudo)



Date: Name of Patient: 1 / 18

Japanese CTO PCI Expert Registry

Date	
PCI ID	

Please fill in the columns highlighted in yellow with Ball Point pen.

---Please fill in the ID if lesion registration is done online.

Patient Basic Information 1

Please note that all fields followed by an asterisk must be filled in.

	○ Case at this affiliated hospital ○ non-affiliated hospital (in own country) ○ non-affiliated hospital (overseas)			
Hospital Name*				
Hospital Dr. in Charge*	Name*		Title*	
	Tel. *		E-mail*	

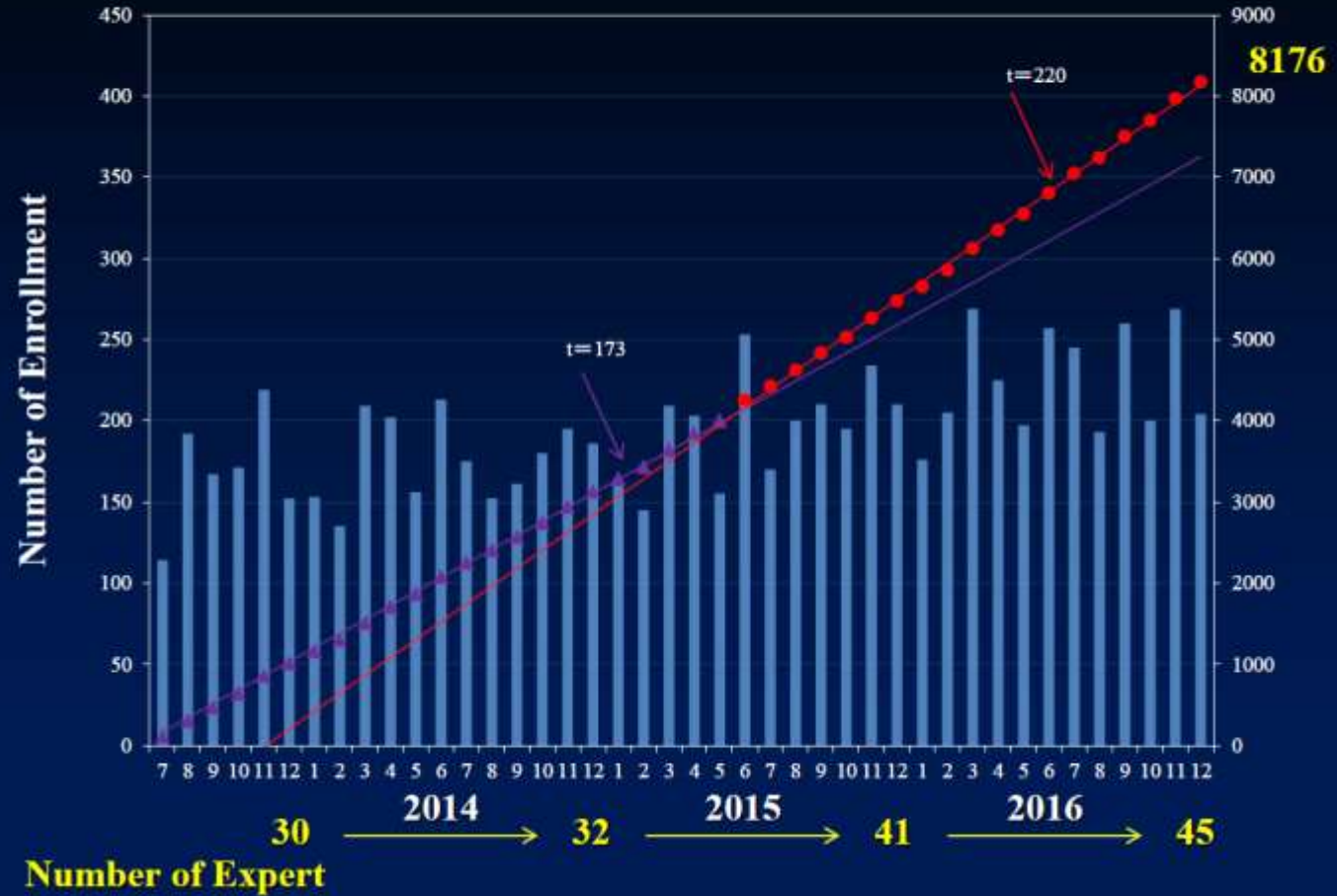
Japanese Operator Name		Operator ID		Registration Date	
Patient identification code			Patient name initials		
Patient identification memorandum					

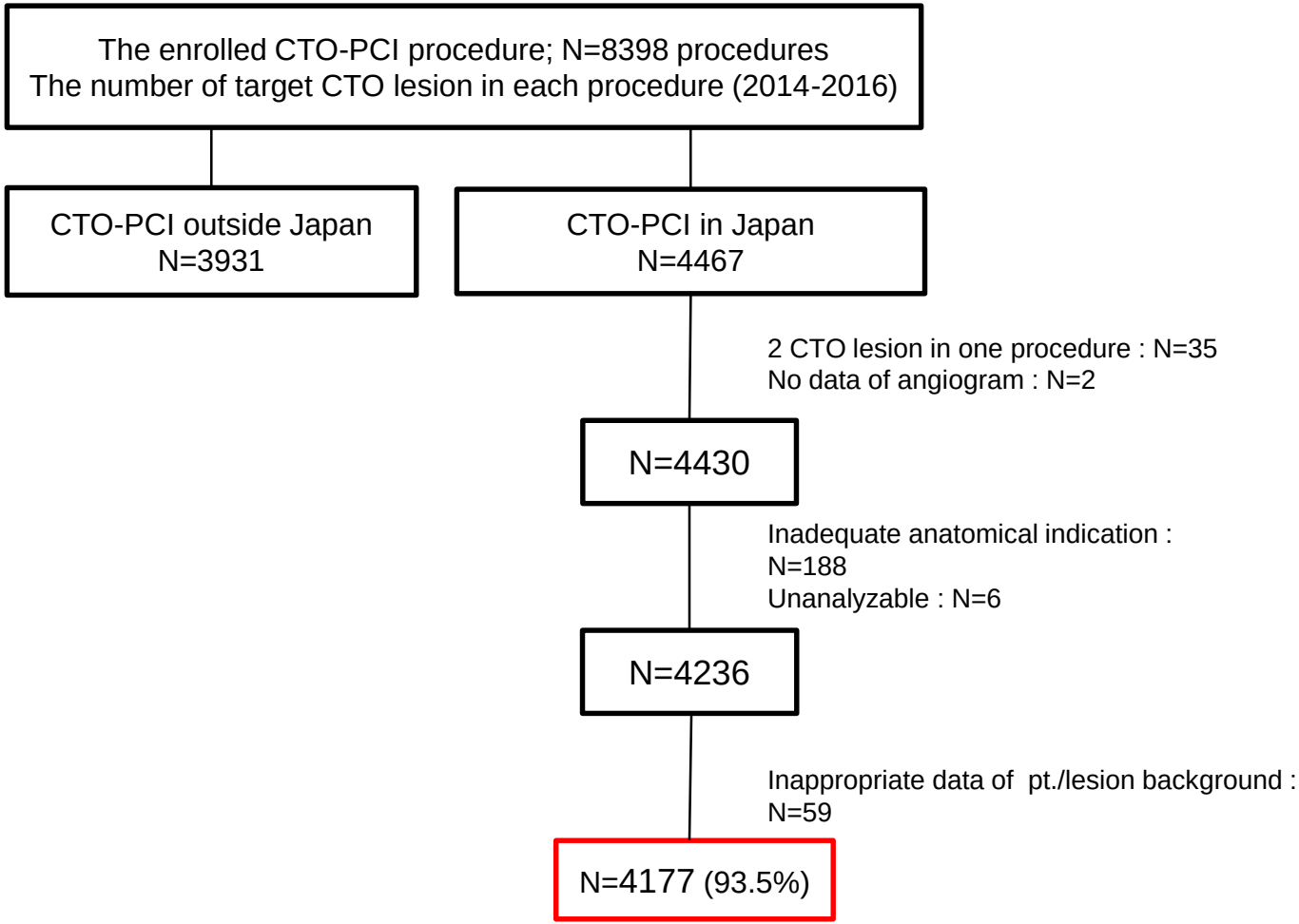
Basic Information	Date of Procedure*		Patient DOB		Age		
	SEX	○ Male ○ Female	Height	cm	Weight*		kg

Registration Method

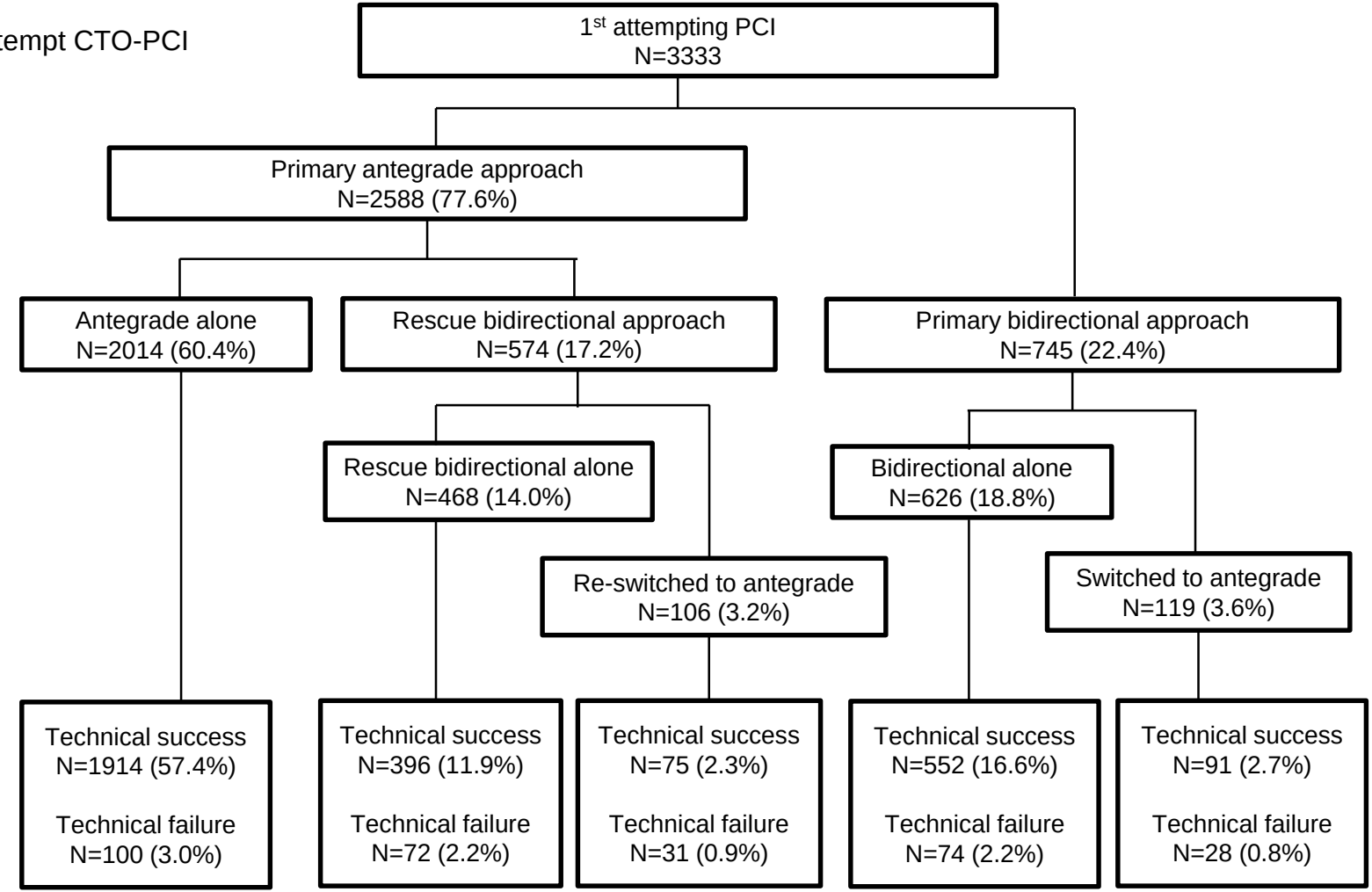
- Web based registration
- All cases registration
- Input articles
  - Patient basic data
  - CTO lesion data
  - Procedure data
  - Procedural and clinical result
  - Follow up data (1M and Max 5years)
- Certificate of Consent
- Angiograms (CAG/PCI) , CTA and IVUS images are sent as DICOM data to Core-labo

Patient Enrollment




The enrolled CTO-PCI procedure; N=8398 procedures
The number of target CTO lesion in each procedure (2014-2016)
CTO-PCI outside Japan
N=3931
CTO-PCI in Japan
N=4467
2 CTO lesion in one procedure : N=35
No data of angiogram : N=2
N=4430
Inadequate anatomical indication :
N=188
Unanalyzable : N=6
N=4236
Inappropriate data of pt./lesion background :
N=59
N=4177 (93.5%)

First-attempt CTO-PCI



Re-attempt CTO-PCI

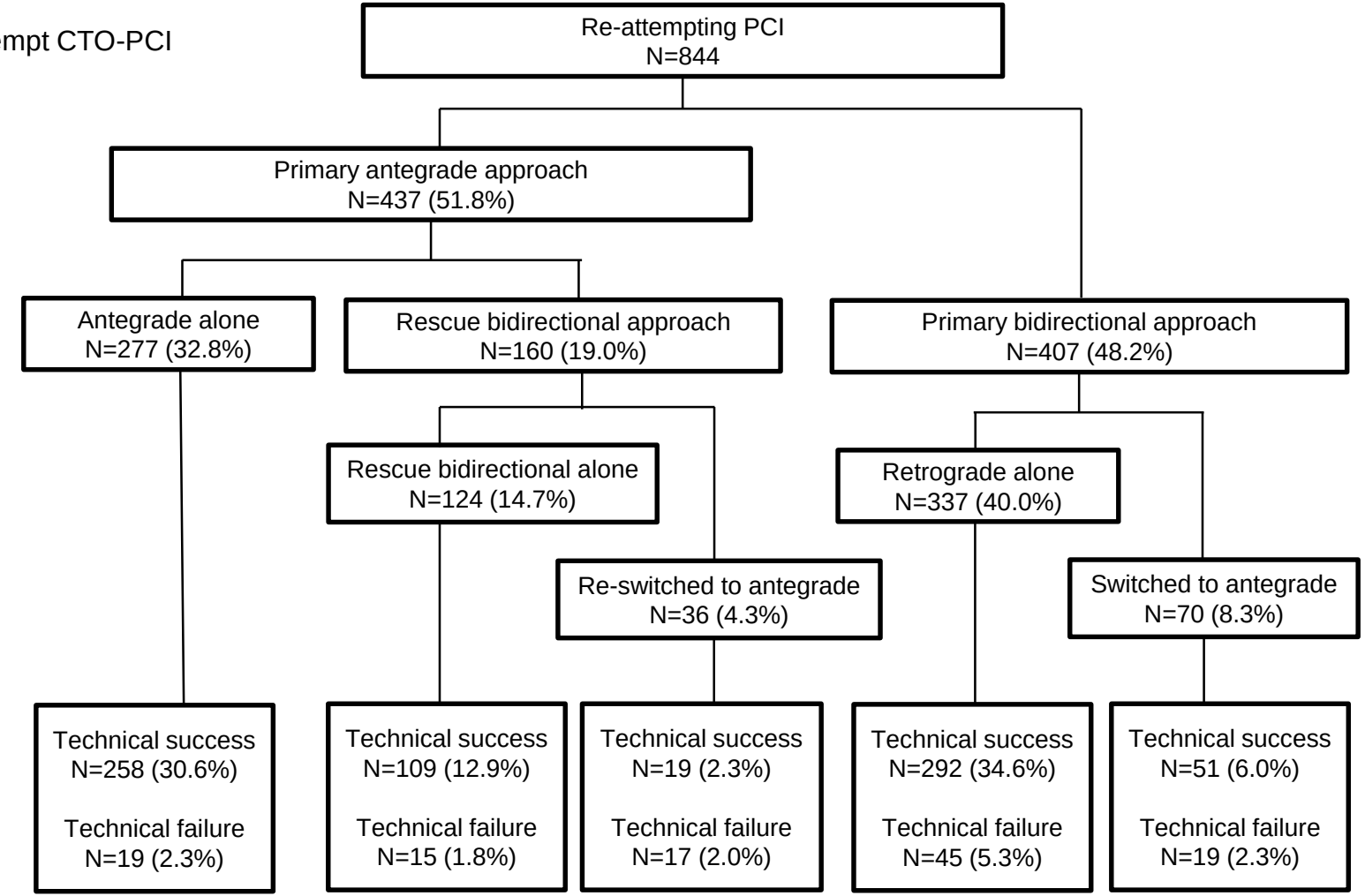


Table 1-1 Baseline Patient Characteristics and Baseline Angiographic Characteristics

	Overall (N = 4177)		1st attempt (N = 3333)		Re-attempt (N = 844)		p Value
Age, yrs	66.8 ± 10.8		67.2 ± 10.9		65.3 ± 10.7		<0.001
BMI, kg/mm	24.7 ± 4.0		24.6 ± 3.7		25.1 ± 4.7		0.004
LVEF, %	54.9 ± 12.9		54.7 ± 13.0		56.0 ± 12.2		0.009
eGFR	63.6 ± 27.2		63.4 ± 27.4		64.4 ± 26.1		0.339
Male	3583	(85.8)	2844	(85.3)	739	(87.6)	0.098
Hypertension	3256	(78.0)	2586	(77.7)	670	(79.7)	0.292
Dyslipidemia	3238	(77.5)	2532	(76.1)	706	(83.9)	<0.001
Diabetes	1885	(45.1)	1497	(45.0)	388	(46.1)	0.437
Dialysis	265	(6.3)	202	(6.1)	63	(7.5)	0.143
Current smoking	2283	(54.7)	1827	(54.9)	456	(54.2)	0.313
OMI	2088	(50.0)	1630	(49.0)	458	(54.5)	0.006
Prior CABG	310	(7.4)	254	(7.6)	56	(6.7)	0.620
Prior PCI	2768	(66.3)	1924	(57.8)	844	(100.0)	<0.001
Number of diseased vessels							<0.001
Single VD	1972	(47.2)	1480	(44.5)	486	(57.7)	
Double VD	1229	(29.5)	990	(29.8)	237	(28.1)	
Triple VD	821	(19.7)	722	(21.7)	98	(11.6)	
LMT + multiple VD	154	(3.7)	133	(4.0)	21	(2.5)	
Target vessel							<0.001
LAD	1328	(31.8)	1068	(32.1)	260	(30.8)	
LCX	715	(17.2)	620	(18.6)	95	(11.3)	
LMT	17	(0.4)	12	(0.4)	5	(0.6)	
RCA	2116	(50.6)	1632	(49.0)	484	(57.3)	

Table 1-2 Baseline Patient Characteristics and Baseline Angiographic Characteristics

	Overall (N = 4177)		1st attempt (N = 3333)		Re-attempt (N = 844)		p Value
Syntax score	16.7 ± 8.9		17.2 ± 9.0		15.0 ± 8.1		<0.001
J-CTO score	1.92 ± 1.15		1.68 ± 1.05		2.86 ± 1.03		<0.001
CTO length ≥ 20mm	2401	(57.5)	1886	(56.6)	515	(61.1)	0.060
calcification	2145	(51.4)	1675	(50.3)	470	(55.6)	0.005
Tortuosity of CTO lesion	959	(23.0)	721	(21.7)	238	(28.2)	<0.001
Morphology of proximal cap							0.016
Blunt	911	(21.8)	724	(21.7)	187	(22.2)	
No stump	768	(18.3)	607	(18.2)	161	(19.1)	
Tapered / tunnel	2457	(58.9)	1978	(59.4)	479	(56.8)	
Unclear	41	(1.0)	24	(0.7)	17	(2.0)	
In-stent occlusion	536	(12.8)	443	(13.3)	93	(11.0)	0.084
Vessel diameter < 3.0mm	2822	(67.6)	2261	(68.3)	561	(67.2)	0.533
Side branch at proximal cap	1514	(36.2)	1226	(36.8)	288	(34.2)	0.161
Proximal tortuosity	2074	(49.7)	1651	(49.6)	423	(50.2)	0.758
Poor distal target	1637	(40.6)	1380	(41.4)	317	(37.6)	0.045
Collateral filling							0.008
Contralateral	2084	(49.9)	1631	(49.0)	453	(53.7)	
Ipsilateral	544	(13.0)	460	(13.8)	84	(10.0)	
Both	1517	(36.3)	1215	(36.5)	302	(35.8)	
None	29	(0.7)	25	(0.8)	4	(0.5)	
Collateral filling grade							0.008
CC0	233	(5.6)	203	(6.1)	30	(3.6)	
CC1	1630	(39.0)	1306	(39.2)	324	(38.4)	
CC2	2312	(55.4)	1822	(54.7)	490	(58.0)	
Unclear	2	(0.1)	2	(0.1)	0	(0)	

Table 2 Procedural and Clinical Results

	Overall (N = 4177)		1st attempt (N = 3333)		Re-attempt (N = 844)		p Value
GW success	3847	(92.1)	3094	(92.8)	753	(89.2)	0.002
Technical success	3757	(88.9)	3028	(90.8)	729	(86.4)	<0.001
Procedural success	3614	(86.5)	2922	(89.7)	692	(84.3)	<0.001
Procedure time, min	158.1 ± 88.9		150.5 ± 86.6		188.5 ± 91.5		<0.001
Contrast volume, ml	222.5 ± 102.6		217.6 ± 100.0		242.2 + 110.1		<0.001
In-hospital death	12	(0.3)	12	(0.4)	0	(0)	0.141
Myocardial infarction	47	(1.1)	30	(0.9)	17	(2.1)	0.001
Acute stent thrombosis	7	(0.2)	5	(0.2)	2	(0.2)	0.634
Stroke	12	(0.3)	7	(0.2)	5	(0.6)	0.073
Emergent CABG	2	(0.1)	2	(0.1)	0	(0)	1
Emergent PCI	7	(0.2)	5	(0.2)	2	(0.2)	0.634
Coronary perforation	190	(4.5)	135	(4.1)	57	(7.0)	0.001
Cardiac tamponade	17	(0.4)	13	(0.4)	4	(0.5)	0.762
Complication of puncture site	63	(1.5)	51	(1.6)	12	(1.5)	1
CIN	246	(5.9)	193	(5.8)	53	(6.3)	0.568

Table 3-1. The Difference Between Successful and Failed Procedure in Re-attempt PCIs

Reattempt (N=844)	Success (N=711)	Failure (N=133)	p value
Age	66.2±10.6	66.2±11.4	0.316
BMI	25.1±4.8	25±4.3	0.867
LVEF	56.2±12.3	54.7±12.9	0.194
eGFR	65.7±25.7	56.4±28.0	<0.001
Male	605 (87.7)	111 (86.0)	0.566
Hypertension	547 (79.5)	106 (82.2)	0.437
Dyslipidemia	582 (84.6)	105 (81.4)	0.543
Diabetes	309 (44.9)	70 (54.3)	0.028
Dialysis	40 (5.8)	19 (14.7)	0.001
Current smoking	365 (53.1)	75 (58.1)	0.099
OMI	362 (52.6)	82 (63.6)	0.064
Prior CABG	45 (6.5)	10 (7.8)	0.695
Syntax score	14.9 (8.0)	15.8 (8.5)	0.259
J-CTO score	2.81 (1.02)	3.19 (1.04)	<0.001
High J-CTO score (3-5)	410 (59.4)	98 (76.0)	<0.001
Number of diseased vessles			0.496
single VD	401 (58.3)	68 (52.7)	
Double VD	188 (27.3)	43 (33.3)	
Triple VD	81 (11.8)	16 (12.4)	
LMT + multiple VD	18 (2.6)	2 (1.6)	
Target vessel			0.141
LAD	233 (32.3)	31 (24.0)	
LCX	77 (11.2)	12 (9.3)	
LMT	5 (0.7)	0 (0)	
RCA	385 (55.8)	86 (66.7)	

Table 3-2. The Difference Between Successful and Failed Procedure in Re-attempt PCIs

Reattempt (N=844)	Success (N=711)	Failure (N=133)	p value
In-stent occlusion	70 (10.1)	20 (15.5)	0.09
Distal runoff < 3.0mm	468 (67.8)	76 (58.9)	0.157
CTO length > 20mm	412 (59.7)	89 (69.0)	0.049
Side branch at proximal cap	235 (34.1)	46 (35.7)	0.762
Collateral filling			0.068
Contralateral	366 (53.0)	76 (58.9)	
Ipsilateral	71 (10.3)	7 (5.4)	
Both	251 (36.4)	44 (34.1)	
None	2 (0.3)	2 (1.6)	
Collal filling grade			0.61
CC0	23 (3.9)	6 (4.7)	
CC1	262 (38.8)	51 (39.5)	
CC2	405 (58.7)	72 (55.8)	
Lesion calcification (J-CTO)	382 (55.4)	75 (58.1)	0.629
Lesion calcification			<0.001
mild	235 (34.1)	28 (21.7)	
moderate	96 (13.9)	21 (16.3)	
severe	51 (7.4)	26 (20.2)	
none	308 (44.6)	54 (41.9)	
Proximal tortuosity	340 (49.3)	70 (54.3)	0.086
Tortuosity of CTO lesion	175 (25.4)	57 (44.2)	<0.001
Mophology of proximal cap			0.214
Blunt	148 (21.4)	34 (26.4)	
No stump	132 (19.1)	27 (20.9)	
Tapered/tunnal	399 (57.8)	64 (49.6)	

Table 4. Multivariate Analysis Investigating Possible Predictor of Failed Re-attempt PCI

	OR	95%CI	P.VALUE
Dialysis	1.18	0.49-2.85	0.71
High J-CTO score (3-5)	1.66	0.50-5.54	0.41
Occlusion length (>20mm)	1.19	0.48-2.99	0.7
Diabetes	0.15	0.01-2.73	0.2
Tortuosity of CTO lesion	1.78	0.73-4.33	0.2
Severe calcification	7.83	2.13-28.80	0.002
Moderate calcification	2.36	0.65-8.49	0.19

Summary of Results 1

- As compared with the first attempt PCIs, the re-attempt PCIs had higher Japanese CTO score (1.68±1.1 vs 2.86±1.0, $p<0.001$), and were more likely to have renal failure on dialysis (5.1% vs 7.0%, $p=0.042$) and to undergo recanalization attempts using the bidirectional approach (40.1% vs 67.6%, $p<0.001$).
- Procedure time (150±87 vs 188±92 min, $p<0.001$) and contrast volume (218±100 vs 242±110 ml, $p<0.001$) were bigger in the re-attempt PCIs.

Summary of Results 2

- The rate of myocardial infarction (0.9% vs 2.1%, p=0.01) and coronary perforation (4.1% vs 7.0%, p=0.001) were higher in the re-attempt PCIs. However, there was no significant difference of the rate of cardiac tamponade, emergent PCI and CABG.
- The technical (90.8% vs 86.4%, p<0.001) and procedural (89.7% vs 84.2%, p<0.001) success rate were lower in the re-attempt PCIs. However, the technical success rate in the prior failure group of this study was higher, compared with the retry cases of Multicenter CTO Registry in Japan which was reported nine years ago and developed J-CTO score system (86.4% vs 68.5%).

Summary of Results 2

- From the analysis of repeat CTO-PCI procedure with a prior failed attempt, compared with the success group (711 patients), the failure group (133 patients) were more likely to have diabetes (44.9% vs 54.3%, p=0.028) and renal failure on dialysis (5.8% vs 14.7%, p=0.001) and higher J-CTO score (2.81$\pm$1.0 vs 3.19$\pm$1.0, p<0.001).
- The success rate of retrogradely guidewire crossing through the collateral channel was higher in the success group of repeat CTO-PCI (84.2% vs 55.6%, p<0.001). Severe lesion calcification was a strong predictor of the failure of repeat CTO-PCI (OR=7.83, 95% CI=2.13-28.80, p=0.002).

Conclusions

- The repeat CTO-PCIs in our registry are associated with patient characteristic and angiographic complexity, longer procedure time and high contrast volume.
- The success rate of repeat CTO-PCI by highly skilled operators following previously failed attempt may be acceptable.
- The CTO lesion with severe calcification remains a difficult problem.

Table 4. Multivariate Analysis Investigating Possible Predictor of Failed Re-attempt PCI

	Univariate Analysis			Multivariate Analysis		
Reattempt (N=844)	Success (N=711)	Failure (N=133)	p value	OR	95%CI	P.VALUE
Dialysis	4.0 (5.8)	19 (14.7)	0.001	1.18	0.49-2.85	0.71
High J-CTO score (3-5)	410 (59.4)	98 (76.0)	<0.001	1.66	0.50-5.54	0.41
Occlusion length (>20mm)	412 (59.7)	81 (69.0)	0.049	1.19	0.48-2.99	0.7
Diabetes	309 (44.9)	70 (54.3)	0.028	0.15	0.01-2.73	0.2
Tortuosity of CTO lesion	175 (25.4)	57 (44.2)	<0.001	1.78	0.73-4.33	0.2
Severe calcification	51 (7.4)	26 (20.2)	<0.001	7.83	2.13-28.80	0.002
Moderate calcification	96 (13.9)	21 816.3)	<0.001	2.36	0.65-8.49	0.19