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## Assessing the landscape of percutaneous coronary chronic total occlusion treatment in Belgium and Luxembourg: the Belgian Working Group on Chronic Total Occlusions (BWGCTO) registry

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### ABSTRACT

**Background:** Important developments in materials, devices, and techniques have improved outcomes of chronic total occlusion (CTO) percutaneous coronary intervention (PCI), and resulted in a growing interest in CTO-PCI. The Belgian Working Group on Chronic Total Occlusions (BWGCTO) working group aims to assess the evolution within the CTO-PCI landscape over the next years.

**Methods:** From May 2016 onwards, patients undergoing CTO-PCI were included in the BWGCTO registry by 15 centres in Belgium and Luxembourg. Baseline, angiographic, and procedural data were collected. Here, we report on the one-year in-hospital outcomes.

**Results:** Over the course of one year, 411 procedures in 388 patients were included with a mean age of  $64 \pm 11$  years. The majority were male (81%). Relatively complex CTOs were treated (Japanese CTO score  $= 2.2 \pm 1.2$ ) with a high procedure success rate (82%). Patient- and lesion-wise success rates were 83 and 85%, respectively. Major adverse in-hospital events were acceptably low (3.4%). Antegrade wire escalation technique was applied most frequently (82%). On the other hand, antegrade dissection and re-entry and retrograde strategies were more frequently applied in higher volume centres and successful for lesions with higher complexity.

**Conclusion:** Satisfactory procedural outcomes and a low rate of adverse events were obtained in a complex CTO population, treated by operators with variable experience levels. Antegrade wire escalation was the preferred strategy, regardless of operator volume.

### ARTICLE HISTORY

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### KEYWORDS

Percutaneous coronary intervention; chronic total occlusion; in-hospital outcomes

## Introduction

The development of new and improved chronic total occlusion (CTO)-dedicated materials, as well as the availability and implementation of treatment algorithms (i.e. hybrid algorithm [1]), have positively

affected the efficacy and safety of CTO percutaneous coronary intervention (PCI) [2–6]. The results of the recent EuroCTO study, a randomised trial that indicated a significant quality of life benefit in favour of CTO-PCI in comparison to medical therapy, supports the treatment of CTO lesions [7].

Previous reports have demonstrated the application of the hybrid algorithm. Contemporary intimal (antegrade (AWE) and retrograde wire escalation (RWE)) and subintimal (antegrade (ADR) and retrograde dissection and re-entry (RDR)) techniques efficiently increase success rates and safety of procedures, in the hands of both skilled and less experienced CTO operators [2–5,8–18]. Therefore, more patients are receiving treatment for CTO and lesions with higher complexity are tackled.

As more patients are being treated, the landscape of operators (and their experience level and skillset), performing CTO-PCI continues to develop as well. The Belgian Working Group on Chronic Total Occlusions (BWGCTO) aims to assess the evolution within the landscape of CTO-PCI in Belgium and Luxembourg over the next years [19]. Here, we report on the in-hospital outcomes and events after one year of inclusions.

## Methods

### Study population

From May 2016 onwards until June 2017, patients undergoing CTO-PCI were prospectively and consecutively included in the BWGCTO registry by CTO operators in a centre in Luxembourg and 23 centres in Belgium. The operators have different levels of experience with CTO-PCI techniques, ranging from AWE only to full hybrid operators. Operators performed the procedures and inclusions conforming to institutional guidelines. Each institutional ethics review board approved the study and all patients provided written informed consent.

### Study procedure

Patient selection for CTO-PCI was based on clinical symptoms and/or documented ischaemia and left ventricular viability. Operators were free to choose strategies, materials, and devices to use. Data on applied strategies were captured for all procedures. Clinical, angiographic, procedural, and outcome data were collected using a web-based reporting system (OpenClinica Community™, LCC, MA). Additional information was obtained by reviewing the medical records locally or via telephone contact, as needed. CTO lesion complexity was assessed using the Japanese CTO (J-CTO) score [20].

### Study definitions and endpoints

CTOs was defined as a lesion of a native coronary artery that exhibited thrombolysis in myocardial

infarction (TIMI) antegrade flow should be equal to zero for at least three months. Occlusion length was estimated from the angiographic image using dual arterial injection and/or the stent and balloon length as reference. Presence of calcification in the CTO segment was determined by fluoroscopy without contrast injection. An unsuitable distal landing zone was defined as the presence of significant distal coronary artery disease, and/or a distal lumen diameter <2 mm. Success was defined as successful CTO revascularization with achievement of <30% residual diameter stenosis within the stented segment and restoration of TIMI grade 3 antegrade flow in all major branches ( $\geq 2$  mm).

In-hospital major adverse cardiac and cerebrovascular events (MACCE) included death, peri-procedural myocardial infarction (MI) (i.e. (non-)ST segment elevated MI), stroke (cerebrovascular accident or transient ischaemic attack), target vessel failure (i.e. vessel re-occlusion during the index hospitalisation with or without intervention), and target vessel revascularization via PCI or coronary artery bypass graft surgery), and were counted mutually exclusive. An MI was defined as ongoing chest pain, electrocardiogram changes, and positive cardiac enzymes. Collection of cardiac enzymes was not mandatory. Patients in whom cardiac markers were routinely drawn post-procedure and were increased, but who were without clinical symptoms, were not considered to have clinically important MI, but rather procedural enzyme leaks (peri-procedural MI). Complications included life-threatening and major bleeding (Bleeding Academic Research Consortium criteria [21]), major vascular complications, acute cardiogenic shock, and renal failure requiring prolonged hospitalisation. Life-threatening bleeding was defined as fatal bleeding, bleeding in a critical area or organ (intracranial, intraspinal, intraocular, pericardial necessitating pericardiocentesis, or intramuscular with compartment syndrome), bleeding causing hypovolemic shock or severe hypotension requiring vasopressors or surgery, and overt source of bleeding with a drop in haemoglobin of  $\geq 5$  g/dl or whole blood/packed cells transfusion  $\geq 4$  units. Major bleeding was defined as access-related and retroperitoneal bleeding, associated with a haemoglobin level drop of at least 3 g/dl or requiring transfusion of  $\geq 2$  units whole blood/packed cells or causing prolonged hospitalisation or permanent injury, or requiring surgery, and included coronary perforation resulting in tamponade without the need of pericardiocentesis. Major complications included coronary perforation necessitating the use of unplanned endovascular (coronary graft/covered stents, coils, or fat

embolisation) or surgical intervention, and vascular access site or access-related vascular injury (dissection, perforation, arterio-venous fistula, or pseudoaneurysm, haematoma), both associated with or leading to death, life-threatening or major bleeding, visceral ischaemia or neurological impairment. Other major vascular complications included aortic dissection, access site-related nerve injury (permanent or requiring surgery), and any new ipsilateral lower extremity ischaemia, documented by symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram.

The primary aim was to assess the landscape of CTO-PCI in Belgium and Luxembourg and report on the outcomes and safety after one year of consecutive inclusions. Application and outcomes of the different individual techniques (AWE, ADR, RWE, and RDR), procedural safety characteristics (i.e. radiation doses, contrast volume, fluoroscopy times, etc.) and materials, and determination of in-hospital MACCE events were collected.

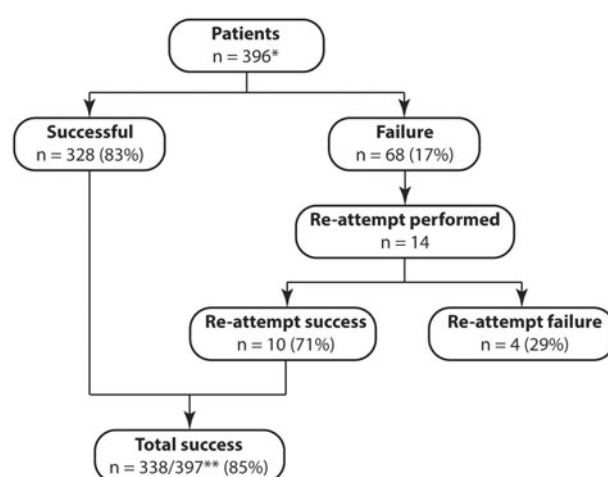
### Statistical analysis

Baseline, angiographic and procedural data were analysed using descriptive statistics. Numerical values were expressed as mean  $\pm$  standard deviation or median (interquartile range) as appropriate, while categorical variables were expressed as percentages. Normality was assessed using the Shapiro-Wilk statistic. Baseline characteristics were analysed patient-wise, based on the first index procedure. Patients could be included multiple times for a re-attempt of the same CTO lesion, a secondary CTO lesion treated at a later stage in time, or a second CTO lesion treated during the same procedure. Comparisons between groups were performed using Pearson's  $\chi^2$  tests for categorical variables and the independent Student's t-test, one-way analysis of variance, Mann-Whitney U test, or Kruskal-Wallis H test for continuous variables, as appropriate. Lesion-specific data (i.e. angiographic characteristics) were analysed using generalised and general linear mixed models as appropriate, with a random effect for patient (multiple procedures (i.e. inclusions) could be performed per patient. All statistical analyses were carried out using SPSS Statistics version 22 (IBM SPSS Inc., Chicago, IL).

## Results

### Demographics and angiographic characteristics

After one year of inclusion, 15 centres included 411 CTO-PCI procedures, performed in 388 patients



**Figure 1.** Flow chart depicting the patient-wise procedural outcomes. \*Unique patient-wise inclusion number, excluding any re-attempt procedures on the same CTO target vessel, but not excluding multiple inclusions due to treatment of a secondary CTO lesion. \*\*One patients had two repeat attempts on the same CTO lesion (i.e. total number of individual lesions = 397).

(Figure 1). Secondary CTO lesion were treated in four patients during the index procedure and in another four at a later stage in time. Fourteen patients had a repeat revascularization attempt (one patient had two re-attempts), meaning 397 CTO lesions were treated in total. Table 1 provides an overview of the number of procedures/ centres and volume. The majority of the population was male (81%) with an average age of  $64 \pm 11$  years. A high number of patients had hypertension (73%), dyslipidemia (85%), and a prior history of PCI (50%). Patients in whom the index procedure was unsuccessful ( $n=67$ ) were significantly older ( $67 \pm 10$  vs.  $63 \pm 11$  years,  $p=.037$ ) and had a higher frequency of prior stroke (14 vs. 7%,  $p=.020$ ), prior bypass surgery (29 vs. 12%,  $p < .001$ ), and prior bypass surgery on the CTO target vessel (21 vs. 8%,  $p=.002$ ), respectively, when compared to successful cases (Table 2).

The majority of the patients presented with stable angina (62%;  $n = 241/388$ ) and 46% ( $n = 180/388$ ) suffered from exertional dyspnoea. Ischaemia and viability testing of the target vessel region were performed in 78 ( $n = 301/388$ ) and 76% ( $n = 294/388$ ) of cases, with presence of ischaemia and viability in 95 ( $n = 286/301$ ) and 99% ( $n = 290/294$ ) of cases, respectively. The majority of the patients had a preserved left ventricular ejection fraction (74%) (Figure 2). CTO target vessels were: right coronary artery (62%), left anterior descending artery (24%), circumflex (14%), and left main coronary artery (0.2%). Overall J-CTO score was high ( $2.2 \pm 1.2$ ) and was significantly higher in centres

**Table 1.** Overview of inclusions per centre and volume.

Centre	Number of cases <sup>a</sup>	J-CTO score <sup>b</sup>	Average procedural success rate <sup>a</sup>
<i>High volume (&gt; 50)</i>	184	2.3 ± 1.3	149 (81)
Center 1	79	2.0 ± 1.3	63 (80)
Center 2	53	2.7 ± 1.1	47 (89)
Center 3	52	2.5 ± 1.5	39 (75)
<i>Intermediate volume (30–50)</i>	139	2.0 ± 1.1	118 (85)
Center 4	42	2.1 ± 1.0	34 (81)
Center 5	34	2.3 ± 1.1	29 (85)
Center 6	32	1.2 ± 2.3	28 (88)
Center 7	31	2.3 ± 1.0	27 (87)
<i>Low volume (&lt; 30)</i>	88	2.1 ± 1.2	71 (81)
Center 8	28	2.3 ± 1.1	19 (68)
Center 9	21	1.9 ± 1.2	18 (86)
Center 10	11	2.7 ± 1.1	10 (91)
Center 11	11	2.5 ± 0.7	9 (82)
Center 12	9	1.6 ± 1.5	9 (100)
Center 13	3	2.0 ± 1.7	2 (67)
Center 14	3	1.3 ± 1.2	2 (67)
Center 15	2	0.5 ± 0.7	2 (100)
<i>Total</i>	411	2.0 (1.0–3.0)	338 (82)

<sup>a</sup>Values expressed as mean ± SD, *n* or *n* (%).

<sup>b</sup>J-CTO score was significantly different between high, intermediate, and low volume centres ( $p = .045$ ). Average success rate per volume was not significantly different ( $p = .602$ ).

J-CTO: Japanese CTO score.

**Table 2.** Demographic characteristics.<sup>a</sup>

	Overall ( <i>n</i> = 388)	Technical success ( <i>n</i> = 321)	Technical failure ( <i>n</i> = 67)	<i>p</i> value
Age (years)	64 ± 11	63 ± 11	67 ± 10	<b>.037</b>
Male	313 (81)	260 (81)	53 (79)	.721
Current smoker	110 (28)	94 (29)	16 (24)	.365
Hypertension	284 (73)	230 (72)	54 (81)	.142
Dyslipidemia	329 (85)	277 (86)	52 (78)	.072
Diabetes mellitus	112 (29)	94 (29)	18 (27)	.691
OSAS	27 (7)	21 (7)	6 (9)	.472
Heart failure	48 (12)	42 (13)	6 (9)	.346
Previous MI	147 (38)	115 (36)	32 (48)	.073
Previous CABG	56 (15)	37 (12)	19 (29)	<b>&lt;.001</b>
Previous CABG on TV	41 (11)	27 (8)	14 (21)	<b>.002</b>
Previous PCI	195 (50)	158 (49)	37 (55)	.384
Previous stroke	27 (7)	18 (7)	9 (14)	<b>.020</b>
Peripheral vascular disease	63 (16)	47 (15)	16 (24)	.064
Chronic Kidney Insufficiency	54 (14)	42 (13)	12 (18)	.304

<sup>a</sup>Values expressed as mean ± SD or *n* (%).

CABG: coronary artery bypass grafting; MI: myocardial infarction; PCI: percutaneous coronary intervention; TV: target vessel.

Bold values are statistically significant  $p \leq .05$ .

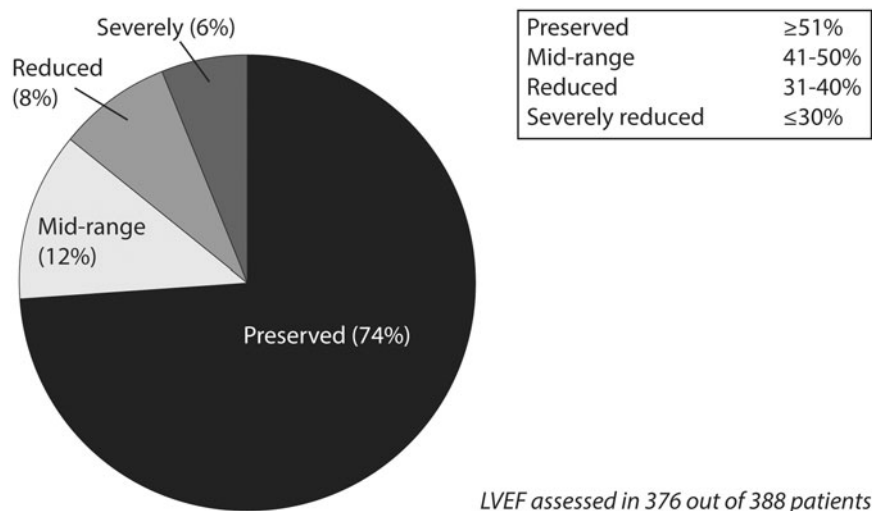
with a greater volume (high volume (>50 cases):  $2.3 \pm 1.3$  vs. intermediate (30–50 cases)  $2.0 \pm 1.1$  vs. low (<30 cases)  $2.1 \pm 1.2$ ;  $p = .045$ ). Overall, negative angiographic characteristics were significantly more present in failed procedures, when compared to successful procedures (Table 3).

### **In-hospital outcomes and techniques**

Overall, procedural success rate was 82% ( $n = 338/411$ ). Calculated success rates were 95% ( $n = 39/41$ ) for easy, 99% ( $n = 82/83$ ) for intermediate, 90% ( $n = 107/119$ ) for difficult, and 65% ( $n = 110/168$ ) for very difficult CTO lesions (i.e. J-CTO score). Patient-wise success rate corresponded to 83% ( $n = 328/396$ ) (excluding repeat revascularization attempts but

including treatment of secondary CTO lesions). Successful repeat attempts (71%;  $n = 10/14$ ) resulted in an average lesion success rate of 85% ( $n = 338/397$ ; Figure 1).

AWE was the most commonly applied technique (82%), followed by RDR (16%), ADR (15%), and RWE (14%). AWE was the successful technique in 72% ( $n = 242/338$ ), ADR in 11% ( $n = 37/338$ ), RWE in 6% ( $n = 20/338$ ), and RDR in 12% ( $n = 39/338$ ) of the successful cases. Application of the four techniques and outcomes per technique differed among centres (Table 4). Higher volume centres applied ADR and retrograde techniques in a higher extent as compared to lower volume centres. Besides this, ADR and RDR were more often applied and successful for lesions with J-CTO score  $\geq 2$  (Figure 3).



**Figure 2.** Left ventricular function of the BWGCTO population. LVEF: left ventricular ejection fraction.

**Table 3.** Angiographic characteristics.<sup>a</sup>

	Overall (n = 411)	Technical success (n = 338)	Technical failure (n = 73)	p value
Preserved LVEF ( $\geq 51\%$ )	279 (74)	233 (74)	46 (74)	.551
CTO target vessel				.964
LAD	99 (24)	84 (25)	15 (21)	
CX	58 (14)	49 (15)	9 (12)	
RCA	252 (62)	203 (60)	49 (67)	
LMCA	1 (0.2)	1 (0.3)	0 (0)	
Ostial lesion	49 (12)	35 (10)	14 (20)	<b>.036</b>
In-stent occlusion	43 (11)	37 (11)	6 (8)	.508
Lesion length $\geq 20$ mm	252 (61)	194 (57)	58 (80)	<b>.001</b>
Blunt stump	209 (51)	157 (46)	52 (71)	<b>&lt;.001</b>
Calcification	204 (50)	146 (43)	58 (80)	<b>&lt;.001</b>
Tortuosity $\geq 45^\circ$	132 (32)	97 (29)	35 (48)	<b>.003</b>
Re-attempt <sup>b</sup>	100 (24)	83 (25)	17 (23)	.739
J-CTO score	2.2 $\pm$ 1.2	2.0 $\pm$ 1.2	3.0 $\pm$ 0.9	<b>&lt;.001</b>
Proximal cap side-branch <sup>c</sup>	192 (47)	152 (45)	40 (55)	.154
Proximal cap ambiguity	186 (45)	134 (40)	52 (71)	<b>&lt;.001</b>
Lack of 'interventional' collaterals	186 (45)	158 (47)	28 (38)	.200
Diseased distal landing zone	159 (39)	118 (35)	41 (56)	<b>.001</b>
Distal cap at bifurcation	111 (27)	83 (25)	28 (38)	<b>.021</b>

<sup>a</sup>Values expressed as n (%), mean  $\pm$  SD or median, or interquartile range.

<sup>b</sup>Re-attempt defined as patient which were included for a second or third attempt of their CTO (i.e. already had a previous failed procedure).

<sup>c</sup>Side-branch with a diameter  $>2$  mm, within  $<5$  mm of the proximal CTO cap.

CTO: chronic total occlusion; LAD: left anterior descending artery; Cx: circumflex artery; J-CTO: Japanese CTO score; LL: lesion length; LMCA: left main coronary artery; LVEF: left ventricular ejection fraction; RCA: right coronary artery.

Bold values are statistically significant  $p \leq .05$ .

### Procedural parameters

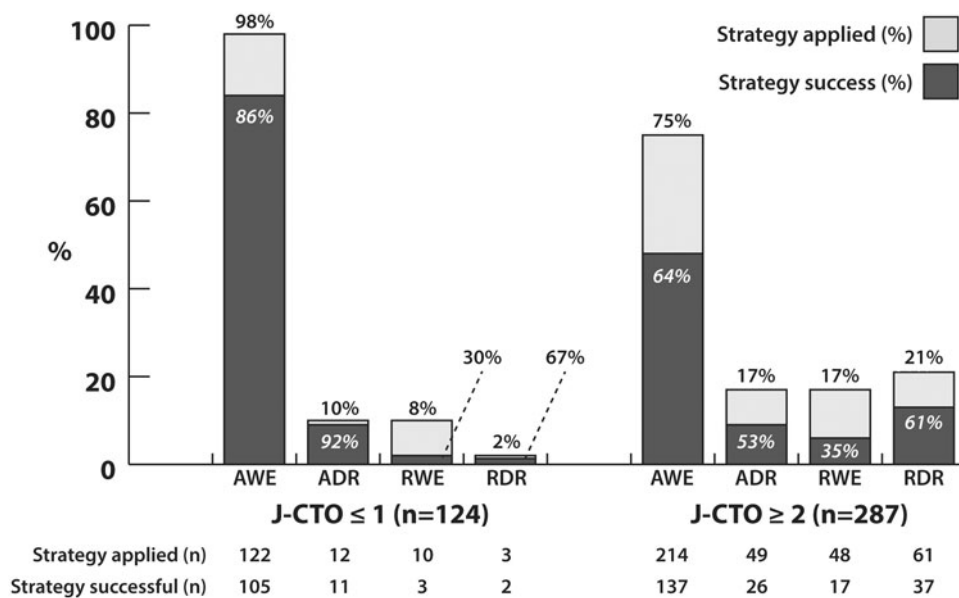
Dual catheter access was performed in 73% of cases and its use was more common in failed procedures (70 vs. 85%;  $p = .011$ ). Reasons for not using bilateral injection were complete antegrade visualisation by bridge and/or ipsilateral collaterals, or the absence of 'interventional' retrograde collaterals on diagnostic angiography (excluding a retrograde technique). A femoral access strategy was applied in 55%, radial access in 9%, and a combination in 36%. Average procedure and fluoroscopy times were 89 (57–120) and 33 min (19–55), respectively, air kerma dose was 1.8 Gy

(1.0–3.4) and contrast volume was 250 ml (180–325). Technical failure was associated with significantly higher procedural times, radiation doses, and contrast volume. On average, four (2–6) guidewires, two (2–4) balloons, one (1–2) microcatheters, and two (1–2) stents were used per procedure. Average stent length was  $64 \pm 30$  mm. Of note, stents were used in 99% of successful procedures ( $n = 333/338$ ), the remaining being treated only by plain balloon angioplasty. Significantly more guidewires and microcatheters were used in failed procedures, compared to successful procedures. Additional devices used included rotablator

**Table 4.** Overview of applied and successful techniques per centre and volume.<sup>a</sup>

Centre	AWE applied	AWE success	ADR applied	ADR success	RWE applied	RWE success	RDR applied	RDR success
<i>High volume (&gt;50)</i>	145 (79)	102 (70)	31 (17)	19 (61)	27 (15)	10 (37)	33 (18)	18 (55)
Center 1	60 (76)	41 (65)	16 (20)	7 (11)	16 (20)	5 (8)	20 (25)	10 (16)
Center 2	35 (66)	26 (55)	10 (19)	8 (17)	9 (17)	5 (11)	10 (19)	8 (17)
Center 3	50 (96)	35 (90)	5 (10)	4 (10)	2 (4)	0 (0)	3 (6)	0 (0)
<i>Intermediate volume (30–50)</i>	118 (85)	84 (71)	20 (14)	11 (55)	23 (17)	6 (26)	22 (16)	17 (77)
Center 4	39 (93)	28 (82)	4 (10)	1 (3)	3 (7)	1 (3)	6 (14)	4 (12)
Center 5	22 (65)	15 (52)	8 (24)	4 (14)	5 (15)	3 (10)	10 (29)	7 (24)
Center 6	28 (88)	23 (82)	4 (13)	3 (11)	8 (25)	1 (4)	1 (3)	1 (4)
Center 7	29 (94)	18 (67)	4 (13)	3 (11)	7 (23)	1 (4)	5 (16)	5 (19)
<i>Low volume (&lt; 30)</i>	73 (83)	56 (77)	10 (11)	7 (70)	8 (9)	4 (50)	9 (10)	4 (44)
Center 8	19 (68)	13 (68)	2 (7)	2 (11)	5 (18)	1 (5)	6 (21)	3 (16)
Center 9	19 (91)	16 (89)	1 (5)	1 (6)	1 (5)	1 (6)	2 (10)	0 (0)
Center 10	10 (91)	8 (80)	2 (18)	1 (10)	1 (9)	1 (10)	0 (0)	0 (0)
Center 11	11 (100)	9 (100)	2 (18)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Center 12	7 (78)	6 (67)	2 (22)	2 (22)	0 (0)	0 (0)	1 (11)	1 (11)
Center 13	3 (100)	1 (50)	0 (0)	0 (0)	1 (33)	1 (50)	0 (0)	0 (0)
Center 14	3 (100)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Center 15	1 (50)	1 (50)	1 (50)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)
<b>Total</b>	<b>336 (82)</b>	<b>242 (72)</b>	<b>61 (15)</b>	<b>37 (61)</b>	<b>58 (14)</b>	<b>20 (34)</b>	<b>64 (16)</b>	<b>39 (61)</b>

<sup>a</sup>Values expressed as n (%).



**Figure 3.** Application and outcomes of the different techniques according to J-CTO lesion complexity. Multiple different techniques could be applied at any stage (primary or subsequently) during the procedure. Outcomes are presented as percentage of applied total. ADR: antegrade dissection and re-entry; AWE: antegrade wire escalation; J-CTO: Japanese CTO score; RDR: retrograde dissection and re-entry; RWE: retrograde wire escalation.

(Boston Scientific, Marlborough, MA;  $0.02 \pm 0.14$ ), Tornus (Asahi Intecc Co., Japan;  $0.01 \pm 0.11$ ), mother-in-child guide catheters ( $0.16 \pm 0.37$ ), CrossBoss (Boston Scientific) ( $0.07 \pm 0.26$ ), and Stingray catheter (Boston Scientific) ( $0.07 \pm 0.25$ ) (Table 5).

### In-hospital events and complications

In-hospital MACCE occurred in 14 cases (3.4%). One patient died due to desaturation, hypotension, electro-mechanic dissociation, and ST segment elevated MI, probably related to diffuse peri-procedural ischaemia.

A non-ST segment elevated MI occurred in seven patients because of a lost side-branch, an occluded right ventricular branch (associated with ventricular fibrillation), and a left main (donor vessel) dissection induced by the guiding catheter. In the remaining four patients, the cause is unknown. Two patients exhibited a ST segment elevated MI: in one patient due to the loss of the posterolateral branch after successful subintimal tracking and re-entry, which was further complicated by post-procedural anaemia requiring transfusion (major bleeding); and in another due to diffuse ischaemia, resulting in death (as mentioned above). In two patients, an intramural contained

**Table 5.** Procedural parameters: classified according to outcome.<sup>a</sup>

	Overall (n = 411)	Technical success (n = 338)	Technical failure (n = 73)	p value
Dual catheter injection (%)	300 (73)	238 (70)	62 (85)	<b>.011</b>
Femoral access (%)	225 (55)	189 (56)	36 (50)	.609
Radial access (%)	36 (9)	29 (9)	7 (10)	
Femoral/Radial access (%)	146 (36)	117 (35)	29 (40)	
Procedure time (min)	89 (57–120)	80 (53–120)	110 (79–135)	<b>&lt;.001</b>
Fluoroscopy time (min)	33 (19–55)	29 (18–50)	47 (34–73)	<b>&lt;.001</b>
Air kerma dose (Gray)	1.8 (1.0–3.4)	1.7 (1.0–3.2)	2.0 (1.4–3.8)	<b>.021</b>
Contrast volume (ml)	250 (180–325)	250 (179–320)	270 (201–370)	<b>.013</b>
Guidewires (n)	4 (2–6)	3 (2–5)	5 (3–7)	<b>&lt;.001</b>
Balloons (n)	2 (2–4)	3 (2–4)	1 (0–2)	<b>&lt;.001</b>
Stents (n)	2 (1–2)	2 (1–3)	0 (0–0)	<b>&lt;.001</b>
Stent length (mm)	64 ± 30	64 ± 30	64 ± 40	.948
Microcatheters (n)	1 (1–2)	1 (1–2)	1 (1–2)	<b>.009</b>

<sup>a</sup>Values expressed as n (%), mean ± SD or median, interquartile range. Bold values are statistically significant  $p \leq .05$ .

haematoma (increased troponins next day) and a sub-intimal haematoma resulted in a MI (not further defined), without further clinical consequences. Target vessel revascularization took place in one patient. A transient ischaemic attack occurred in two patients post-PCI.

The following major peripheral vascular complications ( $n = 8$ ) occurred: pseudoaneurysm treated with embolisation ( $n = 1$ ), requiring prolonged hospitalisation ( $n = 1$ ) or requiring thrombin injection ( $n = 4$ ) (one of which was complicated by a haemoglobin drop necessitating two units of packed cells, and an intra-septal haematoma with collateral vessel perforation, resulting in tamponade (treated with drainage); a vascular closure device failure resulted in acute limb ischaemia necessitating urgent vascular surgery, and was further complicated by renal failure. Apart from this, the patient also had pericardial effusion; a retro-peritoneal bleed at the puncture site resulted in a major bleeding. Major coronary vascular complications included two guidewire perforations requiring coiling (no bleeding, no tamponade), two pericardial tamponades requiring drainage (one as described above), and one donor vessel dissection resolved by stent implantation. Subintimal haematomas not mentioned before and angiographically visible, took place in four patients, of which one resulted in pericardial effusion.

## Discussion

The BWGCTO group evaluated the landscape of CTO-PCI in Belgium and Luxembourg and will continue to assess the evolution over the next years. In this paper, we report the in-hospital outcomes and events after one year of inclusion in the BWGCTO registry. The main study findings are: (1) a high technical success rate is reached in a relatively complex population by operators with mixed experience levels and skillsets; (2) in-hospital events and complications were

acceptably low; and (3) AWE is the preferred strategy. Conversely, the application and outcomes of more complex (ADR, RWE, or RDR) techniques differs amongst operators.

Throughout the last number of years, significant developments in CTO-dedicated materials, devices, techniques, and algorithms have occurred in CTO-PCI. With contemporary wire-based and dissection and re-entry techniques, top expert operators are able to reach >90% success rates [2–4,17]. However, a similar amount of success (>85%) is achievable by moderate to highly experienced operators and in an equally safe manner [5].

A recent meta-analysis showed important benefits of successful CTO-PCI regarding mortality, myocardial infarction, bypass graft surgery, stroke, and angina (but not target vessel revascularization) during follow-up [2]. Furthermore, the first results of the randomised DECISION and European Registry of Chronic Total Occlusion (EUROCTO) trials were recently presented: the DECISION trial failed to show significant differences between CTO-PCI and optimal medical therapy. However, this study had several important study limitations. On the other hand, the EUROCTO trial demonstrated comparable 12-month MACCE rates to optimal medical therapy, but more importantly a significantly better quality of life as well as freedom from angina in favour of CTO-PCI [7,22].

In Belgium, approximately 24000 PCIs are performed yearly. A CTO is observed on average in 16% of patients with significant coronary artery disease [23,24]. Of these, less than 10% will be treated via PCI and the remaining medically (64%) or via surgery (26%) [18,23,25,26]. In our study, a mixed population of operators with a low, moderate, or high level of experience included 411 CTO-PCI procedures, during a period of one year, indicating the rate of CTO-PCI in the BeLux is considerably below 5%. However, despite that the majority of Belgian CTO-PCI centres are



enrolled in our registry, most likely not all CTO procedures will be included. In addition, not all participating centres started inclusions at the same time.

Overall success in the BWGCTO registry was high (82%), comparable to a recent US report (79.7%) and higher than the report by Morino et al. (75.9%) [18,20]. Moreover, this level of success was obtained with a low number of events and in a relatively complex CTO lesion population ( $2.2 \pm 1.2$ ), supporting contemporary CTO-PCI for a wide spectrum of CTO lesion complexities. The in-hospital MACE rate of 3.4% in our registry is similar to the pooled estimate MACE rate of 3.1% in a recent large meta-analysis of 65 studies including 18,061 patients undergoing CTO-PCI [3]. Procedural parameters were acceptable and in line with other studies.

In our registry, centres with a higher volume of inclusions treated significantly more complex CTO lesions. These centres are more experienced, have an overall greater annual volume per year, and treat an overall higher lesion complexity, compared to lower volume and starting centres. Given these centres included more patients in our registry, there could potentially be a shift towards overall higher complexity. Less experienced or AWE-only operators tend to limit CTO-PCI treatment to lesions with lower complexity (i.e. potential selection bias). Without independent core laboratory analysis, reporting of angiographic lesion characteristics is operator-dependent, and assessment of these characteristics is therefore prone to subjective bias.

Centers with a greater volume of inclusions performed (or needed) more complex techniques (ADR, RWE, and/or RDR). Yet, the overall frequency of ADR and retrograde techniques is lower, compared to previously reported results (ranging in-between 20–30% for ADR and 25–40% for retrograde strategies) [4,5,11,12]. In these studies, AWE was also the most applied technique (most commonly as primary strategy). However, it also demonstrates the importance and need for more complex techniques upon greater lesion complexity (most commonly as bail-out strategy). Apart from differences in CTO complexity, the observation that ADR and retrograde techniques are less frequently applied, compared to higher volume centres, might also come from the lower experience level with these techniques, and their specific devices (e.g. CrossBoss, Stingray; Boston Scientific, Marlborough, MA), which might result in reluctance to apply them and potentially in an unsuccessful procedure. With experience comes the use of more complex techniques.

The availability of a broad operator skillset including all contemporary techniques – is imperative to obtain

and further increase technical outcomes. In order to make CTO-PCI more accessible to interventional cardiologists and consequently also to the patients that have an indication for treatment, we should continuously strive for further development of new and/or improved easy-to-use algorithms, materials and devices (guidewires, microcatheters, guide-extensions, trapping devices, etc.). This will help overcome high lesion complexity and improve procedural outcomes, reduce procedure time, and increase safety (e.g. less induction of ischaemia by retrograde equipment due to shorter procedure time). It will be interesting to assess how the landscape of Belgium and Luxembourg will evolve over the next couple of years.

### **Study limitations**

This study has several limitations. First, not all centres started inclusion at the same time due to regulatory issues (ethical committee approval). Second, the choice in techniques, materials, and devices was operator-dependent and could thus influence outcomes. Third, procedural outcomes as well as lesion-specific angiographic characteristics are operator-reported, without an independent core lab, due to financial constraints. Lastly, the number of peri-procedural MIs could be underreported as this too is operator-reported and collection of cardiac enzymes was not mandatory.

### **Conclusions**

The BWGCTO study results demonstrated satisfactory technical and safety outcomes in a complex CTO population when applied by operators with varying skillsets, ranging from a low to a high level of experience. Antegrade wiring is the preferred strategy, while the application of ADR and retrograde techniques vary among operators. In the future, data from the BWGCTO registry will continue to allow the evolutions and longer-term outcomes within the landscape of CTO-PCI in Belgium and Luxembourg to be assessed.

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