Use of the DyeVert System in Chronic Total Occlusion Percutaneous Coronary Intervention

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ABSTRACT: Background. Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) often requires administration of large contrast volume. The DyeVert system (Osprey Medical) is a disposable, Food and Drug Administration (FDA)-approved device that interfaces with standard manifold systems to reduce the amount of contrast used in cardiac catheterization. **Methods.** We compared the procedural outcomes of patients in whom the DyeVert system was used vs those in whom it was not used during CTO-PCI at a single center between 2017 and 2018. **Results.** The DyeVert system was used in 39 of 134 CTO-PCIs performed in 130 patients (30%). Most patients (79%) were men and the mean age was 66.6 ± 10.9 years. The most common target vessel was the right coronary artery (54.5%), followed by the left anterior descending artery (26.1%), and circumflex artery (15.7%). The median contrast volume used in DyeVert patients was significantly lower (200 mL [interquartile range, 153-256 mL] vs 250 mL [interquartile range, 170-303 mL]; *P*=.04). There were no in-hospital major complications with the DyeVert system, nor device-related procedural complications. One patient in the DyeVert group had contrast-induced nephropathy following CTO-PCI that did not require dialysis. **Conclusion.** Use of the DyeVert system is feasible during CTO-PCI and may reduce the contrast volume administered to the patient. Additional larger studies with a primary clinical endpoint are needed to confirm these findings.

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KEY WORDS: acute outcomes, chronic total occlusion, contrast reduction, percutaneous coronary intervention

It is estimated that 7% of patients undergoing percutaneous coronary intervention (PCI) experience contrast-associated acute kidney injury (CAAKI), a complication strongly associated with adverse clinical outcomes, including death and increased hospital costs and length of stay.[1-5] Current guidelines recommend preprocedural assessment of risk for CAAKI prior to PCI and adequate preparatory intravascular volume expansion in high-risk patients.[6] Among patients undergoing CTO-PCI in PROGRESS CTO (the Prospective Global Registry for the Study of Chronic Total Occlusion Intervention), 27% had chronic kidney disease (CKD)[7] and these patients had a higher in-hospital mortality and in-hospital major adverse cardiovascular event (MACE) rate.[7] Previous strategies to reduce CAAKI among patients undergoing PCI have proven unsuccessful,[8] highlighting the need for novel approaches. The DyeVert system (Osprey Medical) is a disposable device that interfaces with standard manifold systems to reduce the amount of contrast delivered to patients in catheterization procedures, while maintaining fluoroscopic image opacity.[9] In a randomized controlled trial of patients scheduled for diagnostic coronary angiogram, DyeVert use resulted in approximately 40% contrast savings;[10,11] however, no study has assessed its use in CTO-PCI or complex interventions that are usually associated with higher dose of contrast administration compared with non-CTO interventions.[12] We examined outcomes associated with the use of the DyeVert system in CTO-PCI patients at a single center.

Methods

We analyzed the clinical, angiographic, and procedural characteristics of 134 consecutive CTO-PCIs performed in 130 patients enrolled in PROGRESS CTO between 2017 and 2018 at Abbott Northwestern Hospital in Minneapolis, Minnesota. The DyeVert system was routinely used for CTO-PCI from May 2018 onward. The study was approved by the institutional review board of the Minneapolis Heart Institute at Abbott Northwestern Hospital.

Coronary CTOs were defined as coronary lesions with Thrombolysis in Myocardial Infarction (TIMI) grade 0 flow of at least 3-month duration. *Estimation of the duration of occlusion* was clinical, based on the first onset of angina, prior history of myocardial infarction in the target-vessel territory, or comparison with a prior angiogram. *Calcification* was assessed by angiography as mild (spots), moderate (involving ≤50% of the reference lesion diameter), or severe (involving >50% of the reference lesion diameter). *Moderate proximal vessel tortuosity* was defined as the presence of at least 2 bends >70° or 1 bend >90° and severe tortuosity as 2 bends >90° or 1 bend >120° in the CTO vessel. *Blunt or no stump* was defined as lack of tapering or lack of a funnel shape at the proximal cap. *Interventional collaterals* were defined as collaterals considered

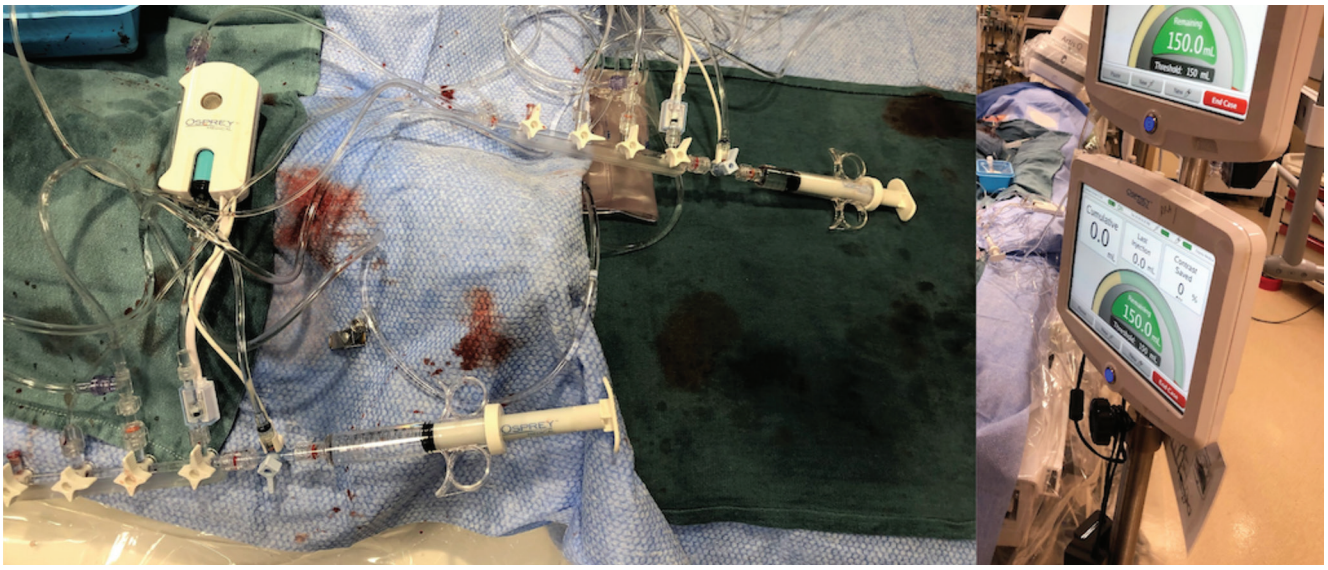

FIGURE 1. The DyeVert system in use.

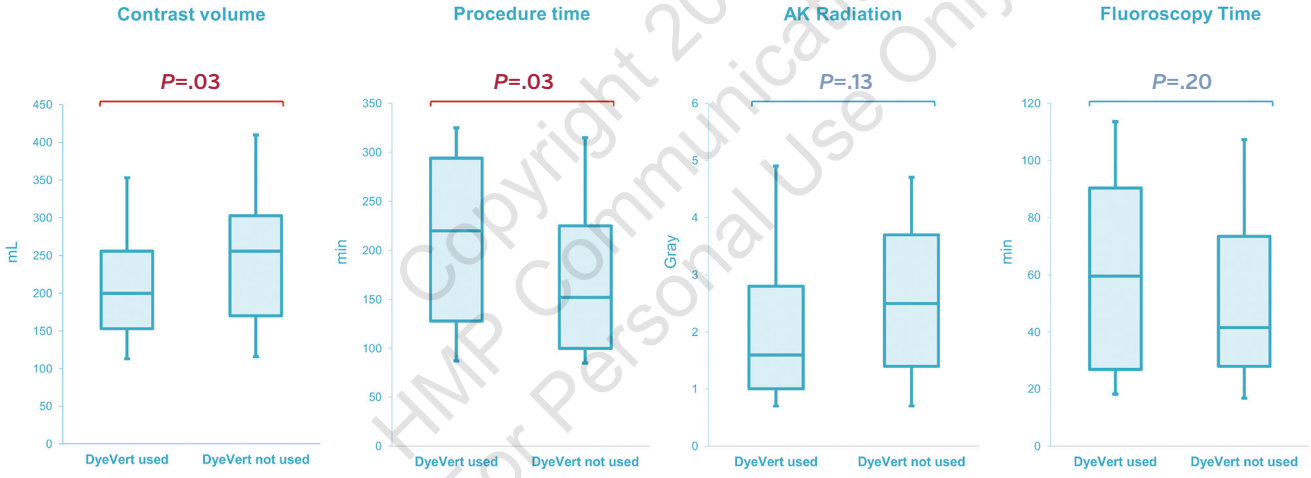

FIGURE 2. Contrast volume, procedure time, air kerma radiation dose, and fluoroscopy time in the study patients classified according to use of the DyeVert system.

amenable to crossing by a guidewire and a microcatheter by the operator.

A procedure was defined as *retrograde* if an attempt was made to cross the lesion through a collateral vessel or bypass graft supplying the target vessel distal to the lesion; otherwise, the procedure was classified as *antegrade only*. *Antegrade dissection/re-entry* was defined as antegrade PCI during which a guidewire was intentionally introduced into the subintimal space proximal to the lesion, or re-entry into the distal true lumen was attempted following intentional or inadvertent subintimal guidewire crossing.

Technical success was defined as successful CTO revascularization with achievement of <30% residual diameter stenosis within the treated segment and restoration of TIMI grade 3 antegrade flow. *Procedural success* was defined as the achievement of technical success without any in-hospital complications. *In-hospital MACE* included any of the following adverse events prior to hospital discharge: death, myocardial infarction, recurrent symptoms requiring urgent repeat target-vessel revascularization with PCI or coronary artery bypass graft surgery (CABG), tamponade requiring either pericardiocentesis or surgery, and stroke. *Myocardial infarction* was defined using the Third Universal Definition of Myocardial Infarction (type 4a MI).[13] *Major bleeding* was defined as bleeding causing reduction in hemoglobin >3 g/dL or bleeding requiring transfusion or surgical intervention. The *J-CTO score* was calculated as described by Morino et al,[14] the *PROGRESS CTO score* as described by Christopoulos

Table 1. Clinical characteristics of the study patients, classified according to use of the DyeVert system.

Variable	Overall (n = 130)	DyeVert Used (n = 39)	DyeVert Not Used (n = 91)	*P*-Value
Age (years)	66.6 ± 10.9	67.7 ± 8.9	66.1 ± 11.7	.38
Men	79.2%	82.1%	78.0%	.60
Body mass index (kg/m²)	31.1 ± 6.3	29.95 ± 6.2	31.6 ± 6.3	.18
CAD presentation				.30
Acute coronary syndromes	18.5%	23.1%	16.5%	
Stable angina	63.8%	61.5%	8.8%	
Other*	10.8%	15.4%	74.7%	
Diabetes mellitus	43.9%	48.7%	41.8%	.46
Dyslipidemia	96.9%	94.9%	97.8%	.37
Hypertension	90.8%	89.7%	82.6%	.79
Smoking (current)	26.2%	15.4%	30.8%	.07
Left ventricular ejection fraction (%)	52.3 ± 13.7	52.6 ± 16.0	52.2 ± 12.7	.91
Family history of CAD	46.9%	60.5%	41.1%	.04
Congestive heart failure	20.0%	20.5%	19.8%	.92
Prior myocardial infarction	40.0%	53.9%	34.1%	.04
Prior coronary artery bypass graft	40.8%	48.7%	37.4%	.23
Prior PCI	65.4%	71.8%	62.6%	.32
Prior cerebrovascular disease	9.3%	15.4%	6.7%	.18
Prior peripheral vascular disease	10.2%	20.5%	5.6%	.01
Chronic pulmonary disease	14.7%	12.8%	15.6%	.69
Currently on dialysis	3.1%	2.6%	3.3%	.77
eGFR (mL/min/1.73 m²)	73.4 (56.8-86.9)	71.6 (54.6-82.5)	77.1 (57.0-88.9)	.26
Baseline creatinine (mg/dL)	1.1 (0.9-1.2)	1.1 (0.9-1.2)	1.0 (0.9-1.2)	.50

Data presented as mean ± standard deviation, percentage, or median (interquartile range).
*Other includes asymptomatic patients and patients with atypical angina symptoms.
CAD = coronary artery disease; eGFR = estimated glomerular filtration rate; MI = myocardial infarction; PCI = percutaneous coronary intervention.

et al,[15] and the *PROGRESS CTO Complications score* as described by Danek et al.[16]

Statistical analysis. Categorical variables are expressed as percentages and were compared using Pearson's Chi-square test or Fisher's exact test. Continuous variables are presented as mean ± standard deviation or median (interquartile range [IQR]) unless otherwise specified and were compared using the t-test and one-way analysis of variance (ANOVA) for normally distributed variables; the Wilcoxon rank-sum test and the Kruskal-Wallis test were applied for non-parametric continuous variables, as appropriate. All statistical analyses were performed with JMP 13.0 (SAS Institute). A two-sided *P*-value of .05 was considered statistically significant.

Results

Of the 134 CTO-PCIs attempted in 130 patients during the study period, a total of 39 patients (30.0%) underwent CTO intervention with the DyeVert system and were compared with the remaining 91 patients (70.0%) in whom the contrast reduction system was not used. One patient in the DyeVert group had 2 CTO-PCIs attempted during the same procedure, while 3 patients underwent PCI attempt of 2 CTOs in the control group.

Mean patient age was 66.6 ± 10.9 years and most (79.2%) were men. The prevalence of coronary artery disease risk factors (diabetes mellitus, hypertension, current smoking, and history of coronary artery disease) was similar in the DyeVert group vs the non-DyeVert group (Table 1). Baseline left ventricular ejection fraction was 52.3 ± 13.7%, and most patients (63.8%) presented with stable angina. Four patients were on dialysis at the time of CTO-PCI, with no significant difference in the DyeVert group vs the non-DyeVert group (2.6% vs 3.3%, respectively; *P*=.77). Baseline creatinine volumes and calculated estimated glomerular filtration rates were similar in both groups (*P*=.50 and *P*=.26, respectively) (Table 1).

The most common target vessel was the right coronary artery (54.5%), left anterior descending artery (26.1%), and circumflex artery (15.7%). The anatomic characteristics of the

Table 2. Angiographic characteristics of the study lesions classified according to the use of DyeVert system.

Variable	Overall (n = 134)	DyeVert Used (n = 40)	DyeVert Not Used (n = 94)	*P*-Value
Target vessel				.65
Right coronary artery	54.5%	50.0%	56.4%	
Left anterior descending	26.1%	30.0%	24.5%	
Left main	2.2%	0.0%	3.2%	
Circumflex	15.7%	20.0%	13.8%	
Other*	0.8%	0.0%	1.1%	
Saphenous vein graft	0.8%	0.0%	1.1%	
CTO length (mm)	30 (20-43)	40 (30-50)	30 (15-40)	.18
Vessel diameter (mm)	2.5 (2.0-3.0)	2.5 (2.0-3.0)	2.5 (2.0-3.0)	.66
Proximal cap ambiguity	40.3%	42.5%	39.4%	.74
Side branch at proximal cap	56.8%	52.6%	58.5%	.54
Blunt stump/no stump	41.8%	45.0%	40.4%	.63
Interventional collaterals	59.0%	55.0%	60.6%	.54
Moderate/severe calcification	61.9%	60.0%	62.8%	.76
Moderate/severe tortuosity	37.3%	42.5%	35.1%	.42
In-stent restenosis	15.8%	17.5%	15.1%	.72
Prior failed CTO-PCI	18.7%	15.0%	20.2%	.48
J-CTO score	2.8 ± 1.2	2.9 ± 1.3	2.8 ± 1.2	.69
PROGRESS CTO score	1.4 ± 1.0	1.5 ± 0.9	1.3 ± 1.1	.45
PROGRESS CTO Complication score	3.7 ± 1.9	3.8 ± 2.2	3.6 ± 1.7	.66

Data presented as mean ± standard deviation, percentage, or median (interquartile range).
*Other includes diagonal and ramus branches.
CTO = chronic total occlusion; J = Japan; PCI = percutaneous coronary intervention; PROGRESS = Prospective Global Registry of Chronic Total Occlusion Interventions.

study lesions were similar in both groups (Table 2). The overall J-CTO scores (2.8 ± 1.2), PROGRESS CTO scores (1.4 ± 1.0), and PROGRESS CTO Complications scores (3.7 ± 1.9) were high.

The overall technical and procedural success rates were 86.6% and 86.2%, respectively, and were similar in the DyeVert and non-DyeVert groups (*P*=.37 and *P*=.61, respectively). The most commonly applied crossing strategy was antegrade wiring (87.3%) in both groups; however, antegrade dissection re-entry and the retrograde approaches were also frequently used (40.3% and 43.3%) (Table 3). Antegrade wiring was the most common initial crossing technique (79.1%); however, it was successful in only 39.6% of all cases. Antegrade dissection re-entry and the retrograde approach were the final successful crossing techniques in the remaining cases (24.6% and 23.1%, respectively). Dual angiography was performed in most cases (82.1%); however, radial access was more often used in the DyeVert group (50.0% vs 16.0% in the non-DyeVert group; *P*<.001). The number of access sites (2 [IQR 2-2] vs 2 [IQR 2-2]; *P*=.26) and sheath sizes (7.5 Fr [IQR, 7.5-8.0 Fr] vs 8.0 Fr [IQR, 7.5-8.0 Fr]; *P*=.05) were similar in both groups. Procedure time was significantly longer in the DyeVert group (220 min [IQR, 128-294 min] vs 152 min [IQR, 100-225 min]; *P*=.03), whereas fluoroscopy time (59.6 min [IQR, 27.0-90.4 min] vs 41.6 min [IQR, 28.0-73.5 min]; *P*=.20) and air kerma radiation dose were similar in both groups (1.6 Gy [IQR, 1.0-2.8 Gy] vs 2.5 Gy [IQR, 1.4-3.7 Gy]; *P*=.13) (Table 4).

The median contrast volume in the DyeVert group was significantly less (200 mL [IQR, 153-256 mL]) than in the non-DyeVert group (250 mL [IQR, 170-303 mL]; *P*=.04) (Figure 2). The most commonly used contrast media with the DyeVert system was iodixanol (Visipaque; GE Healthcare) in 79.5%, whereas iohexol (Omnipaque; GE Healthcare) was used in the remaining patients.

The incidence of in-hospital MACE rate was low (0.77%), and similar in the DyeVert and non-DyeVert groups (0.00% vs 2.20%, respectively; *P*>.99). One patient had ischemic stroke following the CTO-PCI, and 1 patient had periprocedural myocardial infarction likely due to side branch loss. Any procedural complications also occurred with similar frequency in both groups (15.4% vs 15.4%; *P*>.99) and are summarized in Table 4. No device-related complications occurred; however, postprocedural AKI was reported in 3

Table 3. Technical characteristics of the study procedures classified according to the use of DyeVert system.

Variable	Overall (n = 134)	DyeVert Used (n = 40)	DyeVert Not Used (n = 94)	*P*-Value
Dual injection	82.1%	85.0%	80.9%	.57
Crossing strategies used				
AWE	87.3%	85.0%	88.3%	.60
ADR	40.3%	42.5%	39.4%	.74
Retrograde	43.3%	47.5%	41.5%	.52
First crossing strategy				.75
AWE	79.1%	80.0%	78.7%	
ADR	7.5%	5.0%	8.5%	
Retrograde	13.4%	15.0%	12.8%	
Final crossing strategy				.53
AWE	39.6%	42.5%	38.3%	
ADR	24.6%	27.5%	23.4%	
Retrograde	23.1%	15.0%	26.6%	
None	12.7%	15.0%	11.7%	
Balloon uncrossable lesions	24.4%	25.0%	24.2%	.92
Balloon undilatable lesions	18.0%	27.3%	14.6%	.11
Access site				
Right femoral	92.5%	95.0%	91.5%	.48
Left femoral	67.2%	50.0%	74.5%	<.01
Right radial	20.9%	45.0%	10.6%	<.001
Left radial	7.5%	5.0%	8.5%	.72
Number of access sites (n)	2 (2-2)	2 (2-2)	2 (2-2)	.26
Average sheath size (mm)	8.0 (7.5-8.0)	7.5 (7.5-8.0)	8.0 (7.5-8.0)	.05

Data presented as percentage or median (interquartile range).
ADR = antegrade dissection re-entry; AWE = antegrade wire escalation.

patients (1 in the DyeVert group [not requiring dialysis] and 2 in the non-DyeVert group [1 patient required dialysis during the hospital stay]).

Discussion

The main finding of our study is that the DyeVert system can be used during CTO-PCI and was associated with administration of less contrast volume.

Complications related to contrast administration during cardiac catheterization can be categorized into quantitative (contrast volume) and qualitative (contrast type) complication subgroups. Contrast-induced nephropathy is a dose-dependent complication, the likelihood of which could potentially be reduced using various strategies, such as: (1) limiting total volume to <3.7x the patient's creatinine clearance;[17] (2) using iso-osmolar contrast media; (3) performing microinjections through microcatheters when feasible instead of guide injections; (4) using intravascular ultrasound instead of angiography if possible; (5) using various landmarks to guide wiring and equipment delivery; (6) pre- and postprocedural hydration; (7) staging interventions instead of performing multivessel or multilesion PCI during the same setting; and (8) use of contrast-reduction systems, such as the DyeVert system.

The DyeVert system consists of a contrast-monitoring wireless (CMW) display and the DyeVert Plus disposable kit, which is inclusive of a disposable, single-use sterile Smart Syringe and the DyeVert Plus module. The DyeVert Plus disposable kit is intended to be used with the CMW to allow monitoring and display of contrast volumes manually injected. Volumes are displayed and compared with the physician-entered contrast usage threshold during angiographic procedures on the CMW. A prior study showed that the DyeVert system was accurate when compared with direct manual measurement of contrast and was superior to physician estimate of contrast volume used.[18]

Since the introduction of the DyeVert system in 2017,[9] only a few studies have reported a beneficial effect from reducing contrast media use during diagnostic angiography and peripheral interventions. A prior randomized controlled study by Desch et al including 96 patients showed that the

Table 4. Procedural characteristics of the study interventions classified according to use of the DyeVert system.

Variable	Overall (n = 130)	DyeVert Used (n = 39)	DyeVert Not Used (n = 91)	*P*-value
Technical success*	86.6%	82.5%	88.3%	.37
Procedural success	86.2%	82.1%	87.9%	.38
Non-CTO PCI	22.0%	30.0%	18.5%	.14
Length of hospital stay (days)	1 (1-2)	1 (1-1)	1 (1-2)	.06
Procedural time (min)	167 (110-247)	220 (128-294)	152 (100-225)	.03
Fluoroscopy time (min)	48.1 (28.0-81.3)	59.6 (27.0-90.4)	41.6 (28.0-73.5)	.20
Contrast volume (mL)	239 (160-300)	200 (153-256)	250 (170-303)	.03
Air kerma radiation (Gray)	2.1 (1.3-3.5)	1.64 (1.0-2.8)	2.45 (1.4-3.7)	.13
Major adverse cardiac event	0.77%	0.00%	1.10%	>.99
Death	0.00%	0.00%	0.00%	–
Acute myocardial infarction	0.77%	0.00%	1.10%	>.99
Re-PCI	0.00%	0.00%	0.00%	–
Stroke	0.77%	0.00%	1.10%	>.99
Emergency coronary artery bypass graft	0.00%	0.00%	0.00%	–
Pericardiocentesis	0.00%	0.00%	0.00%	–
Procedural complications	15.4%	15.4%	15.4%	>.99
Perforation	4.62%	5.13%	4.40%	.86
Vascular access complication	3.08%	2.56%	2.80%	>.99
Bleeding	1.54%	0.00%	2.20%	>.99
Acute kidney injury	2.31%	0.90%	2.20%	>.99
Aortocoronary dissection	1.54%	2.56%	1.10%	.51
Other	4.62%	7.69%	3.30%	.36
Postprocedural renal function				
eGFR at discharge (mL/min/1.73 m²)	74.3 (58.1-87.7)	73.2 (60.4-85.0)	78.3 (55.4-93.0)	.42
Creatinine at discharge (mg/dL)	1.0 (0.8-1.2)	1.0 (0.8-1.2)	1.0 (0.8-1.2)	.70
Change in eGFR (mL/min/1.73 m²)	-2.8 (-10.7-1.1)	-2.9 (-10.7-0.7)	-1.6 (-11.1 -4.2)	.90
Change in creatinine (mg/dL)	0.1 (0.0-0.1)	0.1 (0.0-0.1)	0.0 (-0.1 -0.1)	.77

Data presented as percentage or median (interquartile range).
*Technical success is calculated on a per-lesion basis.
CTO = chronic total occlusion; eGFR = estimated glomerular filtration rate; PCI = percutaneous coronary intervention.

DyeVert device leads to significant reduction of contrast media in patients undergoing diagnostic angiography (41.0%) without reduction of the image quality.[19] Our observational retrospective study showed 20% lower contrast media volume in patients undergoing CTO-PCI. The slight difference in antegrade and retrograde guiding catheter size (1.1%) is due to selection of larger guiding catheters for stronger antegrade support and smaller guide catheters for the retrograde approach.[20] Reducing contrast administration in CTO-PCI may be more challenging than non-CTO procedures due to the use of larger catheter sizes and need for dual injection. Guide injections through larger catheters do not provide as much resistance, decreasing contrast diversion. Procedure time was significantly higher with the DyeVert group; however, the radial approach was more frequently used in the DyeVert group but did not result in higher radiation dose or fluoroscopy time (Figure 2). In addition, smaller sheath sizes were used in the DyeVert group (7.5 Fr [IQR, 7.5-8.0 Fr] vs 8.0 Fr [IQR, 7.5-8.0 Fr]; *P*=.05), likely because of higher frequency of radial access in the latter group.

Study limitations. First, we only included in-hospital outcomes without long-term follow-up. Second, there was no core laboratory assessment of the study angiograms or clinical event adjudication. Third, the procedures were performed in a dedicated CTO center by experienced operators, limiting the extrapolation to less-experienced operators and centers. Fourth, we did not perform standardized creatinine measurements post PCI, which may have led to under-estimation of the frequency of contrast nephropathy. Fifth, the guide size was slightly smaller in the DyeVert

group, which could have contributed to the lower contrast volume administered.

Conclusion

Use of the DyeVert system is feasible during CTO-PCI and may reduce the contrast volume administered to the patient. Additional larger studies with a primary clinical endpoint are needed to confirm these findings.

Acknowledgments. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Texas Southwestern Medical Center. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

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