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Early clinical experiences with a novel contrast volume reduction system during invasive coronary angiography

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1. Introduction

The use of contrast media (CM) in diagnostic and interventional cardiology is increasing worldwide, while treated patients become older and suffer from more comorbidities. CM is associated with multiple adverse effects (AE) - ranging from clinically insignificant to life-threatening [1]. Guidelines recommend reducing the amount of administered CM as low as reasonably possible [2]. However, following this recommendation in daily practice remains difficult and CM volumes vary greatly [3]. Great efforts have been undertaken to develop contrast-sparing devices [4]: One of the first was the manual stopcock-manifold and hand-held syringe arrangement, which has been used as the standard technique for CM administration for decades. Later, automated contrast injection systems have been developed to optimize workflow efficiency and reduce both CM volume delivery and fluoroscopy time under controlled injection settings [5]. Parallel, the DyeVert system was introduced [6,7]. In brief, this system works as a fluid pathway resistance modulator to reduce CM over-injection via a dedicated diversion valve. The valve is connected to a secondary fluid pathway and works dependent on the injection pressure. In consequence, it diverts some of the CM into the reservoir chamber within the module. The saved overflow would otherwise be injected to the patient as aortic reflux without any positive effects on angiographic image quality. So far, the DyeVert™ Plus was incompatible with power injection systems and was thus restricted to use with the conventional stopcock-manifold-syringe system. However, the DyeVert™ Power XT Contrast Reduction System (DyeVert Power XT System; Osprey Medical, Minnetonka, MN, USA) has now been specifically designed to work in combination with ACIST CVi Contrast Delivery System (ACIST, ACIST Medical Systems, Eden Prairie, MN, USA). This short report summarizes our first experience combining the DyeVert Power XT System with ACIST in a consecutive patient population undergoing diagnostic or interventional ICA at our institution.

2. Methods

We performed this retrospective pilot study using our ethics committee-approved institutional clinical database. We included all patients, who underwent diagnostic and interventional ICA procedures on two consecutive days in November 2018 at our institution using the DyeVert Power XT System in combination with ACIST. We had no specific exclusion criteria. Our primary endpoint was the difference between the amount of the injected compared to the attempted amount of CM. These values are shown as mean value with the range. Furthermore, the percentage of these two values was calculated. Due to the sample size we did not perform statistics on the recorded values. All procedures were performed under conditions of standard clinical practice, without any adaptation to routine diagnostic and guiding catheters, guide wires, balloons, or stents. The contrast injection set-up included the ACIST power injector with the DyeVert Power XT System directly connected between the ACIST CVi stopcock and the angiographic catheter, as shown in Fig. 1C. All procedures were performed using iohexol, a low osmolar, non-ionic, iodine-based contrast medium (Accupaque® 350, GE-Healthcare, Boston, MA, USA). In addition, we asked the performing physicians about their subjective assessment of the image quality compared to their normal daily experiences without the DyeVert Power XT System. Furthermore we questioned about any system failure.

3. Results

The combination of DyeVert Power XT and ACIST power injector was used in a total of nine consecutive patients treated by four different physicians. We recruited mainly patients with congestive heart failure (67%) and prior coronary artery disease (78%). The risk for contrast induced nephropathy (CIN) was assessed with the Mehran's Integer CI-AKI Risk Score [8] and was mainly estimated moderate (67%) or high (22%) (see Table 1). All cases involved coronary diagnostic procedures; two patients also underwent subsequent PCI. 5F/6F (French) diagnostic

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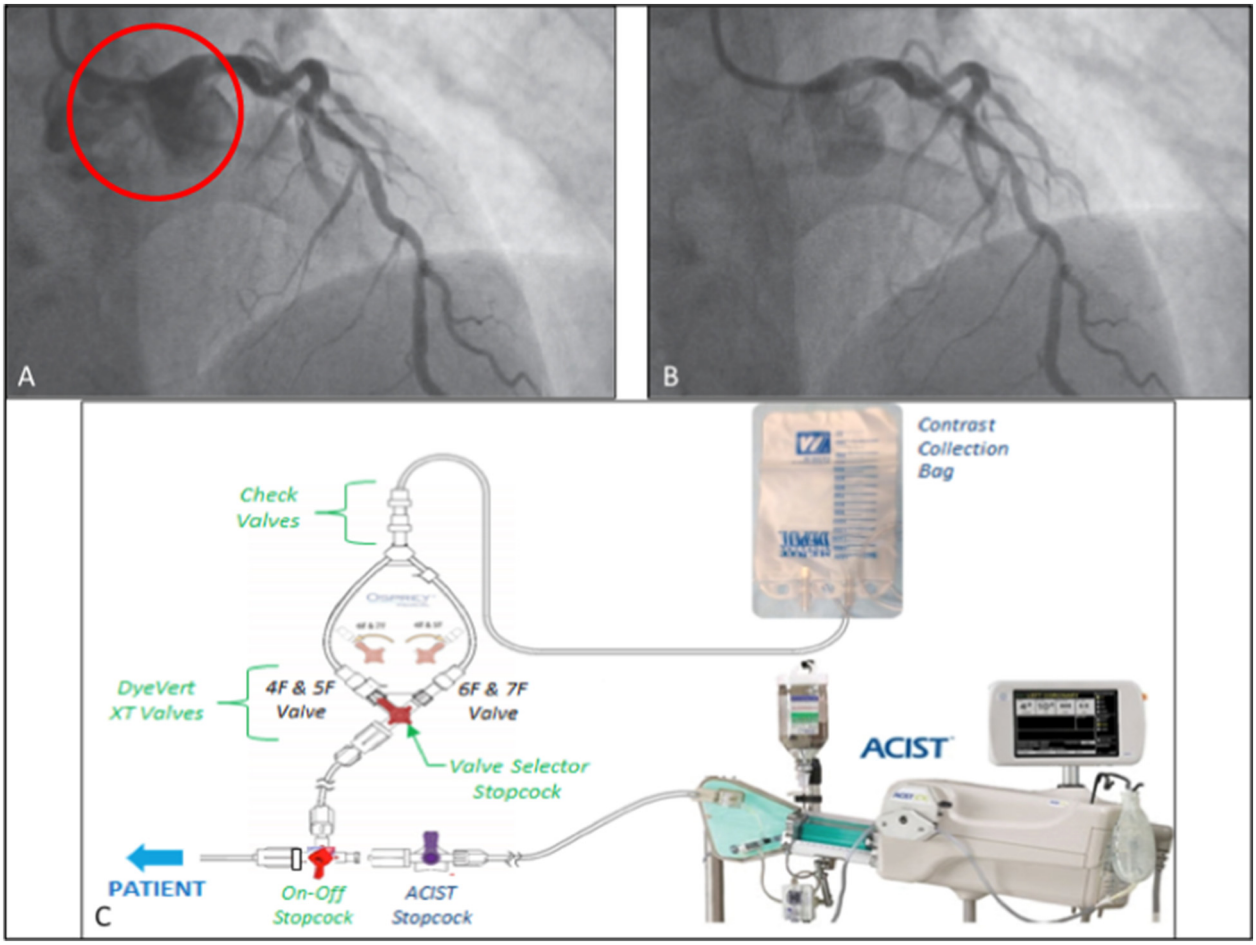

Fig. 1. Combining the DyeVert Power XT with the ACIST power injection system. Angiographic image of the LCA without (1A) and with (1B) use of the DyeVert Power XT System: CM reflux into the aorta (red) is reduced with the system in combination with the ACIST CVi Contrast Delivery System (1C).

and – where necessary for PCI – 6F guiding catheters were used. The ACIST injector system was programmed to standard settings per physician preference for the left and right coronary artery (LCA and RCA). During three procedures the LCA flow rate was increased from 3 mL/s to 4 mL/s; during two procedures the RCA flow rate was decreased due to difficulty maintaining vessel access; during a single procedure the volume was increased from 7 to 10 mL for better coronary artery bypass graft visualization due to difficult catheter engagement. All of these adjustments were considered normal practice and were independent of the DyeVert Power XT. The combination of DyeVert Power XT and the ACIST injector was in place throughout all procedures. The average volume of contrast delivered to the patients was 80.6 mL (range 45.5 mL to 211.9 mL). Attempted delivery was 127.8 mL (range 71.6 mL to 304.9 mL), resulting in average contrast savings of 38.9% (range 31.0% to 47.0%). Furthermore, we know that not only the total amount, but also the ratio of total CM volume to creatinine clearance predicts CIN [9]. We were able to reduce the ratio of total CM volume to creatinine clearance from 1.84 (attempted approach, array: 1.03–4.41) to 1.12 (delivered approach, array: 0.73–3.04). Throughout all procedures, neither a subjective loss of angiographic quality nor any DyeVert Power XT system failure was reported.

4. Discussion

This investigation demonstrates the feasibility of using DyeVert Power XT with ACIST for diagnostic and interventional ICA achieving a meaningful reduction in contrast volume without losing image quality. CIN affects 50% of high-risk subgroups in interventional cardiology – causing approximately 30% of all hospital-acquired acute kidney injury [10]. This is associated with considerable morbidity and both short and long-term mortality [11–13]. CIN and other AE can be reduced by limiting iodine-based contrast usage during procedures [14,15]. Therefore, the use of CM should be as low as possible to reduce AE [2], but recommendations alone urging to reduce the amount of used CM are not sufficient [3]. Basically two types of technical devices had been introduced to assist the treating physician limiting CM without losing image quality. ACIST alone reduces the total volume of administered CM [5,14,16,17] and shows equivalent image quality to that of a manual system [16]. Gurm et al. assessed the impact of manual versus ACIST on renal complications. In a comparison of over 60,000 patients, the use of ACIST was associated with a small but statistically significant difference in the average volume of CM used (mean 199 $\pm$ 84 mL vs. mean 204 $\pm$ 82 mL, $p < 0.0001$). However, Gurm et al. found with no difference in the proportion of patients exceeding contrast volume/calculated CC ratio of 3 (28.4% vs. 29.1%, $p = 0.19$). These findings suggest that ACIST alone is incapable of reducing CM exposure or incidence of AE like CIN in a clinically significant manner [6]. However, ACIST still has a role in CM administration as it offers several advantages to manual manifold systems: ACIST allows abbreviated fluoroscopy time and high flow of contrast (>10 mL/s) with smaller catheters 4–5F [18] and is able to deliver precise CM volumes at higher pressure than manual manifold systems resulting in more consistent coronary visibility [18]. This optimized visualization is particularly advantageous over the manual CM application in patients with hyperdynamic flow states (aortic stenosis/insufficiency), hypertensive cardiovascular disease or in patients with large caliber or dilated atherosclerotic vessels [19].

Table 1
Patients' demographical, laboratory, and predictive characteristics and results.

	Subjects N = 9
Age, years	71 ± 10
Men (%)	5 (56)
Body-mass-index (kg/m^2)	27.4 ± 2.9
Hypertension (%)	7 (78)
Diabetes mellitus (%)	
Insulin therapy	1 (11)
Oral antidiabetics	3 (33)
Congestive heart failure (%)	6 (67)
Prior coronary artery disease (%)	7 (78)
Applied contrast agent (mL)	81.7 ± 57.3
Attempted approach	129.0 (array: 71.6–304.9)
Delivered approach	81.7 (array: 45.5–211.9)
Baseline eGFR (MDRD; mL/min/1.73 m^2)	71.5 ± 9.4
Baseline eGFR (CKD-EPI; mL/min/1.73 m^2)	67.8 ± 10.3
Baseline serum creatinine (mg/dL)	1.15 ± 0.36
Baseline hemoglobin (g/dL)	12.5 ± 2.3
Ratio of total contrast volume/baseline CG-creatinine clearance	
Attempted approach	1.84 (array: 1.03–4.41)
Delivered approach	1.12 (array: 0.73–3.04)
Mehran's Integer CI-AKI Risk Score (score points)	8 (array: 4–13)
≤5 (low-risk)	1 (11)
6–10 (moderate-risk)	6 (67)
11–15 (high-risk)	2 (22)
≥16 (very high-risk)	0 (0)

Data are presented as mean ± SD if not otherwise labeled. CI-AKI = contrast-induced acute kidney injury; eGFR = estimated glomerular filtration rate; CG = Cockcroft–Gault formula.

The DyeVert Plus XT System in combination with manual CM injection techniques has been introduced to perform real-time CM dose monitoring and significantly and consistently reduce CM volumes [7,15,20,21]. Corcione et al. used the DyeVert Plus for coronary and peripheral applications and found a reduction in applied CM of 41.8 ± 7.3% (95% CI, 37.5 to 46.4; $p < 0.05$) [20]. Likewise, Desch et al. found a significant 41.0% CM volume reduction in 96 randomized patients [7], Gurm et al. reported 40.1% CM savings in an observational study of 114 patients [15]. The main limitation of these studies remained: The investigators were forced to use manual manifold CM injection.

In this pilot investigation, we demonstrate for the first time that ACIST can be used effectively in combination with the DyeVert Power XT System to effectively spare CM volume for the patient – without reducing image quality for the physician and increasing risk to the patient for AEs. Regarding CIN, we found a reduction of 61% for the ratio of total CM volume to creatinine clearance. Our study bears several limitations as proof-of-concept study. We have no randomization, no control group, only a very small sample size and our reduction in CM dose is estimated. However, our results – especially the amount of average CM savings – align with those of previous studies of the DyeVert Plus system [7,15,20]: When used in conjunction with the ACIST system, the DyeVert Power XT reduced the amount of CM by nearly 40%.

5. Conclusion

The use of the DyeVert Power XT in combination with the ACIST automated injector results in clinically meaningful contrast volume savings, without loss of image quality in this patient sample. Prospective trials are needed to confirm the impact of this effect on clinical endpoints.

Declaration of Competing Interest

The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. CJ reports to have received speaking fee by Osprey Medical. All other authors report no conflicts of interest regarding the content herein. This work was supported by the Forschungskommission of the Medical Faculty of the Heinrich-Heine-Universität Düsseldorf (No. 2018-32 to Georg Wolff, No. 2018-50 to Ralf Erkens)) for a Clinician Scientist Track. The open-access publication fee for this journal will be covered by the manufacturer of the device *Osprey Medical*.

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