DyeVert Clinical Update

December 2020

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PR0358A

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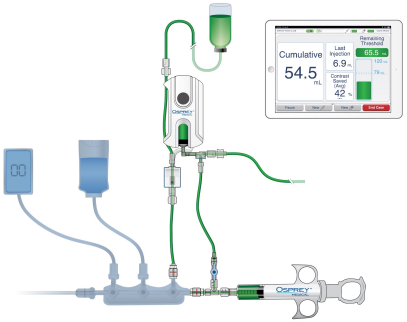
DyeVert – Commitment to Clinical Outcomes

- Validation of DyeVert System's impact on outcomes
  - Over 15 clinical initiatives
  - 22 hospitals with over 70 users, and > 1,500 patients
- Stage 1: Performance outcomes in reducing AKI risk factors
  - Total contrast volume to patients
  - Total contrast relative to the patients baseline renal function
- Stage 2: Therapeutic outcomes in preventing AKI
  - Reduction of contrast delivered to patients
  - Implementing Threshold management

DyeVert™ Contrast Reduction System PLUS EZ



DyeVert AKI Reduction Outcomes Data

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Population Health Studies

Published and/or presented at Scientific Conferences

Control Group Studies

***T**hree published at Scientific Conferences*

One manuscript published in clinical journal

Economic Viability

Population Healthcare Quality Improvement

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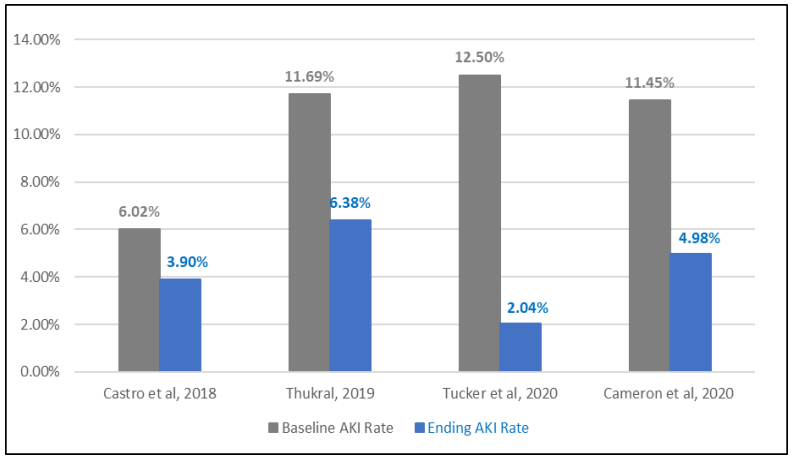
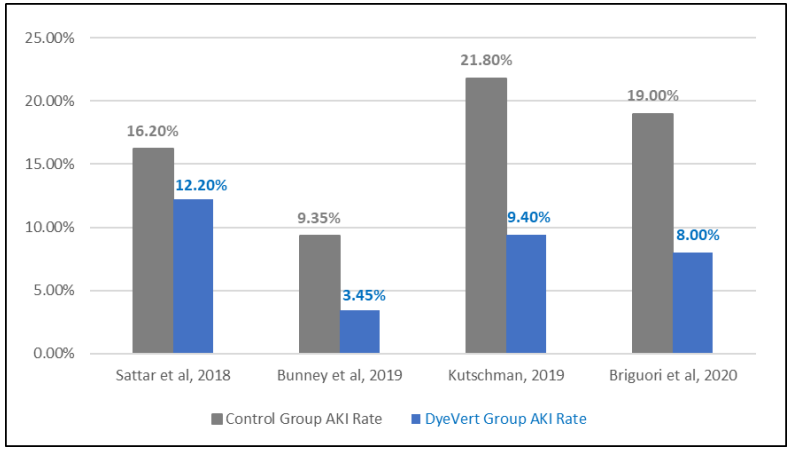
- 4 hospitals, 2016 – 2020
  - Quality improvement (QI) programs
  - Tracked outcomes through CathPCI AKI metric
- Patient centered program defined by clinical guidelines
  - Screening for risk
  - Volume management per SOC
  - Contrast monitoring and minimization
    - DyeVert Use in CKD/high risk patients
- **55% Reduction in AKI**
  - *35% - 84% AKI reduction range*



Author/Year	Baseline AKI Rate	Ending AKI Rate	Absolute AKI Reduction	Relative AKI Reduction
Castro et al, 2018	6.02%	3.90%	2.1%	35%
Thukral, 2019	11.69%	6.38%	5.3%	46%
Tucker et al, 2020	12.50%	2.04%	10.5%	84%
Cameron et al, 2020	11.45%	4.98%	6.5%	57%

DyeVert vs Control Group Comparative Data

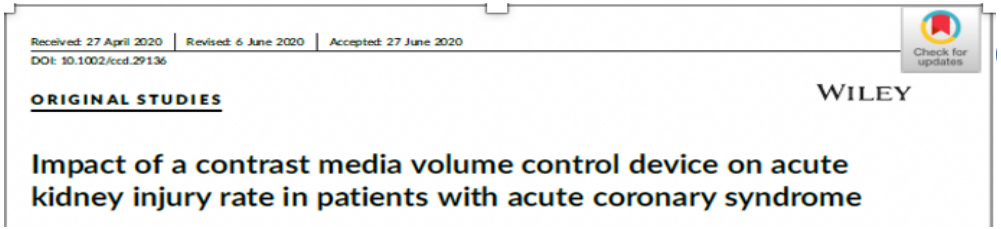
- 4 hospitals, 2017 – 2020
- Clinical practice guidelines based program
  - Screening for risk
  - Volume management per SoC
  - Contrast monitoring and minimization
    - DyeVert Use in CKD/high risk patients
- Retrospective data abstraction of DyeVert & Control cases during the same time periods
- **51% Reduction in AKI**
  - *25% - 63% AKI reduction range*



Author/Year	Control Group AKI Rate	DyeVert Group AKI Rate	Absolute AKI Reduction	Relative AKI Reduction
Sattar et al, 2018	16.20%	12.20%	4.0%	25%
Bunney et al, 2019	9.35%	3.45%	5.9%	63%
Kutschman, 2019	21.80%	9.40%	12.4%	57%
Briguori et al, 2020	19.00%	8.00%	11%	58%

SCAI Society for Cardiovascular Angiography & Interventions

Catheterization & Cardiovascular Interventions



Received: 27 April 2020 | Revised: 6 June 2020 | Accepted: 27 June 2020
DOI: 10.1002/ccd.29136

ORIGINAL STUDIES

WILEY

Impact of a contrast media volume control device on acute kidney injury rate in patients with acute coronary syndrome

A Closer Look at Briguori, et al Propensity Matched Study comparing DyeVert vs. Control Group

- Purpose
  - Impact of DyeVert on contrast media in ACS patients
  - Impact of DyeVert on AKI rate in ACS patient
- Single-center, retrospective, two-arm study n=180
- Patients with Acute Coronary Syndrome
  - STEMI or high risk NSTEMI
  - Excluded ESRF w/Dialysis, recent CM exposure, and referrals for stroke center
- Hydration
  - IV 0.9% Sodium Chloride – all patients, except pulmonary congestion or CS
  - POSEIDON protocol intra procedure
- Propensity Matched Control
  - Age, Gender, LVEF, ACS type, BP, SCr, eGFR, Diabetes, PAD
- AKI analysis
  - SCr at baseline, 24, 48, and 72 hours
  - Calculated eGFR
  - CM Threshold Max = 3x eGFR

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Patients and Procedural Info:

- 90 patients included per group – control and DyeVert
- Primarily STEMI's – Control (81%) DyeVert (85%)
- Median Hydration volume – Control (1680 ml's) and DyeVert (1690 ml's)
  - 91% of controls hydrated > 960 ml's and 95.5% of DyeVert hydrated > 960 ml's
- ≥ 97% patients treated via radial approach
- All patients treated with PCI except for 3
- Mean CM volume – Control (130 ml's) and DyeVert (99 ml's)*
- CM Volume > 3x eGFR – Control (60%) and DyeVert (47%)
- DyeVert was never turned off under any circumstance due to inadequate image or device related reason

** $p < .001$*

DyeVert vs Control Group

Outcomes

- AKI Rate in Control vs. DyeVert* Group
  - Control – 19% (17/90)
  - DyeVert – 8% (7/90)
- AKI reduction in DyeVert Group
  - 11% absolute vs. Control
  - 58% relative vs. Control
- Contrast reduction in DyeVert Group
  - 38% CMV savings vs. Control
- Reduced LOS in DyeVert** vs. Control Group

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Carlo Briguori MD, PhD[1] | Marco Golino MD[1] | Nicola Porchetta MD[1] | Mario Scarpelli MD[1] | Francesca De Micco MD[1] | Carmine Rubino RN[1] | Amelia Focaccio MD[1] | Giuseppe Signoriello PhD[2]

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Abstract

BACKGROUND: The DyeVert™ system (Osprey Medical Inc., Minnesota, MN) may reduce contrast media (CM) volume during coronary procedures while maintaining fluoroscopic image quality. Here, we assessed whether the use of the DyeVert system reduces acute kidney injury (AKI) rate in patients with acute coronary syndrome (ACS) undergoing invasive coronary procedures.

METHODS: ACS patients scheduled for coronary procedure from January 2017 to December 2019 were included. Two groups were identified: (a) *Control group* (*n* = 339), including patients in which a conventional manual injection syringe was used; and (b) *DyeVert group* (*n* = 112), in which CM injection was handled by the DyeVert™ system. A propensity score matching was performed to reduce the effect of treatment selection bias and potential confounders. In all cases, a low-osmolar, nonionic CM was administered. The primary objective was the rate of AKI, defined as a serum creatinine increase ≥0.3 mg/dl within 72 hr after CM exposure.

RESULTS: CM volume was higher in the *Control group* than in the *DyeVert group* (130 [120–188] ml vs. 99 [69–136] ml; $p < .001$). In the *DyeVert group* the mean percent CM volume saved was 38 ± 13%. AKI occurred in 7/90 patients (8%) in the *DyeVert group* and in 17/90 (19%) patients in the *Control group* (odds ratio = 0.37; 95% confidence interval 0.14–0.95; $p = .047$).

CONCLUSIONS: This preliminary result suggests that CM volume reduction obtained by the DyeVert™ system is an effective strategy to prevent AKI in ACS patients undergoing invasive procedure.

KEYWORDS
acute coronary syndrome, acute kidney injury, contrast media

1 | INTRODUCTION

Acute kidney injury (AKI) is a common complication in patients suffering from acute coronary syndrome (ACS).[1,2] This complication has been associated with higher early and late adverse events.[1-4] The pathogenesis of AKI in ACS patients is multifactorial.[5,6] Although some data suggest that it is unlikely that contrast media (CM) is a primary pathogenic factor responsible for renal dysfunction in ACS patient treated by percutaneous coronary intervention (PCI), avoiding excess CM volume has been advocated.[6-8]

The DyeVert™ system (Osprey Medical Inc., Minnesota, MN) is a novel device designed to reduce CM volume during coronary procedures, while maintaining fluoroscopic image quality.[9,10] The aim of the present study is to assess whether the use of the DyeVert system is

** p < 0.047 ** p < 0.003*

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DyeVert vs Control Group

Discussion:

- Patients with ACS at high risk for AKI
  - Ranges from 15 – 30%
- Majority of patients Stage 1 CKD at baseline
- Significant AKI Reduction in DyeVert group even with a high hydration regimen

Conclusion:

- *38% CM volume reduction with the DyeVert System is associated with significantly lower AKI rates vs. Control Group*

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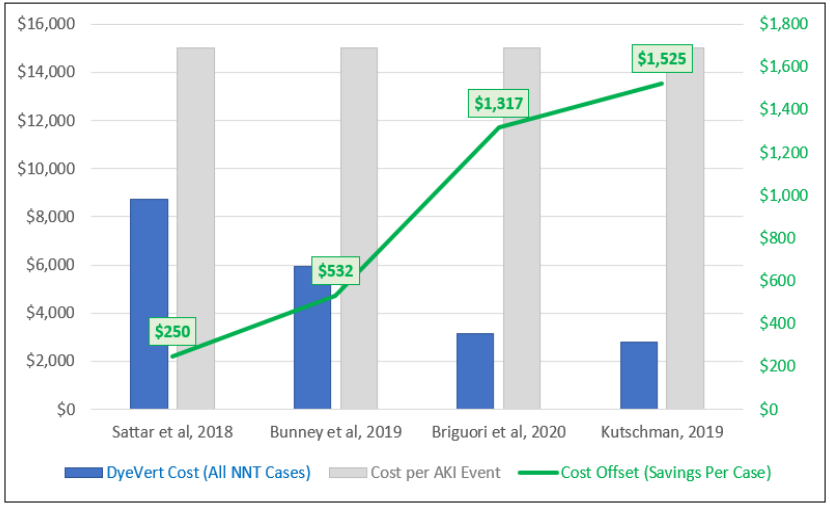
Cost Savings with DyeVert + AKI Reduction

- 4 hospitals
  - DyeVert vs. Control Group Data
- Overall number-needed-to treat
  - 8 to 25 to prevent 1 AKI event
  - Mean NNT = 15
- High cost of an AKI event vs low cost of DyeVert ($15,000 vs $350/case)
- Per case cost savings $250 to $1,525
- Conservative estimate:
  - Does not consider ongoing renal morbidity
  - Does not consider related downstream health outcomes



Author/Year	Absolute AKI Reduction	Overall NNT (1/AR)	DyeVert Cost (All NNT Cases)	Cost per AKI Event	Cost Offset (Savings Per Case)
Sattar et al, 2018	4.0%	25	$8,750	$15,000	$250
Bunney et al, 2019	5.9%	17	$5,950	$15,000	$532
Briguori et al, 2020	11.0%	9	$3,150	$15,000	$1,317
Kutschman, 2019	12.4%	8	$2,800	$15,000	$1,525
Average	**8.3%**	**15**	**$5,163**		**$906**

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Thank you

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