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
Population Health Studies
Published and/or presented at Scientific Conferences

Control Group Studies
Three published at Scientific Conferences
One manuscript published in clinical journal

Economic Viability
Population Healthcare Quality Improvement

• 4 hospitals, 2016 – 2020
  • Quality improvement (QI) programs
  • Tracked outcomes through CathPCI AKI metric

• Patient centered program defined by clinical guidelines
  o Screening for risk
  o Volume management per SOC
  o Contrast monitoring and minimization
    ➢ DyeVert Use in CKD/high risk patients

• 55% Reduction in AKI
  • 35% - 84% AKI reduction range
DyeVert vs Control Group Comparative Data

• 4 hospitals, 2017 – 2020
• Clinical practice guidelines based program
  o Screening for risk
  o Volume management per SoC
  o 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

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

- **Purpose**
  - Impact of DyeVert on contrast media in ACS patients
  - Impact of DyeVert on AKI rate in ACS patients

- **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
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

* p < 0.047
** p < 0.003
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
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

• Castro D, Dang TT. Reducing Contrast-Induced Acute Kidney Injury in the Cath Lab. Poster presentation at the ACC Quality Summit. 2018. (also published in: Castro D, Marban A. Reducing Contrast-Induced Acute Kidney Injury in the Cath Lab at Houston Methodist Sugar Land Hospital. Cath Lab Digest. 2018;26(6)).


Thank you

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CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.