Problem: Contrast-Induced Nephropathy (CIN)

CIN Remains a Problem
- Caused by a combination of factors:
  - Ischemia/hypoxia, viscosity/clogging, direct cellular toxicity/apoptosis
  - Risks increasing:
    - Seeing sicker patients (CKD ↑, Diabetes ↑)
    - Dye loads increasing (CTD, TAVI, etc)
  - Outcomes for patients who develop CIN remain poor:
    - Increases mortality
    - Worsens cardiac outcomes
    - Speeds progression of chronic kidney disease

Induced Diuresis to Prevent CIN
Theory: Inducing diuresis flushes contrast out of the kidney, reducing concentration, preventing clogging and hypoxia.
Results: Induced diuresis alone found to be worse than control.
What happened? All patients who received induced diuresis lost fluid relative to control patients.
PRINCE Study² found matching hourly urine output could reduce CIN rate 50% in patients who achieved 350 ml/hr urine output, but most patients did not achieve that urine rate.
Guidelines now encourage 350 ml/hr urine output, but provide no predictable guidance for achieving that rate.

Answer: RenalGuard Therapy

RenalGuard® enables the benefits of high urine flows while preventing the negative effects of dehydration.

RenalGuard Therapy*: Provides automated matched fluid replacement in real-time, reducing risk of over- or under-hydration.
- Creates and maintains high urine output
- Prevents contrast agents from clogging tubules
- Limits toxin exposure in kidneys
- Fits into normal cath lab flow: begins 1 hr before catheterization, continues during procedure and for 4 hours afterwards.

Results: Four Clinical Reports

Pilot Study Urine Rates²
Average urine rates from the 23 patients enrolled in US Pilot Study. Average eGFR 39.1 +/- 9.3. All patients reached the 300 ml/hr urine rate shown to reduce incidence of CIN. The rapid increase and wide variation in urine rates demonstrates need for the automated matched replacement RenalGuard provides.

MYTHOS³
RenalGuard Therapy vs. Overnight Hydration

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<thead>
<tr>
<th></th>
<th>RG</th>
<th>Control</th>
<th>P</th>
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<tbody>
<tr>
<td>Diabetes</td>
<td>38 (55%)</td>
<td>29 (35%)</td>
<td>0.24</td>
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<tr>
<td>eGFR (ml/min)</td>
<td>38±11</td>
<td>41±10</td>
<td>0.17</td>
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<tr>
<td>Contrast volume (ml)</td>
<td>181±104</td>
<td>158±109</td>
<td>0.17</td>
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REMEDIAl II⁴
RenalGuard Therapy vs. Sodium Bicarbonate

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<thead>
<tr>
<th></th>
<th>RG (N=146)</th>
<th>Control (N=146)</th>
<th>P</th>
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<tbody>
<tr>
<td>Diabetes</td>
<td>69%</td>
<td>71%</td>
<td>0.51</td>
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<tr>
<td>eGFR (ml/min)</td>
<td>32±7</td>
<td>41±10</td>
<td>0.83</td>
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<tr>
<td>Contrast volume (ml)</td>
<td>145±79</td>
<td>135±76</td>
<td>0.29</td>
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University of Modena Study⁵
RenalGuard vs. Sodium Bicarbonate vs. CVVH
Investigators treated 100 consecutive patients with sodium bicarbonate (32 pts), CVVH (35 pts) and RenalGuard Therapy (33 pts).

RenalGuard Therapy Overview

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- Provides automated matched fluid replacement in real-time, reducing risk of over- or under-hydration.
- Creates and maintains high urine output
- Prevents contrast agents from clogging tubules
- Limits toxin exposure in kidneys
- Speeds progression of chronic kidney disease
- Worsens cardiac outcomes
- Increases mortality

For More Information visit www.plcmed.com

¹Stevens et al., J Am Coll Cardiol 1999;33(2):403-11
⁴Bertelli et al., International Journal of Cardiology. Dec 2011.
⁵Briguori et al., Circulation 2011;124(11):1260-1266