Restrictions for the Use of Fenoldopam

Drug Information Center
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Fenoldopam is a selective, peripheral dopamine, agonist approved for the management of severe hypertension. Fenoldopam was added to the formulary in June of 1999 with criteria for use in the management of hypertension in patients with contraindication or intolerance to nitroprusside.

Indications for use
Fenoldopam is approved for the short-term treatment of severe hypertension where rapid, emergent reversal of blood pressure is warranted. Although not approved indications, clinical trial data demonstrate benefit with fenoldopam in the prevention and treatment of postoperative renal failure.

Restrictions for use
Fenoldopam should be reserved for the following scenarios or patient characteristics:

• Severe hypertension
  - Documented contraindication to nitroprusside
  - Nitroprusside dose greater than 10 mcg/kg/min
  - Nitroprusside dose greater than 1 mcg/kg/min in severe renal insufficiency, defined by a creatinine clearance less than 20 mL/min, serum creatinine of greater than 1.8 mg/dL, or a BUN greater than 40
  - Nitroprusside dose greater than 2 mcg/kg/min in severe liver disease

• Oliguric acute renal failure due to ischemia or suspected renal vasoconstriction, occurring in patients with shock, sepsis (or conditions leading to low SVR), CHF, liver failure, or associated with nephrotoxic agents.
  - Less than 0.5 mL/kg/hr of urine output for greater than two hours despite sufficient fluid administration or if adequate filling pressures are documented via a pulmonary artery catheter.
  - Fenoldopam is not recommended for rhabdomyolysis-induced renal injury.

• Prevention of renal failure following cardiac surgery requiring cardiopulmonary bypass
  - Abnormal serum creatinine (≥ 2.0 mg/dL) or
  - Borderline serum creatinine (1.5-2.0 mg/dL) plus an additional risk factor:
    ▪ Age ≥ 70 years
    ▪ Concomitant valve surgery
    ▪ Diabetes mellitus
    ▪ Severe left ventricular dysfunction [EF <30%, recent CHF, IV inotropic therapy or intra-aortic balloon pump]
    ▪ Recent radiocontrast dye due to cardiac catherization within 24 hours

Dosing

• Hypertension
  - Initially, begin fenoldopam infusion at 0.1 mcg/kg/min, which may be increased in increments of 0.05 – 0.2 mcg/kg/min until target blood pressure is achieved. Usual dose ranges from 0.25 – 0.5 mcg/kg/min.
  - Ideally, within 24 hours of initiation of fenoldopam, an effective oral antihypertensive regimen should be established, and the fenoldopam infusion should be weaned.
  - When discontinuing, taper dose by 10% every 15 – 30 minutes.

• Acute renal failure (oliguria) in critically ill patients
  - Begin fenoldopam infusion at 0.01 mcg/kg/min and titrate dose in 0.01 mcg/kg/min increments every hour until target urine output is achieved or as patient begins to experience hypotension.
  - Concomitant use of fenoldopam and dopamine is not recommended.

• Prevention of renal failure following cardiac surgery requiring cardiopulmonary bypass
  - Fenoldopam 0.1 mcg/kg/min initiated prior to cardiopulmonary bypass and continuing for no longer than 24 hours postoperatively.
Endpoints
Treatment with fenoldopam should be discontinued if/when the following circumstances occur:

- **Hypertension**
  - Initiate oral antihypertensive regimen within 24 hours of beginning fenoldopam infusion.
  - Wean fenoldopam as effective oral antihypertensive regimen becomes established.

- **Acute renal failure (oliguria) in critically ill patients**
  - Target urine output is not achieved with appropriate titration of dose within 12 hours of initiating fenoldopam.
  - If target urine output is achieved, attempt to wean fenoldopam every 24 hours to determine the minimum dose of fenoldopam required to maintain urine output.
  - Renal replacement therapy (RRT) becomes necessary.

- **Prevention of renal failure following cardiac surgery requiring cardiopulmonary bypass**
  - 24 hours following CPB

**SUMMARY OF FENOLDOPAM RESTRICTIONS**

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<tr>
<th>Indication</th>
<th>Restrictions</th>
<th>Dosing</th>
<th>Duration</th>
<th>Comments</th>
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<tr>
<td>Hypertension</td>
<td>Documented contraindication to NP</td>
<td>Initially, 0.1 mcg/kg/min titrating by 0.05 – 0.2 mcg/kg/min</td>
<td>Ideally, no more than 24 hours</td>
<td>Establish oral antihypertensive management within 24 hours of fenoldopam</td>
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<td>NP dose &gt; 10 mcg/kg/min</td>
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<td>Oliguric acute renal failure due to ischemia or suspected renal vasoconstriction</td>
<td>Less than 0.5 mL/kg/hr of urine output for &gt; 2 hours despite adequate fluid administration</td>
<td>Begin at 0.01 mcg/kg/min and titrate by 0.01 mcg/kg/min increments until target UOP is achieved</td>
<td>12 hours if treatment fails versus 24 hour weaning attempts with treatment success</td>
<td>Risk of hypotension may limit use</td>
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<td>Prevention of renal failure following cardiac surgery requiring cardiopulmonary bypass</td>
<td>Abnormal serum creatinine (≥ 2.0 mg/dL)</td>
<td>Low-dose fenoldopam 0.1 mcg/kg/min initiated prior to CPB and continued for 24 hours postoperatively</td>
<td>24 hours</td>
<td>Adequate hydration should be established to limit hypotension</td>
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<td>Borderline serum creatinine (1.5-2.0 mg/dL) plus additional risk factor: age ≥ 70 years, concomitant valve surgery, diabetes mellitus, severe left ventricular dysfunction, recent radiocontrast dye due to cardiac catheterization within 24 hours</td>
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References