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<tr><th colspan="2">Background and Overview</th></tr>
<tr><td colspan="2"><u>Safety and Feasibility of Opening Tamsulosin Capsules for Enteral Feeding Tube Administration</u>
• Journal of Pharmacy Practice
• Impact Factor: 1.0
• No funding/conflicts of interest
• Hackensack Meridian Health JFK University Medical Center Pharmacy Department</td></tr>
<tr><td>Background</td><td>Tamsulosin (Flomax®)
• Selective alpha$_{1a}$ receptor antagonist indicated for benign prostatic hyperplasia (BPH)[1]
• Other uses – nephrolithiasis, dysfunction voiding, urinary retention
• Do not crush, chew, or open capsules per package insert[1]
  ○ Common practice at some institutions
• Formulated as sustained release beads within a capsule to avoid rapid absorption and hypotension
No previous studies administering opened tamsulosin capsules in adults – pediatric studies
• Tsuda et al (2010) – open capsule over applesauce or yogurt. No major pharmacokinetic differences noted compared to adult population pharmacokinetics[2]
• Tasian et al (2014) – open capsule on drink/yogurt/pudding. No adverse effects noted[3]
Doxazosin
• Nonselective alpha$_1$ receptor antagonist indicated for BPH, hypertension[4]
  ○ Increased risk for hypotension (tamsulosin 10x more selective for alpha$_{1a}$)
• No restrictions on crushing immediate release tablets[4]
• Common replacement for tamsulosin for patients on enteral feeding tubes</td></tr>
<tr><td>Objective</td><td>Examine the feasibility and safety of administering tamsulosin capsule content via an enteral feeding tube compared to doxazosin</td></tr>
<tr><th colspan="2">Methods</th></tr>
<tr><td>Study Design</td><td>Retrospective chart review
• Across 2 hospital sites within same network
• January 1st 2021 to December 31st 2021
• Approval from IRB
Medications
• Tamsulosin
  ○ Administration instructions: “If administering via feeding tube, open capsule and administer intact granules (do not crush) with apple juice”
• Doxazosin
  ○ No specific administration instructions
  ○ Blood pressure hold parameters</td></tr>
<tr><td>Primary Endpoints</td><td>Rates of documented tube obstruction
• Search patient’s chart for: ‘tube clog’, ‘tube replaced/replacement’, ‘tube removed’, ‘tube obstructed,’ and ‘tube blockage’
Medication associated hypotension
• Decrease in baseline systolic blood pressure by 25% within 4 hours of administration
  ○ Assume opening tamsulosin capsules would affect the rate-controlled absorption
• Last known blood pressure before medication administration as baseline
• Only collected for up to first 5 doses of medication
  ○ Assume if hypotensive beyond 5 doses, therapy changed/discontinued</td></tr>
<tr><td>Study Population</td><td>Inclusion criteria
• All adult patients (18 years and older) with enteral feeding tube
• Received at least 1 dose of either tamsulosin or doxazosin
• Documented route of administration via nasogastric (NG), gastrostomy (G), orogastric (OG), jejunostomy (J) tube
Exclusion criteria
• Received a dose of BOTH tamsulosin and doxazosin during hospitalization</td></tr>
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<tr><td></td><td>• Exclusion from hypotension endpoint if receiving any vasopressors</td></tr>
<tr><td>Statistical Analysis</td><td>Relative risk (RR) with a significance level of 0.05
• Appropriate to compare incidence of events with binary outcomes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Baseline Characteristics</td><td>169 patients included
<table>
<tr><td></td><td>Tamsulosin Group (110)</td><td>Doxazosin Group (59)</td></tr>
<tr><td>Average age in years (SD)</td><td>69.3 (14.9)</td><td>59.4 (17.9)</td></tr>
<tr><td>Average weight in kg (SD)</td><td>80 (16.2)</td><td>84.3 (19.7)</td></tr>
<tr><td>Male, n (%)</td><td>84 (76.4)</td><td>43 (72.9)</td></tr>
<tr><td>Home medication, n (%)</td><td>57 (51.8)</td><td>7 (11.9)</td></tr>
<tr><td colspan="3">Tube type, n (%)</td></tr>
<tr><td>G</td><td>67 (60.9)</td><td>26 (44.1)</td></tr>
<tr><td>J</td><td>—</td><td>1 (1.7)</td></tr>
<tr><td>NG</td><td>35 (31.8)</td><td>20 (33.9)</td></tr>
<tr><td>OG</td><td>8 (7.3)</td><td>10 (16.9)</td></tr>
<tr><td>Combination</td><td>—</td><td>2 (3.4)</td></tr>
<tr><td>Number of hypertension medications, median (IQR)</td><td>1 (1)</td><td>2 (1.75)</td></tr>
<tr><td>Number of treatment doses, median (IQR)</td><td>8 (10)</td><td>7 (9.5)</td></tr>
<tr><td colspan="3">Indication for treatment use, n (%)</td></tr>
<tr><td>BPH</td><td>46 (41.8)</td><td>14 (23.7)</td></tr>
<tr><td>Hypertension</td><td>—</td><td>13 (22)</td></tr>
<tr><td>Historical</td><td>8 (7.3)</td><td>1 (1.7)</td></tr>
<tr><td>Urinary dysfunction</td><td>51 (46.4)</td><td>24 (40.7)</td></tr>
<tr><td>Unknown/other</td><td>5 (4.5)</td><td>7 (11.9)</td></tr>
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SD – standard deviation; IQR – interquartile range
Combination tubes – patient with NG and G tube and patient with G and OG tube during the same admission
Historical medication includes treatment with therapy since patient was receiving prior to hospital admission.
Urinary dysfunction is classified as urinary retention, dysfunctional voiding, and neurogenic bladder.</td></tr>
<tr><td>Outcomes</td><td>
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<tr><td></td><td>Tamsulosin Group (110)</td><td>Doxazosin Group (59)</td><td>Relative Risk (95% CI)</td><td>P Value</td></tr>
<tr><td>Enteral feeding tube obstructions, n (%)</td><td>4 (3.64)</td><td>6 (10.17)</td><td>.36 (.11-1.22)</td><td>.099</td></tr>
<tr><td></td><td>Tamsulosin Group (98)</td><td>Doxazosin Group (49)</td><td>Relative Risk (95% CI)</td><td>P Value</td></tr>
<tr><td>Episodes of medication associated hypotension, n (%)</td><td>22 (22.4)</td><td>20 (40.8)</td><td>.55 (.33-.91)</td><td>.019</td></tr>
<tr><td>1 episode, n (%)</td><td>19 (86.4)</td><td>16 (80)</td><td>—</td><td>—</td></tr>
<tr><td>≥2 episodes, n (%)</td><td>3 (13.6)</td><td>4 (20)</td><td>—</td><td>—</td></tr>
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CI – Confidence Interval

Documented tube clogs – 4/4 on G tubes in tamsulosin group (median 14.5 doses); 3/6 on G tubes and 3/6 on NG tubes in doxazosin group (median 8 doses given)
• All on enteral tube nutrition

Medication associated hypotension
<table>
<tr><td></td><td>Tamsulosin Group (22)</td><td>Doxazosin Group (20)</td></tr>
<tr><td colspan="3">Indication for treatment use, n (%)</td></tr>
<tr><td>BPH</td><td>10 (45.5)</td><td>5 (25)</td></tr>
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	Hypertension	—	5 (25)
	Historical	1 (4.5)	1 (5)
	Urinary dysfunction	10 (45.5)	8 (40)
	Unknown/other	1 (4.5)	1 (5)
	Number of additional hypertension medications, n (%)		
	0	3 (13.6)	3 (15)
	1	11 (50)	4 (20)
	≥2	8 (36.4)	13 (65)
	Use of respective medications prior to admission, n (%)		
	Yes	11 (50)	2 (10)
	No	11 (50)	18 (90)

Authors' Conclusion	No statistical significance between tube obstructions. Tamsulosin was 45% less likely to be associated with medication associated hypotension. The authors suggest that tamsulosin can be opened and administered via enteral feeding tubes if the integrity of the contents is preserved.

Discussion and Conclusion

Strengths	Limitations

• Simple study design
• No bias with patient selection
• Appropriate comparator
• Reasonable primary endpoints
	• Small study size
	• No information on doses – wider range of doses for doxazosin vs tamsulosin
	• Unclear if medication administration caused tube obstructions
	  ○ Dependent on documentation
	  ○ Flush orders not assessed
	• Confounding variables – other hypotension causes, other medications
	• No efficacy measures
	• Potential bias with authors reviewing an institution/department guideline

Caştur et al (2024) – doxazosin caused significantly decrease in systolic blood pressure compared to baseline while tamsulosin had no significant effect compared to baseline[5]

Conclusion	Opened tamsulosin capsules may cause less hypotension and tube obstructions compared to doxazosin when administered via enteral tubes. Limited conclusions due to nature of retrospective study. Likely safe, but unclear efficacy versus crushable alpha$_1$ receptor antagonists. Future studies should be prospective randomized control trials to evaluate causality, along with comparisons against other agents and examining efficacy.
References	Fazio V, Altshuler J, Song YB. Safety and Feasibility of Opening Tamsulosin Capsules for Enteral Feeding Tube Administration. *J Pharm Pract*. Published online February 20, 2024. doi:10.1177/08971900241233615 1. Flomax [package insert]. Ridgefield, CT: Boehringer Ingelheim; 2009. 2. Tsuda Y, Tatami S, Yamamura N, et al. Population pharmacokinetics of tamsulosin hydrochloride in paediatric patients with neuropathic and non-neuropathic bladder. *Br J Clin Pharmacol*. 2010;70(1):88-101. doi:10.1111/j.1365-2125.2010.03662.x 3. Tasian GE, Cost NG, Granberg CF, et al. Tamsulosin and spontaneous passage of ureteral stones in children: a multi-institutional cohort study. *J Urol*. 2014;192(2):506-511. doi:10.1016/j.juro.2014.01.091 4. Cardura [package insert]. New York, NY: Pfizer; 2009 5. Caştur L, Uzunlulu M, Eken E, et al. Effect of different alpha-receptor antagonists on metabolic parameters: a head-to-head comparison. *Int Urol Nephrol*. 2024;56(8):2489-2494. doi:10.1007/s11255-024-03968-z