Case Study: RW, a 74-Year-Old Man With Worsening Lightheadedness

Chief Complaint and History

Chief Complaint
- RW is a 74-year-old retired engineer with worsening symptoms of lightheadedness and dizziness of 4 months duration
- His primary care physician has requested a cardiovascular consultation to exclude cardiac etiology

Medical History
- No frank syncope; patient has enough warning with current symptoms of dizziness to sit or get to his knees
- 10-year history of Parkinson’s disease
- Recently developed symptoms of lightheadedness and imbalance
- 10-year history of hypertension
- No history of diabetes
- No history of heart disease
Case Study: RW, a 74-Year-Old Man With Worsening Lightheadedness (Cont’d)

Medications and Social History

Medications
- Lisinopril 20 mg daily for hypertension
- Carbidopa/levodopa immediate release 25/100 QID for Parkinson’s disease
- Daily multivitamin

Social History
- Nonsmoker
- RW is married with a daughter and 3 grandchildren who live out of state
- His wife has noted that he is hesitant to travel to visit his grandchildren as he is concerned he may pass out while visiting

Clinical Assessment
- Office blood pressure and heart rate was 116/84 mm Hg and 72 beats/min in the sitting position
- Standing BP fell to 84/72 mm Hg within 90 seconds of standing (patient reported “feeling faint”), with accompanying heart rate of 74 beats/min
- Cardiac exam:
  – Normal S1, S2, fourth heart sound present
  – Normal LV function via echocardiogram (LVEF=60%)
  – Stress testing negative for ischemia
  – ECG normal sinus rhythm and no conduction disturbance
- Carotid arteries with non-occlusive disease
- Serum creatinine, blood urea nitrogen, and electrolytes normal

Discussion

How do you recognize symptomatic nOH in your patients?
Diagnosis and Treatment

Diagnosis

- Patient is determined to have symptomatic neurogenic orthostatic hypotension secondary to preexisting Parkinson’s disease

How would you manage this patient?

Case Study: RW, a 74-Year-Old Man With Worsening Lightheadedness (Cont’d)

Initial Treatment

- Patient is advised to increase hydration
- Patient is advised to eat small meals frequently and avoid standing up suddenly after eating
- Compression garments (compression stockings, corset, or belt) are also recommended
- Physical therapy/aquatic therapy or home exercises to increase skeletal muscle pump recommended (recumbent exercises)

4-Week Assessment

- Symptoms persist after 4 weeks of non-pharmacologic treatment
- Standing BP is 82/72 mm Hg within 90 seconds of standing (patient reported “feeling faint”), with accompanying heart rate of 74 beats/min

How would you continue to manage this patient?
Cardiovascular Continuum

AF  POTS  NMS  Normotension  Labile HBP  HBP

- Bradycardia/hypotension ~500,000 Americans
- Orthostatic tachycardia ~500,000 Americans
- Orthostatic hypotension ~100,000 Americans

Orthostatic tachycardia ~500,000 Americans
Orthostatic hypotension ~100,000 Americans

Bradycardia/hypotension ~500,000 Americans

Orthostatic tachycardia ~500,000 Americans
Orthostatic hypotension ~100,000 Americans

Severe Dysautonomias
Orthostatic Hypotension

- Orthostatic hypotension
  - Defined as a fall in blood pressure on standing\(^1\)
  - Can result in symptoms of cerebral hypoperfusion
  - Is underdiagnosed\(^2\)


Primary Causes of Orthostatic Hypotension (OH)

- **NEUROGENIC**
  - Primary autonomic failure
  - Autonomic neuropathies

- **IATROGENIC**
  - Vasodilators
  - Antihypertensives
  - Some antidepressants

- **NON-NEUROGENIC**
  - Hypovolemia
  - Cardiac insufficiency
  - Impaired venous return


Diagnosing Autonomic Failure as a Cause of Symptoms in Neurogenic OH

- OH: orthostatic hypotension; NSC: neurogenic syncope; CSN: carotid sinus hypersensitivity; POTS: postural orthostatic tachycardia syndrome; CFS: chronic fatigue syndrome.

### Normal Physiology vs. "Vasovagal" Syncope vs. POTS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal Physiology</th>
<th>&quot;Vasovagal&quot; Syncope</th>
<th>POTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venous return</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Stroke volume</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Pulse pressure</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Sympathetic tone</td>
<td>↑</td>
<td>↑↑↑</td>
<td>↓</td>
</tr>
<tr>
<td>Vagal tone</td>
<td>↓</td>
<td>↑</td>
<td></td>
</tr>
<tr>
<td>Heart rate</td>
<td>↑ (10 – 15 bpm)</td>
<td>↓</td>
<td>↑↑↑ (&gt;30 bpm)</td>
</tr>
<tr>
<td>Systolic pressure</td>
<td>Stable</td>
<td>↓↓</td>
<td>↓</td>
</tr>
<tr>
<td>Diastolic pressure</td>
<td>(~10 mm)</td>
<td>↓</td>
<td>↓</td>
</tr>
</tbody>
</table>

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**Autonomic Disorders Associated With Symptomatic Neurogenic Orthostatic Hypotension (nOH)**

**Parkinson’s Disease**
- Affects ~1 million patients in the US
- ~18% of patients will experience symptomatic nOH

**Multiple System Atrophy (Shy-Drager)**
- Very rare, exact incidence unknown
- Idiopathic disorder characterized by nOH with evidence of more widespread autonomic failure
- No evidence of cerebellar or Parkinson’s symptoms
- 100% will experience symptomatic nOH

**Pure Autonomic Failure (Bradbury-Eggleston)**
- Very rare, exact incidence unknown
- Idiopathic disorder characterized by nOH with evidence of more widespread autonomic failure
- No evidence of cerebellar or Parkinson’s symptoms
- 100% will experience symptomatic nOH

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**Heart rate and blood pressure patterns observed in head-up tilt table testing**

Heart rate and blood pressure responses seen during tilt table testing in patients with various strategies of syrines, including autonomic failure, neurologically mediated syncope, and postural orthostatic tachycardia syndrome (POTS).

**Blood pressure rises in a pattern that is consistent with the presence of autonomic failure.**

- Systolic pressure
- Diastolic pressure
- Pulsatile pressure

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**Estimated mean incidence 0.6-0.7 cases per 100,000 person-years**
- Mean survival of 6-10 years from onset of symptoms
- Characterized by autonomic dysfunction, parkinsonism, and ataxia
- ~96% will experience neurogenic bladder symptoms and/or incontinence
- ~81% of patients will experience symptomatic nOH

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- Idiopathic disorder characterized by nOH with evidence of more widespread autonomic failure
- No evidence of cerebellar or Parkinson’s symptoms
- 100% will experience symptomatic nOH
Standing results in the pooling of ~500-1000 mL of blood in the lower extremities and splanchnic circulation. This compensatory reflex response is regulated by the autonomic nervous system and the release of norepinephrine.

THE ORTHOSTATIC RESPONSE

- The orthostatic response is divided in 3 phases:
  
  1. Initial Response (the first 30 seconds)
     
     - SV remains normal for 6 beats despite fall in venous return (due to pulmonary blood) then
     - Gradual decline in both cardiac filling and arterial pressure
     - This results in activation of 2 groups of pressure receptors: High pressure sites in the carotid sinus and aortic arch and low pressure sites in the cardiac and pulmonary areas

- Local axon reflex called “veno-arterial axon reflex” also constricts arterial flow to muscle, skin, and adipose tissue which can account for up to half of the increase in limb resistance seen during standing.
THE ORTHOSTATIC RESPONSE

2. Early Steady State Period (after 1-2 minutes)
- Steady increase in diastolic BP of 10%
- Little or no change in systolic BP
- Increase in heart rate about 10 bpm
- 30% less blood volume in the thorax
- Cardiac output is 30% less

3. Prolonged Orthostasis (5 minutes post standing)
- Activation of the RAAS
- Activation of Vasopressin & Endothelin
- However, the arterial baroreceptors especially the carotid sinus is principal mechanism

The Role of the Baroreflex in Maintaining Blood Pressure

Patient 2:
Continuous BP3

Patient 1:
MCA Blood Flow Velocity2

Symptoms disappear


nOH, neurogenic orthostatic hypotension; BP, blood pressure; MCA, middle cerebral artery; Vm, velocity measurement.

Supine Hypertension Is Common in Neurogenic OH Patients1

<table>
<thead>
<tr>
<th>Percentage of Patients2</th>
<th>MSA (n=25)</th>
<th>PD (n=23)</th>
<th>Control (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>With reduced BP fall at night</td>
<td>68 %</td>
<td>48 %</td>
<td>8 %</td>
</tr>
<tr>
<td>With reversed circadian BP</td>
<td>48 %</td>
<td>22 %</td>
<td>4 %</td>
</tr>
<tr>
<td>With supine hypertension</td>
<td>60 %</td>
<td>48 %</td>
<td>12 %</td>
</tr>
</tbody>
</table>

OH, orthostatic hypotension; BP, blood pressure; MSA, multiple system atrophy; PD, Parkinson’s disease.


Recognizing Symptomatic Neurogenic OH in Your Patients

**COMMON SYMPTOMS:**
- Lightheadedness
- Dizziness
- Presyncope
- Syncope

**LESS COMMON SYMPTOMS:**
- Weakness
- Headache
- Leg buckling
- Neck pain
- Fatigue
- Cognitive slowing
- Orthostatic dyspnea
- Chest pain
- Visual blurring

- Common symptoms occur on standing1
- Symptoms typically worse in the early morning2
- May also worsen after meals
- Occur in patients with diseases associated with specific neurodegenerative disorders such as Parkinson’s disease1

OH, orthostatic hypotension.

Measuring Orthostatic Blood Pressure


Have patient lie down for 5 minutes
Measure patient's blood pressure and pulse rate while lying down
Have patient stand
Measure blood pressure and pulse rate after standing for 1 minute, then again at 3 minutes

OH is defined by a sustained drop in systolic blood pressure of ≥20 mm Hg or diastolic blood pressure of ≥10 mm Hg within 3 minutes of standing due to an underlying neurologic disorder.

Head-Up Tilt (HUT) Testing


Cardiovascular response to HUT can be used to diagnose neurogenic OH in patients for whom standing BP is not an option.
– Patient rests supine for 15 minutes prior to HUT while beat-to-beat BP and heart rate are recorded
– Automated table is tilted slowly (~10 seconds) to an upright angle of 70°
– Patient remains upright for 5 minutes, followed by a 5-minute supine measurement interval
Management Strategies to Consider in Neurogenic OH Patients

- Goal of therapy: Reduce postural symptoms without introducing unacceptable side effects

**Non-Pharmacologic Approaches**

- Increase salt and fluid intake
- Elevate head of bed
- Expand intravascular volume
- Remove aggravating factors
- Increase vascular tone
- Recommend compression stockings

**Pharmacologic Approaches**

- Goal of therapy: Reduce postural symptoms without introducing unacceptable side effects

ABOUT NORTHERA® (droxidopa)

NORTHERA is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been demonstrated. The continued effectiveness of NORTHERA should be assessed periodically.

**WARNING: SUPINE HYPERTENSION**

Monitor supine blood pressure prior to and during treatment and more frequently when increasing doses. Elevating the head of the bed lessens the risk of supine hypertension, and blood pressure should be measured in this position. If supine hypertension cannot be managed by elevation of the head of the bed, reduce or discontinue NORTHERA.

Both Parkinson’s Disease and nOH Are Characterized by Deficiencies in Neurotransmission

The exact mechanism of action of NORTHERA® (droxidopa) in the treatment of symptomatic nOH is unknown

NORTHERA is a prodrug of norepinephrine

Figures supplied by Horacio Kaufman.
In Both Parkinson’s Disease and nOH, Therapies Replenish a Deficient Neurotransmitter

- Levodopa and droxidopa are both metabolized by DDC

In both Parkinson’s disease and nOH, therapies replenish a deficient neurotransmitter.

Levodopa and droxidopa are both metabolized by DDC.

![Chemical structures]


Droxidopa Pharmacokinetics in Healthy Subjects

- Mean peak plasma concentrations (Cmax): ~2 hours post-dose (range, 1-4 hours)
  - High-fat meals delay Cmax by ~2 hours
- Peak norepinephrine plasma levels: within 3-4 hours post-dose (<1 ng/mL)
- Mean elimination half-life: ~2.5 hours
  - Major route of elimination is via the kidneys
- The clinical relevance of the plasma pharmacokinetics of droxidopa has not been established


Most Common Adverse Events Occurring More Frequently With NORTHERA® (droxidopa)

<table>
<thead>
<tr>
<th></th>
<th>Study 301 and 302 (1- to 2-Week Randomized Treatment)</th>
<th>Study 306 (8- to 10-Week Randomized Treatment)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo (N=132) n (%)</td>
<td>NORTHERA (N=131) n (%)</td>
</tr>
<tr>
<td>Headache</td>
<td>4 (3.0)</td>
<td>8 (6.1)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2 (1.5)</td>
<td>5 (3.8)</td>
</tr>
<tr>
<td>Nausea</td>
<td>2 (1.5)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0</td>
<td>2 (1.5)</td>
</tr>
</tbody>
</table>

- The table displays adverse reactions that were reported in >5% of patients in the NORTHERA group and with ≥3% greater incidence in the NORTHERA group in relation to the placebo group.

NORTHOR (package insert). Deerfield, IL: Lundbeck; August 2014.

### Supine Systolic BP in Study 306

<table>
<thead>
<tr>
<th>Study 306</th>
<th>During 1- to 2-Week Titration Phase (% of patients)</th>
<th>At End of 8-Week Treatment Phase (% of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo (n=108)</td>
<td>NORTHERA (n=112)</td>
</tr>
<tr>
<td>Supine Systolic BP &gt;180 mm Hg</td>
<td>0</td>
<td>2.6</td>
</tr>
<tr>
<td>Supine Systolic BP &gt;160 mm Hg</td>
<td>1.9</td>
<td>2.6</td>
</tr>
<tr>
<td>Supine Systolic BP &gt;150 mm Hg</td>
<td>10.4</td>
<td>16.7</td>
</tr>
</tbody>
</table>

- Evaluation of blood pressure (BP) at each visit was a secondary endpoint.
- Supine BP measurements were taken with the upper body at 30° elevation.
- Sustained severe hypertension (systolic BP ≥180 mm Hg or diastolic BP ≥110 mm Hg in the seated or supine position) at the screening visit was an exclusion criterion.
- Dose escalation stopped if supine systolic BP rose to ≥180 mm Hg or diastolic BP to ≥110 mm Hg.


### Management of Supine Hypertension with NORTHERA® (droxidopa)

- **Supine hypertension with NORTHERA**
  - NORTHERA carries a black box warning for supine hypertension.1
  - Monitor blood pressure.1
  - Consider non-pharmacologic interventions such as:
    - Elevate head of the bed.1,4
    - Advise patient to avoid lying flat.1

- **Avoid NORTHERA dosing within 3 hours before bedtime.1**
  - Blood pressure (including lying down) should also be monitored as NORTHERA dose is up-titrated.
  - For more severe or persistent blood pressure elevations, NORTHERA dose can be reduced or NORTHERA can be discontinued.
  - Short-acting antihypertensive agents were allowed in the NORTHERA pivotal trial.3


### Cardiac Conduction and Heart Rate Were Not Affected by NORTHERA® (droxidopa)

- In Study 102, no effects of droxidopa were observed on conduction parameters following 600 mg and 2000 mg in a thorough QT study (52 healthy volunteers).

<table>
<thead>
<tr>
<th>Study 102 (mean ± from baseline)</th>
<th>Placebo</th>
<th>600 mg Droxidopa</th>
<th>2000 mg Droxidopa</th>
<th>400 mg Moxifloxacin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate (bpm)</td>
<td>0.0</td>
<td>−1.3</td>
<td>−1.5</td>
<td>1.1</td>
</tr>
<tr>
<td>PR (ms)</td>
<td>−0.3</td>
<td>0.4</td>
<td>0.7</td>
<td>−1.6</td>
</tr>
<tr>
<td>QRS (ms)</td>
<td>0.0</td>
<td>−0.1</td>
<td>−0.5</td>
<td>−0.3</td>
</tr>
<tr>
<td>QTcF (ms)</td>
<td>−3.1</td>
<td>−2.8</td>
<td>−2.6</td>
<td>6.1</td>
</tr>
<tr>
<td>QTcB (ms)</td>
<td>−3.1</td>
<td>−4.2</td>
<td>−4.2</td>
<td>7.4</td>
</tr>
</tbody>
</table>

**Important Safety Information**

**WARNING: SUPINE HYPERTENSION**

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**CONTRAINdications**

- None

**WARNINGS AND PRECAUTIONS**

- Supine Hypertension: NORTHERA therapy may cause or exacerbate supine hypertension in patients with NOH, which may increase cardiovascular risk if not well-managed.

NOH, neurogenic orthostatic hypotension.


**ADVERSE REACTIONS**

- The most common adverse events (greater than 5%) were headache, dizziness, nausea, hypertension, and fatigue.

**DRUG INTERACTIONS**

- Administering NORTHERA® (droxidopa) in combination with other agents that increase blood pressure (e.g., norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension. DOPA-decarboxylase inhibitors may require dose adjustments for NORTHERA.

**USE IN SPECIFIC POPULATIONS**

- Clinical experience with NORTHERA in patients with severe renal function impairment (GFR less than 30 mL/min) is limited. There are no adequate and well-controlled trials of NORTHERA in pregnant women. Women who are nursing should choose nursing or NORTHERA. The safety and effectiveness of NORTHERA in pediatric patients have not been established. No overall differences in safety or effectiveness were observed between subjects aged 75 years and older and younger subjects in clinical trials, but greater sensitivity of some older individuals cannot be ruled out.

GFR, glomerular filtration rate.


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**Important Safety Information (Cont’d)**

**WARNINGS AND PRECAUTIONS**

- Hyperpyrexia and Confusion: Postmarketing cases of a symptom complex resembling neuroleptic malignant syndrome (NMS) have been reported in Japan with NORTHERA® (droxidopa) use. Observe patients carefully when the dosage of NORTHERA is changed or when concomitant levodopa is reduced abruptly or discontinued, especially if the patient is receiving levodopa. NMS is an uncommon but life-threatening syndrome characterized by fever or hyperthermia, muscle rigidity, involuntary movements, altered consciousness, and mental status changes. The early diagnosis of this condition is important for the appropriate management of these patients.

- Ischemic Heart Disease, Arrhythmias, and Congestive Heart Failure: NORTHERA therapy may exacerbate symptoms in patients with existing ischemic heart disease, arrhythmias, and congestive heart failure.

- Allergic Reactions: The product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.


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GFR, glomerular filtration rate.

**NORTHERA® (droxidopa) Experience in Geriatric Patients or Patients With Renal Impairment**

**GERIATRIC USE**
- 197 patients ≥75 years of age with symptomatic NOH were included in the NORTHERA clinical program
- No overall differences in safety or effectiveness were observed between these and younger patients, although greater sensitivity of some older patients cannot be ruled out

**PATIENTS WITH RENAL IMPAIRMENT**
- Patients with mild/moderate renal impairment (GFR ≥30 mL/min) were included in clinical trials and did not have a higher frequency of adverse reactions
- Clinical experience with NORTHERA in patients with severe renal function impairment (GFR <30 mL/min) is limited

NOH, neurogenic orthostatic hypotension; GFR, glomerular filtration rate.


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**Concomitant Use**
- NORTHERA® (droxidopa) has no contraindications
- NORTHERA has been used concomitantly in clinical trials with levodopa/carbidopa, dopamine agonists, monoamine oxidase B (MAO-B) inhibitors, catechol-O-methyltransferase (COMT) inhibitors, and other medications used to treat Parkinson’s disease
- Administering NORTHERA in combination with other agents that increase blood pressure (eg, norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension. DOPA-decarboxylase inhibitors may require dose adjustments for NORTHERA
- Dopamine agonists, amantadine derivatives, and MAO-B inhibitors do not appear to affect NORTHERA clearance, and no dose adjustments are required

In Clinical Trials, NORTHERA® (droxidopa) Was Taken TID

- The recommended starting dose of NORTHERA is 100 mg, taken orally TID
  - Upon rising in the morning
  - At midday
  - In the late afternoon at least 3 hours prior to bedtime (to reduce the potential for supine hypertension during sleep)

NORTHERA is supplied in 3 dosage strengths: 100, 200, and 300 mg to facilitate customized dosing

Additional Dosing Considerations

- Take NORTHERA® (droxidopa) whole, the same way each time, either with food or without food
- If a dose is missed, the next dose should be taken at the regularly scheduled time. The patient should not double the next dose
- Use of or change in dose of dopamine decarboxylase inhibitors (such as carbidopa) may require dose adjustments for NORTHERA

In Clinical Trials, NORTHERA® (droxidopa) Was Titrated Every 24-48 Hours

- Titrate in increments of 100 mg TID every 24-48 hours

Monitor supine blood pressure prior to initiating NORTHERA and after increasing the dose. Elevating the head lowers the risk of high blood pressure while lying down.
In Clinical Trials, Titration Was to Tolerability and Symptomatic Response

Clinical Trial Titration Experience
- NORTHERA® (droxidopa) was shown to be safe and well tolerated in total daily doses from 300 to 1800 mg
- ~70% of patients received a dose of 400-600 mg NORTHERA TID
- Titration phase lasted a maximum of 14 days

Case Study: RW, a 74-Year-Old Man With Worsening Lightheadedness (Cont’d)

Treatment
NORTHERA® (droxidopa) Treatment
- Patient is started on NORTHERA 100 mg TID
- He is instructed to take his blood pressure lying down daily before and after increasing NORTHERA dose and to record his results and symptoms in a diary
- NORTHERA dose is increased by 100 mg TID every 48 hours
- Patient reaches dose of 400 mg TID, symptoms of lightheadedness persist

Discussion

How would you continue to manage this patient?