MEDICATION USE IN THE ELDERLY PATIENT: PHYSIOLOGY, PHARMACOLOGY, PRESCRIBING

Anthony J. Caprio, MD
Kevin Biese MD, MAT
Ellen Roberts PhD, MPH
Jan Busby-Whitehead, MD
University of North Carolina Chapel Hill
Division of Geriatric Medicine
Center for Aging and Health
Department of Emergency Medicine

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OBJECTIVES

• Identify the physiologic changes associated with normal aging in relation to drug absorption, distribution, neurological effects, metabolism, and excretion
• Identify risk factors for adverse drug events in older adults
• Recognize adverse drug events when an older adult patient presents with a common clinical condition or complaint
• Identify and avoid potentially harmful medications for older adults
CASE STUDY: “MRS. ANDERSON”

- 87-year-old woman from nursing home; fell last night and complains of left hip and back pain
- Unable to recall events; agitated; says “yes” when asked if she is in pain
- Reportedly able to ambulate short distance with walker at baseline; needs assistance with dressing, bathing, toileting; able to feed herself
- Note from nursing home about rectal bleeding 2 days ago
- Electronic medical record (WebCIS) indicates that she was in ED last month for a heavily bleeding laceration after a fall and supratherapeutic INR of 5.6 (while on antibiotics for a urinary tract infection)
<table>
<thead>
<tr>
<th></th>
<th>Case Study: Past Medical History</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dementia (MMSE 20/30)</td>
</tr>
<tr>
<td>2</td>
<td>Parkinson’s disease</td>
</tr>
<tr>
<td>3</td>
<td>CVA with residual L-sided weakness</td>
</tr>
<tr>
<td>4</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>5</td>
<td>Urinary incontinence</td>
</tr>
<tr>
<td>6</td>
<td>Recurrent UTIs</td>
</tr>
<tr>
<td>7</td>
<td>Hypertension</td>
</tr>
<tr>
<td>8</td>
<td>CAD; stent 2 years ago</td>
</tr>
<tr>
<td>9</td>
<td>CHF (EF 30%)</td>
</tr>
<tr>
<td>10</td>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>11</td>
<td>Hyperlipidemia</td>
</tr>
<tr>
<td>12</td>
<td>Osteoarthritis, especially hips and knees</td>
</tr>
<tr>
<td>13</td>
<td>Macular degeneration</td>
</tr>
<tr>
<td>14</td>
<td>Type 2 DM</td>
</tr>
<tr>
<td>15</td>
<td>Peripheral neuropathy</td>
</tr>
<tr>
<td>16</td>
<td>Chronic renal insufficiency</td>
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<tr>
<td>17</td>
<td>Anemia</td>
</tr>
<tr>
<td>18</td>
<td>Hypothyroidism</td>
</tr>
<tr>
<td>19</td>
<td>COPD on oxygen</td>
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<tr>
<td>20</td>
<td>Diverticulosis</td>
</tr>
</tbody>
</table>
CASE STUDY: PHYSICAL EXAM (1 of 2)

- **Vitals:** T: 38.0; BP: 150/95; HR: 110; RR: 20; O$_2$ sat: 89% on RA, 96% on 2L

- **General:** very thin, frail, agitated elderly female; appears uncomfortable; inattentive and able to answer only simple questions

- **HEENT:** quarter-sized contusion on L forehead; EOMI; PERRLA; moist mucous membranes

- **CVS:** S1, S2 irregularly irregular; unable to assess JVP due to agitation

- **Chest:** poor effort; faint crackles at bilateral bases
CASE STUDY: PHYSICAL EXAM (2 of 2)

• Abdomen: mildly distended; diminished bowel sounds; diffusely tender; no rebound

• Rectal: large amount of hard stool, guaiac negative

• Extremities: L leg shortened and externally rotated; pain with movement; groin tenderness; 2+ edema in bilateral LE; pulses intact
<table>
<thead>
<tr>
<th></th>
<th>Medication</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Donepezil (Aricept)</td>
<td>5 mg PO daily</td>
</tr>
<tr>
<td>2</td>
<td>Carbidopa/Levodopa 10/100</td>
<td>PO TID</td>
</tr>
<tr>
<td>3</td>
<td>Aspirin</td>
<td>325 mg PO daily</td>
</tr>
<tr>
<td>4</td>
<td>Warfarin (Coumadin)</td>
<td>5 mg PO qHS</td>
</tr>
<tr>
<td>5</td>
<td>Tolterodine (Detrol)</td>
<td>2 mg PO BID</td>
</tr>
<tr>
<td>6</td>
<td>Atorvastatin (Lipitor)</td>
<td>40 mg PO qHS</td>
</tr>
<tr>
<td>7</td>
<td>Insulin</td>
<td>(long-acting and sliding scale)</td>
</tr>
<tr>
<td>8</td>
<td>Gabapentin (Neurontin)</td>
<td>300 mg PO TID</td>
</tr>
<tr>
<td>9</td>
<td>Iron sulfate</td>
<td>325 mg PO TID</td>
</tr>
<tr>
<td>10</td>
<td>Trazodone</td>
<td>50 mg PO qHS</td>
</tr>
<tr>
<td>11</td>
<td>Levothyroxine 50 mcg</td>
<td>PO daily</td>
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<tr>
<td>12</td>
<td>Furosemide (Lasix)</td>
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<tr>
<td>13</td>
<td>Potassium chloride</td>
<td>20 mEq PO daily</td>
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<tr>
<td>14</td>
<td>Metoprolol</td>
<td>100 mg PO BID</td>
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<tr>
<td>15</td>
<td>Lisinopril</td>
<td>20 mg PO daily</td>
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<tr>
<td>16</td>
<td>Amlodipine</td>
<td>10 mg PO daily</td>
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<tr>
<td>17</td>
<td>Acetaminophen</td>
<td>1,000 mg PO TID</td>
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<tr>
<td>18</td>
<td>Docusate sodium</td>
<td>100 mg PO BID</td>
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<tr>
<td>19</td>
<td>Polyethylene glycol powder</td>
<td>(Miralax) 17 g PO daily</td>
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<td>20</td>
<td>Tiotropium (Spiriva)</td>
<td>18 mcg inhaled daily</td>
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<td>21</td>
<td>Montelukast (Singulair)</td>
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<tr>
<td>22</td>
<td>Fluticasone/salmeterol</td>
<td>100/50 inhaled BID</td>
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<td>23</td>
<td>Albuterol/Atrovent nebulizers</td>
<td>PRN for wheezing</td>
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<tr>
<td>24</td>
<td>Multivitamin</td>
<td>one PO daily</td>
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<tr>
<td>25</td>
<td>Vitamin E</td>
<td>400 IU PO daily</td>
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<tr>
<td>26</td>
<td>Calcium carbonate</td>
<td>500 mg PO TID</td>
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<tr>
<td>27</td>
<td>Vitamin D</td>
<td>800 units PO daily</td>
</tr>
<tr>
<td>28</td>
<td>Nitrofurantoin</td>
<td>(Macroductin) 100 mg PO qHS</td>
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</tbody>
</table>
CHALLENGES OF PRESCRIBING FOR OLDER ADULTS

- Multiple medical conditions
- Multiple medications
- Multiple prescribers
- Different metabolisms and responses
- Lack of evidence for use in elderly
- Adherence and cost
- Supplements, herbals, and over-the-counter drugs

• 2/3 of older adults are on regular medications
• People aged >65 account for 1/3 of all prescriptions written, but they represent only 15% of the US population
• Dangers of multiple medications (“polypharmacy”)
  - Adverse effects
  - Drug-drug interactions
  - Duplication of drug therapy
  - Poor adherence
  - Cost
  - Decreased quality of life
ADVERSE DRUG EVENTS (ADEs)

• Adverse symptoms
• Adverse clinical outcomes
  ➢ Doctor visits or hospitalizations
  ➢ Falls
  ➢ Functional decline
  ➢ Changes in cognition (delirium)
  ➢ Death
• Poor adherence, poor quality of life
• Increased cost
ADEs AND OLDER ADULTS (1 of 2)

- 35% of community-dwelling older adults experience an ADE annually

- ADEs in the emergency department
  - 2.0 per 1000 for adults under 65
  - 4.9 per 1000 for aged 65 years or older
  - 6.8 per 1000 for aged 85 years or older

JAMA. 2006; 296:1858-1866.
JAGS. 1997;45:945-948.
ADEs AND OLDER ADULTS (2 of 2)

• 2/3 of nursing home patients experience an ADE over a 4-year period
• 1.6 per 1000 older adults require hospital admission because of an ADE (7 times the rate in younger adults)
• Nearly 1/3 of all geriatric hospital admissions are due to ADEs

JAMA. 2006; 296:1858-1866.
JAGS. 1997;45:945-948.
MOST COMMONLY ASSOCIATED WITH ADEs IN OLDER ADULTS

Outpatient ADEs
• Antibiotics
• Analgesics
• Anticoagulants
• Antihistamines
• Anticonvulsants
• Antipsychotics
• Cardiovascular medications
• Diabetes medications

ADEs in the Emergency Department
• Warfarin (17.3%)
• Insulin (13%)
• Digoxin (3.2%)

*JAMA.* 2006; 296:1858-1866.
POTENTIAL RISK FACTORS FOR ADEs

- ≥6 chronic diseases
- >12 doses/day
- ≥9 medications
- Low BMI (<22 kg/m²)
- Age > 85 years
- Creatinine clearance < 50 mL/min
- History of prior ADE

CASE STUDY: IS MRS. ANDERSON AT RISK OF AN ADE?

- 6 chronic diseases — yes
- >12 doses/day— yes
- ≥9 medications — yes
- Low BMI (<22 kg/m²) — likely
- Age >85 years — yes
- Creatinine clearance < 50 mL/min — possibly
- History of prior ADE — yes
- Nursing home resident — yes
CASE STUDY: WHY IS MRS. ANDERSON AT RISK?

• Multiple drugs (high “exposure”)
  ➢ Risk of ADE is proportional to number of drugs
  ➢ Increased probability of drug-drug interactions

• Physiologic changes (increased susceptibility)
  ➢ Associated with disease states
  ➢ Associated with normal aging
PHYSIOLOGIC CHANGES ASSOCIATED WITH DISEASE STATES

- Cardiac diseases
  - Impaired cardiac output (decreased absorption, metabolism, clearance)
  - Greater susceptibility to cardiac adverse effects
- Kidney and liver diseases
  - Decreased drug clearance
- Neurological diseases
  - Diminished neurotransmitter levels
  - Impaired cerebral blood flow
  - Greater sensitivity to neurological effects
PHYSIOLOGIC CHANGES ASSOCIATED WITH NORMAL AGING

• Less water
• More fat
• Less muscle mass
• Slowed hepatic metabolism
• Decreased renal excretion
• Decreased responsiveness of the baroreceptors
ABSORPTION

- Not affected by the normal aging process
- Can be altered by drug interactions
  - Antacids
  - Iron
- Can be affected by disease
  - Lack of intrinsic factor (Vitamin B12 absorption)
  - Delayed gastric emptying
DISTRIBUTION

• **Less water** = ↓ volume of distribution = higher concentration of water-soluble drugs

• **More fat** = ↑ volume of distribution = prolonged action of fat-soluble drugs (increased half-life)

• **Lower level of serum proteins** (e.g., albumin) increases the concentration of the unbound (free or active) form of drugs
METABOLISM

• Slowed phase I (including cytochrome P450) reactions
  ➢ Oxidation, reduction, dealkylation
  ➢ Warfarin and phenytoin levels may be higher because of altered metabolism

• Phase II reactions are essentially unchanged
  ➢ Conjugation, acetylation, methylation

• Drug-drug interactions
  ➢ Increased risk with increased number of drugs
EXCRETION

• Hepatic

• Renal
  - Renal clearance may be reduced
  - Serum creatinine may not be an accurate reflection of renal clearance in elderly patients (decreased lean body mass)

• Active drug metabolites may accumulate
  - Prolonged therapeutic action
  - Adverse effects
CASE STUDY: WHY DID MRS. A FALL?

• Functional status
  ➢ Uses walker at baseline
  ➢ Dependent in other ADLs (like bathing)

• Sensory impairments
  ➢ Macular degeneration
  ➢ Peripheral neuropathy

• CNS diseases
  ➢ Dementia
  ➢ Parkinson’s disease

• Comorbid diseases
  ➢ Cardiovascular (syncope)
  ➢ Diabetes mellitus (hypoglycemia)
  ➢ Anemia (hypotension)
ORTHOSTATIC HYPOTENSION, FALLS, AND HIP FRACTURES

• Baroreceptor sensitivity decreases with age

• Trazodone
  - New medication according to nursing home record
  - Associated with orthostatic hypotension

• Diuretic use can cause volume depletion and orthostatic hypotension

• Falls and hip fractures are associated with significant morbidity and mortality in older adults
CASE STUDY:
WHY IS MRS. ANDERSON CONFUSED?

• Head injury?
  ➢ Contusion on forehead
  ➢ Recent history of supratherapeutic INR

• Dementia
  ➢ Moderate dementia by history
  ➢ What is her baseline?

• Delirium
  ➢ Infection (history of UTIs)
  ➢ Drugs (adverse drug event)
  ➢ Hospital (change in environment)
DELIRIUM

• More than confusion
  ➢ Acute onset, fluctuating course
  ➢ Inattention
  ➢ Disorganized thinking or altered level of consciousness

• Associated with low levels of acetylcholine
  ➢ Low levels in patients with dementia at baseline
  ➢ Use of anticholinergic medications is a risk factor
ANTICHLINERGIC MEDICATIONS

• Drug classes
  ➢ Antihistamines
  ➢ Tricyclic antidepressants
  ➢ Antispasmodics and muscle relaxants

• Adverse effects
  ➢ Dry mouth
  ➢ Urinary retention
  ➢ Constipation
  ➢ Confusion, delirium
PHARMACOLOGIC TUG-OF-WAR

• Tolterodine (Detrol)
  - Potent anticholinergic
  - Relaxes detrusor muscle to treat urge incontinence (detrusor hyperactivity; “overactive bladder”)
  - Can worsen constipation

• Donepezil (Aricept)
  - Acetylcholinesterase inhibitor
  - Raises levels of acetylcholine to help improve cognition
  - Can cause detrusor hyperactivity and diarrhea
  - Could cause symptomatic bradycardia, syncope (Mrs. A is also on β-blocker)

• Incontinence and falls
  - Dementia is a risk factor for both incontinence and falls
  - May be adverse drug events related to donepezil
  - Diuretic use can worsen incontinence and cause orthostatic hypotension
“THINK DRUGS” BEFORE MAKING A NEW DIAGNOSIS

• Consider adverse drug effect as etiology of new signs/symptoms
• Remember that an over-the-counter drug, supplement, or herbal remedy can be the culprit
• Consider discontinuing or dose-reducing medications
• Avoid prescribing a new medication to treat an adverse drug effect (“prescribing cascade”)

Slide 29
## COMMON CONDITIONS COULD REALLY BE ADVERSE DRUG EFFECTS

<table>
<thead>
<tr>
<th>Condition</th>
<th>Could be caused by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>• Calcium channel blocker</td>
</tr>
<tr>
<td></td>
<td>• Iron</td>
</tr>
<tr>
<td>Incontinence</td>
<td>• α-blocker</td>
</tr>
<tr>
<td>Memory loss</td>
<td>• Antihistamines</td>
</tr>
<tr>
<td>Syncope</td>
<td>• Tricyclic antidepressant</td>
</tr>
<tr>
<td></td>
<td>• α-blocker</td>
</tr>
<tr>
<td>Falls</td>
<td>• Benzodiazepine</td>
</tr>
<tr>
<td>Weight loss</td>
<td>• Fluoxetine (Prozac)</td>
</tr>
</tbody>
</table>
CASE STUDY (continued)

• Labs
  ➢ Hb/Hct = 10/30.1 (baseline)
  ➢ INR = 1.9
  ➢ Creatinine = 2.0 (baseline 1.5)
  ➢ Trop T = 0.090 (ref 0.000-0.034); normal CK and CK-MB
  ➢ UA negative

• EKG: unchanged; anterior T-wave flattening

• CT of head
  ➢ Atrophy, chronic small-vessel ischemic disease
  ➢ No acute bleed
CASE STUDY: PELVIS AND LEFT HIP X-RAYS
CASE STUDY: ACUTE MANAGEMENT

• Pain
  ➢ Already given morphine 2 mg IV × 2 doses for pain

• Nausea and vomiting
  ➢ Complains of “sick stomach”
  ➢ Emesis after morphine

• Agitation
  ➢ Increasingly agitated, trying to climb out of bed
  ➢ Shouting “Veronica” repeatedly
CASE STUDY:
WHAT DO YOU ORDER?

• Pain
• Nausea
• Agitation
POTENTIALLY INAPPROPRIATE MEDICATION USE IN OLDER ADULTS: Beers Criteria (1 of 2)

• A consensus-based list of medications that are potentially inappropriate for the elderly
• The Beers criteria were published in 1991, revised in 1997 and 2002
• Statistical association with adverse drug events has been documented
• Does not account for the complexity of the entire medication regimen

POTENTIALLY INAPPROPRIATE MEDICATION USE IN OLDER ADULTS: Beers Criteria (2 of 2)

• Table 1: Independent of disease or condition
  - Describes concern for prescribing certain drugs or classes of drugs for older adults
  - Gives severity rating (low or high)

• Table 2: Considering diagnosis or condition
  - Describes drugs or classes of drugs that can cause or worsen a particular disease or condition
  - Gives severity rating (low or high)

PAIN MEDICATIONS

• Propoxyphene (Darvon) has limited efficacy and significant side effects (has been withdrawn from the market)
• Caution with nonsteroidal anti-inflammatory drugs
  ➢ Indomethacin has significant CNS side effects
  ➢ Ketorolac (Toradol) can cause serious GI and renal effects
• Meperidine (Demerol) has low oral efficacy, active metabolites and CNS effects
• Morphine metabolites are renally cleared

ANTI-EMETICS

• Antihistamines: promethazine (Phenergan)
  ➢ Anticholinergic, may worsen delirium (↓ acetylcholine)
  ➢ Included on Beers list (Table 1)

• Dopamine antagonists: metoclopramide (Reglan)
  ➢ May worsen parkinsonism (↓ dopamine)
  ➢ Included on Beers list (Table 2)

• Serotonin (5-HT3) antagonists: odansetron (Zofran)
  ➢ Expensive, but likely safest for this patient

MANAGING AGITATED DELIRIUM

• Treat pain
  - Opioids may cause confusion, but untreated pain may precipitate and perpetuate delirium

• Assess for other sources of discomfort
  - Hunger, thirst, cold
  - Fecal impaction; urinary retention

• Address sensory impairment
  - Eye glasses and hearing aids
  - Try to minimize sensory “overload”
  - Reorientation
ANTIPSYCHOTIC MEDICATIONS

• **Black-box warning** for increased risk of stroke, death

• **Typical antipsychotics** (eg, haloperidol)
  - Potent anti-dopaminergic effects
  - Can severely worsen parkinsonism
  - Included on Beers list (Table 2)
  - IV haloperidol is associated with arrhythmias

• **Atypical antipsychotics** (eg, risperidone, quetiapine, olanzapine)
  - Olanzapine may be best choice in setting of prolonged QTc
  - Quetiapine safest for Parkinson’s disease but may not be as useful for acute management
BENZODIAZEPINES FOR ACUTE AGITATION

• Avoid entirely if possible (included in Beers list, Table 1)
  ➢ Appropriate if being used to treat alcohol withdrawal
• May cause a paradoxical reaction in the elderly
  ➢ Increasing agitation and anxiety
  ➢ May lead to prescribing cascade (eg, antipsychotic use)
• Long-acting benzodiazepines
  ➢ Prolonged half-life in older adults (days)
  ➢ Sedation, aspiration, delirium
  ➢ Increased risk of falls and fractures
• Short-acting benzodiazepines
  ➢ Increased sensitivity in older adults
  ➢ If necessary to use, prescribe lowest dose possible

“START LOW AND GO SLOW…”

• Start one medication at a time
• Start with a low dose and increase gradually
• You can always give more, but you can’t “take back”
• Monitor for therapeutic response and adverse effects
OTHER DOSING CONSIDERATIONS

• Renal
  - Adjust dose based on estimated creatinine clearance
  - Gabapentin is renally cleared and can precipitate falls and delirium

• Drug interactions
  - Warfarin
CONCLUSION: MRS. ANDERSON

• Medicated with morphine for pain

• Given 1 dose of odansetron (Zofran) for nausea

• Evaluated by orthopedics; plan is for operative repair for pain control and since patient was ambulatory at baseline

• Disimpacted; eye glasses and hearing aids brought to hospital by family

• Admitted to Medicine for syncope work-up
SUMMARY:
CHANGES WITH AGING

• Absorption usually does not change
• ↑ concentrations of water-soluble and free (unbound) drugs
• Longer half-life of lipophilic drugs
• Slower phase I metabolism
• Impaired excretion
• Decreased responsiveness of the baroreceptors
SUMMARY: PRESCRIBING FOR OLDER ADULTS

- Adverse drug events are common in elderly patients presenting to the Emergency Dept.
- “Think drugs” before making a new diagnosis
- Use caution with medications on the Beers list
- “Start low and go slow” when prescribing a drug that is new to the patient
- Adjust dosing for renal impairment and drug interactions
Mr. Johnson is an 83-year-old man with a history of benign prostatic hypertrophy (BPH) and hypertension. He recently started taking the antihistamine diphenhydramine (Benadryl) for a viral respiratory infection and now presents to the ED because he is unable to urinate.

Mr. Johnson is diagnosed with acute urinary retention due to BPH. A Foley catheter is placed and 1200 cc of urine is drained. The physician prescribes terazosin, a peripherally acting α1-adrenergic antagonist, to help with his urinary retention. The catheter is left in place, and he is discharged home with instructions to follow up with his primary care physician later that week.

Two days later, Mr. Johnson falls while getting out of bed and returns to the ED for evaluation of hip pain. He complains of feeling light-headed when standing up and is admitted for a syncope work-up.
CASE 1, QUESTION 1

What physiologic change associated with normal aging may affect Mr. Johnson’s clinical response to drugs?

a) Decreased gastric absorption of orally administered medications
b) Decreased responsiveness of the carotid baroreceptors
c) Generally lower concentrations of water-soluble drugs, due to increased total body water
d) Relatively lower concentrations of free (unbound) drug in serum, due to higher concentrations of carrier protein
CASE 1, QUESTION 2

Anticholinergic medications, which include antihistamines, can cause which of the following?

a) Delirium and diarrhea  
b) Diarrhea and urinary urgency  
c) Dry mouth (xerostomia) and delirium  
d) Urinary urgency and xerostomia
CASE 2

• Mr. Jones is a 87-year-old man with a history of moderate dementia, prior falls, and gait instability. He presents to the ED with severe left groin pain after falling at his nursing home. His left leg appears shorter and externally rotated. Head CT reveals only significant atrophy. His left hip and pelvis x-rays reveal an intertrochanteric femur fracture.

• Mr. Jones is in acute distress but able to answer simple questions appropriately. He is oriented to person, knows he is in the hospital, and remembers falling. He is given morphine for pain and then 30 minutes later receives promethazine (Phenergan) for nausea and an additional dose of morphine for uncontrolled pain. He becomes very agitated and confused and is given lorazepam (Ativan), but this only seems to worsen his agitation. He is then given haloperidol (Haldol). He becomes less agitated but now appears stuporous.

• He undergoes open reduction and internal fixation. His post-op course is complicated by several days of waxing and waning delirium. However, his cognition slowly improves and he is discharged to his nursing home.
CASE 2, QUESTION 1

What physiologic change associated with normal aging may affect Mr. Jones’ clinical response to medications?

a) Decreased gastric absorption of orally administered medications

b) Generally lower concentrations of water-soluble drugs, due to increased total body water

c) Prolonged half-life of lipid-soluble drugs, due to a higher relative composition of body fat

d) Relatively lower concentrations of free (unbound) drug in serum, due to higher concentrations of carrier proteins
CASE 2, QUESTION 2

Although Mr. Jones was initially diagnosed with a hip fracture and treated for pain, he became very agitated and confused with subsequent medication administration. Which of the following is the best explanation for his overall clinical presentation?

a) Anticholinergic effects of the morphine and lorazepam precipitated delirium
b) Anticholinergic effects of the promethazine precipitated delirium, and the lorazepam had a paradoxical effect
c) Lorazepam had a paradoxical effect and the haloperidol precipitated delirium
d) Mr. Jones experienced an acute intracranial hemorrhage after his fall
ANSWER KEY

• Case 1
  ➢ Question 1: b
  ➢ Question 2: c

• Case 2
  ➢ Question 1: c
  ➢ Question 2: b
ACKNOWLEDGEMENTS AND DISCLAIMER

This project was supported by funds from the American Geriatrics Society/John A. Hartford Geriatrics for Specialists Grant. This information or content and conclusions are those of the authors and should not be construed as the official position or policy of the American Geriatrics Society or John A. Hartford Foundation, nor should any endorsements be inferred.

The UNC Center for Aging and Health and Department of Emergency Medicine also provided support for this activity. This work was compiled and edited through the efforts of Jennifer Link, BA.
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