Top New Medications: What’s Hot? What’s Not?

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Objectives

Upon completion of the lecture, the participant will be able to:
1. Identify 8-10 new medications being utilized in a primary care setting and hospital based setting
2. Discuss the use, side effects, drug-drug interactions, and benefits of each of the medications
3. Discuss case studies of individuals using the medications

Savella

► Savella (milnacipran HCL)
► Class: SNRI
► Indications:
  • Fibromyalgia
  • Not indicated for the treatment of depression although it is an SNRI
► Pregnancy Category: C

Dosing of Savella

► Begin dosing at 12.5 mg on the first day and increase to 100 mg/day over a 1-week period:
  • Day 1: 12.5 mg once
  • Days 2-3: 25 mg/day (12.5 mg twice daily)
  • Days 4-7: 50 mg/day (25 mg twice daily)
  • After Day 7: 100 mg/day (50 mg twice daily)
► Recommended dose is 100 mg/day
► May be increased to 200 mg/day based on individual patient response
► With or without food; food makes more tolerable

Savella: Efficacy

► More patients in the Savella treatment arms experienced at least a 30% reduction in pain from baseline (VAS) and considered themselves globally improved (PGIC) than did patients in the placebo arm.
► Benefit noted as early as 1 week into treatment

Savella

► Side effects
  • Like all SNRI’s – you must monitor blood pressure
  • Nausea
  • Dizziness
  • Vomiting
  • Worsening of obstructive uropathies
  • Insomnia
Savella

- Contraindications
  - MAO use
  - Narrow angle closure glaucoma
- Precautions
  - Hepatic and renal impairment
  - Suicidal ideations
  - Seizure disorders
  - Elevated AST/ALT
  - Increased risk of bleeding

Likely to see...

- Use of Savella with other medications
  - i.e. Lyrica (pregabalin)
  - Muscle relaxants
  - Tramadol

Uloric

- ULORIC (febuxostat)
- Class: xanthine oxidase (XO) inhibitor
- Indicated for the chronic management of hyperuricemia in patients with gout
- ULORIC is not recommended for the treatment of asymptomatic hyperuricemia

Uloric: Dosing Information

- Dosage:
  - 40 mg or 80 mg once daily
  - Starting dose - 40 mg once daily
  - For patients who do not achieve a serum uric acid (sUA) less than 6 mg per dL after 2 weeks with 40 mg, increase dosage 80 mg
  - At two weeks – recheck uric acid level
  - May be taken with or without food

Efficacy

- 80 mg dose of Uloric worked better than allopurinol; a 40-milligram dose worked at least as well as allopurinol
- Unlike allopurinol, very little Uloric is excreted through the urine, making Uloric safe for patients with kidney problems

Table 2: Proportion of Patients with Serum Uric Acid Levels

<table>
<thead>
<tr>
<th>Study</th>
<th>ULORIC - 40 mg daily</th>
<th>ULORIC - 80 mg daily</th>
<th>Allopurinol</th>
<th>Placebo</th>
<th>Difference in Proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1 (6 months)</td>
<td>48%</td>
<td>57%</td>
<td>42%</td>
<td>41%</td>
<td>-1% (0%, 5%)</td>
</tr>
<tr>
<td>Study 2 (3 months)</td>
<td>73%</td>
<td>59%</td>
<td>1%</td>
<td>35%</td>
<td>(9%, 42%)</td>
</tr>
<tr>
<td>Study 3 (12 months)</td>
<td>75%</td>
<td>26%</td>
<td>-1%</td>
<td>35%</td>
<td>(30%, 40%)</td>
</tr>
</tbody>
</table>

*Comparison was balanced between the treatment groups, except in Study 2 in which two of the patient treatment groups combined to placebo.

Package insert, 2009; accessed 02-25-2009
Uloric

► Instructions
  ▪ If gout flare occurs, may treat with colchicine, NSAIDs
  ▪ Gout flares are more common following initiation with Uloric as urate is be mobilized from tissue deposits
  ▪ Consider: prophylaxis with colchicine vs. NSAIDs is recommended (8 weeks - 6 months)

► Precautions
  ▪ Monitor liver enzymes periodically
  ▪ Hepatic/renal dysfunction

► Contraindications
  ▪ Patients taking the following medications
    - Theophylline
    - Azathioprine
    - Mercaptopurine

Cardiovascular Issues

► In 2005, the FDA refused to approve Uloric because there were slightly more deaths and heart problems in patients taking the drug than in patients taking allopurinol.
► As people with gout problems already are at higher risk of heart disease, the FDA issued an "approvable" letter.
► 3 large clinical trials were then performed. These new studies found no more deaths and no more heart problems in patients taking Uloric than in patients taking allopurinol.
► 2008 - approved by FDA (12-0 vote)

Cardiovascular Events

► In the randomized controlled studies, there was a higher rate of cardiovascular thromboembolic events (cardiovascular deaths, non-fatal myocardial infarctions, and non-fatal strokes) in patients treated with ULORIC (0.74 per 100) than allopurinol (0.60 per 100)
► Monitor closely for any symptoms

Trilipix

► Trilipix (delayed-release capsules) belongs to a class of drugs called fibrates.
► Trilipix is the first fibrate to be specifically approved for use along with a statin. Other fibrates are often prescribed with statins, but that's technically an off-label use of those drugs.
► Patients who take Trilipix with a statin must either have coronary heart disease or a coronary heart disease risk equivalent and who are on optimal statin therapy to achieve their LDL cholesterol goal, according to the FDA.

Table 1: Adverse Reactions Occurring in 3% of Uloric-Treated Patients and at Least 2% Greater than Seen in Patients Receiving Placebo in Controlled Studies

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Placebo</th>
<th>Uloric 40 mg daily</th>
<th>Uloric 80 mg daily</th>
<th>Allopurinol</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (n=134)</td>
<td>(n=257)</td>
<td>(n=257)</td>
<td>(n=257)</td>
<td>(n=1,577)</td>
</tr>
<tr>
<td>Liver Function Abnormalities</td>
<td>0.7%</td>
<td>4.8%</td>
<td>6.4%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Nausea</td>
<td>0.7%</td>
<td>1.1%</td>
<td>1.1%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Anorexia</td>
<td>0%</td>
<td>0.7%</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Rash</td>
<td>0.7%</td>
<td>0.5%</td>
<td>0.6%</td>
<td>1.6%</td>
</tr>
</tbody>
</table>
**Nucynta**

- Tapentadol
- First new opioid in 25 years
  - Schedule II
- Dual mechanism of action
  - μ opioid receptor agonist
  - Norepinephrine reuptake inhibitor
- Indication: 18 years of age and older; moderate – severe acute pain
- Competition to oxycodone

- Dosing:
  - 50 mg, 75 mg and 100 mg
  - Administer every 4 – 6 hours prn pain
  - Tmax = 1.25 hours
  - Half-life: 4 hours
- Does not use CYP450 for metabolism

- Caution:
  - Moderate – severe hepatic disease
  - In these individuals – utilize 50 mg; no more than three doses in 24 hours
- Drug-Drug Interactions
  - SSRIs, SNRIs, TCA’s and triptans – caution re: serotonin syndrome
- Contraindications
  - MAOI’s within previous 14 days

**New PPI**

- Kapidex
- Dexlansoprazole; R-isomer of lansoprazole
- Biphasic release mechanism
  - First peak: 1 – 2 hours
  - Second peak: 4 – 5 hours
- Prescription PPI
- Indications: Heartburn/GERD and EE
- Available in 30 and 60 mg dosages

**Onglyza**

- Saxagliptin
- DPP-4 inhibitor (same class as Januvia)
- Approved by FDA - 8/1/2009
- Indication: Type 2 diabetes
- Dosages:
  - 2.5 mg and 5.0 mg once daily
  - 2.5 mg – utilize for individuals with moderate - severe renal impairment (C. Cl < 50 mL/min) and for individuals on strong CYP450 3A4 inhibitors (ketoconazole)
### Onglyza

- **Side effects**
  - Very similar to placebo
  - URI, headache and UTI (slightly higher than placebo)
  - Peripheral edema (higher in individuals treated with TZD and Onglyza)

- **Additional information**
  - Category B: Crosses placenta
  - Decrease in absolute lymphocyte counts; unsure of relevance

### Efficacy

- A1C: decrease by 0.4 – 0.5%
- Fasting glucose: decrease by 9 – 15 mg/dL
- Postprandial glucose: decrease by 43 – 45 mg/dL

### Sumavel

- **Sumavel Dosepro**
  - Needle free delivery system
  - Administers sumatriptan into subcutaneous tissue with “pressurized system”

- **Contains:** sumatriptan

- **Indications:**
  - Acute treatment of migraines and cluster headaches

- **Dosage:** 6mg sumatriptan

- **Same contraindications, precautions as sumatriptan**

### Plan B – One Step

- One pill for prevention of pregnancy
- Should be taken within 72 hours of unprotected intercourse
- If patient vomits within 2 hours of taking pill, patient should repeat dose
- Available without RX for those 17 and up
- Available with RX for those under 17
- Contains levonorgestrel 1.5 mg only

### Combination Therapy is the Future
First Triple Drug Available

► Exforge HCT for Hypertension
  ▪ Valsartan
  ▪ Amlodipine
  ▪ Hydrochlorothiazide

New Approach

► Combination of Avodart or Proscar with an alpha blocker
► Most common combination:
  ▪ Avodart (dutasteride) and Flomax (tamsulosin)
► Recommended for men > 50 with high risk of BPH progression
► FYI ~ Flomax is going generic in 2008
► Will likely see this combo pill in 2009

Additional Approvals and Important Bits of Information

Chantix and Zyban Warnings

► People who are taking Chantix or Zyban and experience any serious and unusual changes in mood or behavior or who feel like hurting themselves or someone else should stop taking the medicine and call their healthcare professional right away.
► Friends or family members who notice these changes in behavior in someone who is taking Chantix or Zyban for smoking cessation should tell the person their concerns and recommend that he or she stop taking the drug and call a healthcare professional right away.

Intranasal Zinc

► FDA is alerting consumers that Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Nasal Swabs, Zicam Cold Remedy Swabs, Kids Size, a discontinued product that consumers may still have in their homes, have all been associated with long lasting or permanent loss of smell (referred to as anosmia).

New Indication

► Reclast
  ▪ Indicated for osteopenia
  ▪ May be administered every two years for the individual with osteopenia
► Lexapro
  ▪ Now indicated for the treatment of MDD in the adolescent patient
New Warning re: Reclast
► Reports to FDA of patient’s developing acute renal failure after infusion
► Majority responded to IV fluids
► Need to counsel re: this during discussion with patients

Gelnique
► Oxybutin chloride gel (10%)
► Indications: Overactive bladder
► Dosage:
  - 1 gram delivered to thigh, arm, abdomen once daily
  - Delivered transdermally which decreases side effects frequently associated with these medications
    - Dry mouth (6.9%)

Zolpimist
► Zolpimist™ (zolpidem oral spray) delivers zolpidem tartrate, which is currently marketed as Ambien.
► Zolpimist™ has been approved by the FDA for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
► Zolpimist™ offers the potential benefit of a faster rise in drug blood levels potentially leading to a faster onset of action, without having to take with water

Vectical
► New vitamin D3 ointment for the treatment of mild-moderate psoriasis
► Calcitriol, the naturally-occurring, active form of vitamin D3, and is one of the only vitamin D3 products shown in clinical trials to be well-tolerated even when used on sensitive skin fold areas

Generic Available
► First-time generic formulations for zaleplon are now available
► Zaleplon is equivalent to Sonata, which is indicated for the short-term treatment of insomnia (sleep-onset type)
► Sumatriptan generic is available (Imitrex)
► Prevacid (generic is available)

Risperdal – Available Generic
► The FDA has approved first-time generic formulations for risperidone.
► Risperidone is equivalent to Risperdal, which is indicated for the treatment of schizophrenia and the acute mania of bipolar disorder in adults and children.
► It is also approved for irritability symptoms in children with autistic disorder.
Warnings

- Provigil
  - Increase in reports of anxiety, hallucinations and suicidal ideations in patients taking this medication
  - Also reports of angioedema and life threatening skin reactions i.e. Stevens-Johnson and Toxic Epidermal Necrolysis

June....

- Provigil has now been replaced by Nuvigil
- Once daily formulation
- This is a prodrug – isomer formulation

New Indication

- Welchol
  - Colesevelam
  - Indicated for the treatment of Type 2 diabetes
  - Reduces A1C approximately .5%

New Information

- Exelon (rivastigmine)
  - Received FDA approval for mild to moderate Parkinson's disease dementia
  - Side effects: nausea and vomiting
- Exelon patch is now available
  - Apply once daily
  - Decrease in side effects

Now Available

- Sanctura XR
  - Once daily option for overactive bladder will become available
  - Less drug/drug interactions than some of the other products

Recommendation Regarding Stimulants

- Cardiac examination is now recommended on all adults and children who are being prescribed a stimulant for AD/HD
- This includes methylphenidate products as well as Adderall
Updates

- **Gardasil**
  - Observe for 15 minutes following vaccine administration due to syncope
  - Vasovagal episode
- **Influenza**
  - CDC is now recommending that all children receive influenza vaccine - regardless of risk
  - Increased reports of rhabdomyolysis with amiodarone and simvastatin

Patients on PPI’s

- Please make sure that they are taking calcium citrate NOT carbonate
- Carbonate requires an acidic environment for absorption
- Until further notice, may want to consider PPI other than omeprazole in any individual on Plavix

Moxatag

- Once daily version of Amoxicillin for Strep throat
- 775 mg tablet; once daily x 10 days
- Indicated: 12+
- Cost: $90.00 for 10 days

Coming in 2009 - 2010

- **Cervarix**
  - GSK’s answer to Gardasil
- **Prevacid OTC**
  - 15 mg once daily for frequent heartburn
- **Once weekly Byetta**
  - First quarter - 2010

Anticipate

- Gardasil approval for boys
  - May occur as early as November/December
- Let’s talk about H1N1
  - Two injections
  - Separate by 3 weeks
  - Provided by federal government
  - Tiered roll-out of injections

Thank You!

I Would Be Happy To Entertain Any Questions
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