First do no Harm: Drug Therapy in Geriatrics & Palliative Care

UNA Gerontology Course

Florence, AL

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Florence, AL

Disclaimer & Quiet Reminder

- Please place pagers and cell phones on mute or vibrate.
- Question period at the end.

Disclaimer Statement

- I have no financial COI/affiliation disclosures
- There are no unapproved medication usages

Why are we here? To learn from the mistakes of others

Will Rogers said…

- There are 3 kinds of men. The ones who learn by reading. The few who learn by observation. The rest of them have to pee on the electric fence for themselves.

- Never kick a cow chip on a hot day.

Outline

1. Guidelines for Drug Therapy in Srs
2. Working in the *Illusion of Certainty*
3. High Risk Drugs for Seniors
    1. Beers list and others
    2. Polypharmacy
4. Goal focused care for seniors
5. Pearls to Ponder

1. Guidelines for Safe & Cost-Effective Drug Therapy in Srs

Foundations for Decision-Making

1) First, do no harm
2) Start low, go slow
3) Relieve suffering - the goal of Medicine
4) Take no drugs?
5) Remember the placebo effect
6) Providers have a stewardship responsibility

Palliative Care's impact

Foundation 1: First, do no Harm !

- Evidence why should we be concerned
  - Srs = 13% population; take 30% Rx *[Williams,2002]*
  - 25% of ADE in those >80yr resulted in admissions *[Williams]*
  - 14-52% srs take at least 1 inapprop. med *[McLeod]*
  - 23% community elders on 1 Beers medication [Buck]
  - $1 on drug Rx triggers $1 for iatrogenic illness
- Srs are physiologically different
  Polypharmacy [>4 Rx] is harmful

Why are drugs a Problem for Srs?

Physiologically, elders not "just older adults":

- Usually several chronic diseases
- Physiology changes:
  - Impaired drug metabolism in liver
  - Decreased renal creat.clearance
  - Changes in fat and blood distribution
- Increased brain sensitivity

Which leads to:

More side-effects from drugs

- More falls and fractures
- More confusion/delirium
- More nausea, constipation or diarrhea
- JUST FEEL WORSE !!

- Stubborn/feisty seniors on few meds live longer…

Polypharmacy is Harmful !

- POLYPHARMACY: **the use of multiple medications and/or the administration of more medications than are clinically indicated.** ***[Am J Geriatr Pharmacother. 2007]***

- More than five (5) Rx = reduced QOL *[Morley]*
- Increasing published evidence supports fewer drugs…

References re Benefits to Reducing Meds in Elders

- Hajjar ER,et al. Unnecessary drug use in frail older people at hospital discharge. J Am Geriatr Soc 2005;
- Steinman MA,et al. Polypharmacy and prescribing quality of older people. J Am Geriatr Soc. 2006;
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- Medication as a risk factor for falls: critical systematic review.Hartikainen S, Lonnroos E, Louhivuori K. J Gerontol A Biol Sci Med Sci. 2007 Oct;62(10):1172-81.
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- Risk of falls after withdrawal of fall-risk-increasing drugs: a prospective cohort study.van der Velde N, Stricker BH, Pols HA, van der Cammen TJ. Br J Clin Pharmacol. 2007 Feb;63(2):232-7. Epub 2006 Aug 30.
- Psychotropic drugs and risk of recurrent falls in ambulatory nursing home residents.Thapa PB, Gideon P, Fought RL, Ray WA. Am J Epidemiol . 1995 Jul 15;142(2):202-11.

…"Foundations 2,3,4,5"…

2: Start low, go slow !

3: The goal of medicine is to prevent & relieve suffering *[Cassel, 2004]*

4: Take no drugs???

- 21-55% non-compliance suggests seniors don't want to take Rx regularly [*Williams, 2002*]

5: Remember the *placebo* effect/benefit

- Up to 39% improve regardless ! [*Cochrane 2010*]
- Caution when interpreting studies/"evidence" [*Why almost everything you hear about medicine is wrong. Newsweek 1/24/11.*]

Foundation 6: Stewardship in Healthcare

- Stewardship: "A [fiduciary & ethical] responsibility to take care of something one does not own."
- Stewardship implies avoiding things which are non-beneficial/futile for another person !

[Futile Care: care which will not help a patient reach their goal.]

Stewardship

- 5% of Medicare beneficiaries die each year
- 30% of budget [total = $461B in '08] is for last year of life
- Of those dying, 50%-80% of costs spent on last 2 mo. of life [w/ no "gain in quality"]
- Do ALL of us not have a stewardship responsibility – to avoid futile or non-beneficial care?

* 1. USA Today; 2. J. Lubitz, DHHS, report to US Congress 2004; 3. LA Times 2010.

What is Palliative Care (& its impact):

1) Helps patients clarify their goals in the face of a LLD*, to make informed decisions and avoid non-beneficial treatments;
2) Helps those with life-limiting disease live comfortably (soothing symptoms) as long as possible; plus
3) when they are at the very end of life, PC ensures a natural death w/ comfort and dignity.

*LLD = Dementias, cancers, end-stage organ disease (e.g. lung/ heart/renal/liver), ALS

Palliative Care:

- Is NOT only for those nearing death or the end of life !
- Should be offered simultaneously with all other appropriate medical treatment to anyone with a chronic/ incurable illness

PC's Beneficial Impact on "First, do no Harm"…

- PC does NOT accelerate dying
  - Cost Savings Impact Study 2009 at ECM
    - 97% of patients in both the control group and the PC consult group died in the same 6 mo. (while saving hospital $386,000)

and…

- PC improves survival & QOL in lung cancer
  - Patients receiving chemotherapy and PC lived 3mo longer (11.6mo v 8.9mo) than those on just chemoRx. *[Temel. NEJM 2010.]*

and…

…PC's Impact

- Pts who choose hospice live ~29 days longer than those not in hospice

  * *Connor S. Comparing hospice & non-hospice patient survival among patients who die within a three-yr window. J Pain Symptom Manage 2007*

- Cancer pts who discuss EOLC wishes w/ MD have better QOL & lower costs in final wk of life
  - Less aggressive care/admissions to hospital
  - Improved QOL w/ more peaceful death

  ** Zhang B. Health care costs in the last week of life. Arch Intern Med. 2009*

PC's Positive Impact: why?

Implementing PC principles can help:

- Stop all/most non-comfort tx/meds
- Aggressively control symptoms which helps them to feel better and eat/socialize/exercise more and fight illness
- Encourage patient/family-driven goals
  - Avoid futile/unnecessary tx & hospitalizations
- Encourages EOLC planning that confronts the *illusion of certainty*…

2. What's Risk & the Illusion of Certainty

To help avoid inappropriate prescribing (& prevent harm), need to:

- Understand the Illusion of Certainty
- Avoid misleading stats

What's the Illusion of Certainty?

- Some people want "Illusion of Certainty"
  - Don't want to know!! ??
- Illusion of Certainty: the belief that an event is absolutely certain although may not be ! Examples:
  - Treatments have only benefits but no harm
  - There's only one best treatment
  - A diagnostic test is absolutely certain

But, in reality…

- "In this life, nothing is certain but death & taxes"- Franklin's Law
- All real world events are uncertain
- Every healthcare decision is one between two risks, not between a certainty and a risk
  - ***All attempts to do good, also generate unwelcome side-effects …!!***

Rx for Side-effects !

Communicating Risk …

- **"Risk"** [*the possibility of harm*] is an uncertainty that can be expressed numerically (via probabilities & frequencies)

- **Forms of Risk Communication**:
  - Probabilities [confusing]
    - Single event probability
    - Conditional Probabilities
  - Natural Frequencies [less confusing]

Communicating Risk …poorly

"The bad presentation of medical statistics such as the risk associated with a particular intervention can lead to patients making poor decisions on treatment."

- the failure to communicate effectively…

* G.Gigerenzer. Simple tools for understanding risks. BMJ 2003;3:621


whatever happened to our sexual relations?
I don't know. I don't even think we got a Christmas card from them this year.
parodyville.com

Communicating & Common Sense:

- Public has right to clear information
- If guidelines being debated, that usually indicates ***uncertainty*** !! e.g. HR Therapy, Vit.D, *[Newsweek 1/24/11]*

- Use 'natural frequencies' to explain risks via
  - ARR & NNT - not RRR !
  - Frequency Tree
  - Population Visual aid [Paling Palette]

Avoid Misleading Statistics

- Relative Risk Reduction (RRR): measure (as a %) of effect of treatment relative to number people improved/saved [typical in journal & newspaper articles]
  - RRR amplifies small differences and makes the insignificant appear significant
  - RRR doesn't reflect the baseline risk of outcome events

[* *Henley. Edwards. Paling*]

…How to represent benefits/risks better:

- Absolute Risk Reduction (ARR):
  measure of effect of treatment in terms of absolute number people improved/saved

- Number Needed to Treat (NNT):
  number of people who need to be treated to improve/save one

Real World Example:

Benefits & Risks of Treatments to Reduce CVA Risk in A.Fib.

How much does warfarin or ASA actually reduce the risk of having a stroke or cause a major bleed from the drug used?

[* Hart RG. Ann Intern Med 2007. Taylor FC. BMJ 2001.]

Benefits of Warfarin v. ASA (in A.Fib)

Treatment	Risk of CVA
• No treatment:	3.5% (1-18%: CHAD2 risk score 0-6)
• ASA:	RRR = 37% (2.5/3.5 x100)
	decreases ~1% (ARR)
	NNT = 100 (100/1)
• Warfarin:	RRR = 71% (1.3/3.5 x100)
	decreases ~2% (ARR)
	NNT = 50 (100/2)

but, increases Bleeding Risk ~1%

3. High Risk Drugs for Seniors

- Beers List
  - What is it and what are the criteria
  - Why is it important – who uses it
- Other drugs/classes

What is Beers List?

- Dr. Mark Beers – geriatrician –first list published 1991 re LTCF only
- Update published 1997 – included guideline for all seniors >65yrs; revised by Fick in 2003.
- Used Delphi method for group consensus and literature review – drug's risk s/e > benefit
- Two Lists [as of 2003 Update]:
  1. Meds generally to be avoided
     - 48 meds or classes of meds
  2. Meds to be avoided in certain conditions
     - 20 diseases/conditions w/ meds to avoid

Beers List: Drugs/classes

List includes: 1) drug; 2) reason for concern; 3) severity of risk potential.

Examples:

1. Flurazepam [Dalmane] - long T ½, prolonged sedation, increased falls/fx; high risk
2. GI antispasmodic drugs: dicyclomine [Bentyl], hyoscyamine, etc. – highly anticholinergic w/ uncertain effectiveness; high

Beers List: Conditions

3. Heart Failure: drugs – disopyramide [Norpace], and high sodium content drugs; concern – negative inotropic effect; promote fluid retention, exacerbate HF; high [risk].
4. HTN: drugs – pseudoephedrine, diet pills, amphetamines – elevate BP; high.
5. Gastric/Duod.Ulcers: NSAIDS, ASA – may exacerbate or induce ulcers; high.

Common Problem Meds

- Oxybutynin [Ditropan] +
- Cyclobenzaprine +
- Diphenhydramine [Benadryl] +
- Meperidine [Demerol]
- Ketorolac [Toradol]
- NSAIDs – naproxen [Naprosyn/Aleve], piroxicam, indomethacin [Indocid] – **all** NSAIDs

NSAID adverse effects

- Renal insufficiency & edema
  - maintain adequate hydration
  - COX-2 selection inhibitors
- Inhibition of platelet aggregation
  - assess for coagulopathy - GI Bleed
- Confusion/delirium in elders
- **Avoid in <u>DM2</u> and <u>CHF</u> – <u>and in elders</u> !**
  - per AGS 2009

* Hospice & Palliative Care Formulary USA, 2nd edition. 2008

…more of Common Problems…

- Amiodarone [Cordarone]
  - Pulm.fibrosis/interst.pneumonitis [10-17%],
  - Arrhythmias [torsades]; abn.LFT [?fatal]; thyroid hyper/hypo; n/v, fatigue;
  - Drug interactions – digoxin, warfarin, statins
- Fluoxetine [Prozac]
  - $T_{1/2}$ too long: agitation, insomnia, anorexia

…Common Problems

- Amitriptyline [Elavil] + [doxepin, imipramine]
  - Anticholinergic s/e: urine retention/incont; sedation; constipation; falls; arrhythmias
- Diazepam [Valium] + [chlordiazepoxide, clorazepate]
  - Long $T_{1/2}$: depression, dependence, sedation, confusion, falls, fractures, incontinence

Impact of Beers List

- 1999 CMS [Medicare in USA] adopted List to evaluate quality of care in nursing homes.
- Medical-legal – could be used against you [as in *inappropriate Rx* when patient falls]
- Conflict between geriatric/PC 'best practice' and other specialties [e.g. cardiology - amiodarone, statins]

Resources for Beers List

- Fick DM, et al. Updating the Beers Criteria for potentially inappropriate medication use in older adults. Arch Intern Med. 2003.
- Beers M. Explicit criteria for determining potentially inappropriate medication use by the elderly. Arch Intern Med. 1997.
- Beers Criteria (Medication List): Duke Univ. Clinical Research Institute. [links to each drug]
- Beers Criteria. Wikipedia. [links s/a]
- Medication Management and Polypharmacy. Beers List. www.tahsa.org [Texas Association of Homes and Services for the Aging - 2 helpful tables]

Other Drugs of Concern

- PPI's [Proton Pump Inhibitors] – omeprazole [Prilosec]
  - Increase risk: c.diff. colitis; aspiration pneumonia; incidence hip fracture
- Antibiotics ! "Statins" !
  - *[see comfortcarechoices.com website articles]*
- Amlodipine [Norvasc]
  - CCB s/e – edema, reflux
  - Tx – SBP goal 130-160 ! *[Morley]*

Polypharmacy is not new !!

- *The battle against polypharmacy, or the use of a large number of drugs (of the action of which we know little, yet we put them into the bodies of which we know less), has not been brought to a finish.*
  - Sir William Osler [Medicine in the 19th Century. 1901]

4. Goal-focused Care

- Why are goals important
- What do seniors/families want
- How to help them choose goals and avoid futile care

Why Goal-Focused Care?

Goal-Focused care means choose only that care which will help reach a goal!

Why set goals for our medical care?

- Care goals shape expectations & priorities
- Goals may be dependent on understanding risks & benefits of options and on prognosis
  - BUT, if we haven't discussed the goal and prognosis, how can we establish an appropriate plan of care and obtain an informed consent?

What do Patients & Families with Serious Illnesses Want [their goals?]

- Pain and symptom control
- ***Avoid inappropriate prolongation of the dying process***
- Achieve a sense of control
- ***Included in decisions & to be listened to***
- ***Honest information***
  - Everyone wants adverse event info [1/100,000 - Ziegler. Arch Intern Med 2001]

* *Singer et al. JAMA 1999;281(2):163-168.*
* *Tolle et al. Oregon report card.1999 www.ohsu.edu/ethics*

How to Help Choose Goals

1) Clarify status & prognosis of condition & treatment options [doctors task: dx, etiology, tx, prognosis]
2) Help patient/family identify their goals !!

   E.g. Is it comfort, longevity, or mixture of both?
3) Point out & accept that goals may change w/ more info or as disease progresses !

   i.e. Learning new risks/ benefits of **available options** may affect a decision.

5. Pearls to Ponder

- **Develop a personal Rx philosophy !**
  - Encourage Goal-focused care
  - Work toward goal of "NO drugs"??!
  - Treat the 'person', not just the disease !
- If see behavior or ADL change: stop all non-essential meds, including vitamins
- Use shorter treatments – e.g. 3 days antibiotic for UTI
- Rarely need a Rx 'for the rest of your life' !

…Pearls

- Avoid thinking *we need a drug to help* – do a test instead of a Rx
- Individualize the Rx !
- Everything we do has Placebo Effect –
  - Remember that therapeutic relationship !
  - Need EBM to help because we've created situations that cause suffering
- Focus on ***TLC*** ! Involve the family !

Steps to Reduce Polypharmacy

1) Review all meds regularly
2) Stop any drug w/o known benefit or w/o clinical indication
3) Use least 'toxic' drug of class
4) Avoid duplicating drugs
5) Avoid drugs w/ anticholinergic properties
6) Follow "one disease, one drug, once-a-day"
7) Consider drug s/e as cause for symptoms

[Williams. AFP.2002]

How to Improve QOL & Aging: Be informed

- Internet information – Understand Risk
  - Bandolier - www.medicine.ox.ac.uk/bandolier/
  - Paling Perspective Scale – www. trci.info
  - Patient Decision Aids - http://www.npc.nhs.uk/patient_decision_aids/pda.php

- Advance Directives & Discussions
  - OneSlideProject – engagewithgrace.org

…Improve *Aging*: Be informed

- Other information
  - Risk Charts for Men/Women – J Nat'l Ca Inst
  - **Comfortcarechoices.com** – R.Webb's website w/ info about EOLC and palliative care choices
  - Gerd Gigerenzer. *Calculated Risks. 2002*
  - ***InfoPOEMS*** *– website & daily service* www.essentialevidenceplus.com/

Thank You !

As you slide down the banister of life, may all the slivers point down!

- Maxine

Grow'n old ain't for sissies !

- Betty Davis

So, enjoy yourself while you can !