Getting Up To Speed on Medications to Treat ADHD in Youth

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Question 1

If a child with ADHD lives in a household with recovering drug abusers, the drug of choice would be

- A-methylphenidate-immediate release
- B-Ritalin LA
- C-dextroamphetamine sulfate
- D-Atomoxetine
- E-Adderall XR

Question 2

- If a child has ADHD and Tourette's Disorder, which of the following statements is true?
- A-Psychostimulants should never be used
- B-Psychostimulants should only be used after treatment with atypical antipsychotics
- C-Psychostimulants can be used with careful tracking of tics
- D-Psychostimulants should only be used if nortriptyline is used first
- E- None of these statements is true

Question 3

- If a child has co-morbid ADHD and anxiety disorder, which statement is true?
- A-Psychostimulants should never be used
- B-Psychostimulants should be added only after buspirone
- C-Psychostimulants should be used only after atomoxetine has been tried
- D-Atomoxetine is the drug of choice
- E-Psychostimulants can be used as first choice

Question 4

- If a child has ADHD and PDD-NOS, which of the following statements is true?
- A-Psychostimulants should never be use
- B-Psychostimulants may be used but only 20 % of children will respond
- C-Psychostimulants should only be used if their IQ is less than 60
- D-Psychostimulants may be used, but only about half are likely to respond
- E-None of these statements is true

Question 5

- Which of the following statements is true?
- A-Atomoxetine should be dosed by weight
- B-Atomoxetine is the drug of choice for children with ADHD and co-morbid tics
- C-Atomoxetine is the drug of choice for children with ADHD and co-morbid anxiety
- D-Atomoxetine is a schedule 2 substance
- E-Atomoxetine has been shown to be effective in depression

Preview

- Warnings about ADHD Drugs
- Psychostimulants
- Atomoxetine
- Bupropion
- Noradrenergic alpha 2 agonists
- Tricyclic antidepressants (TCAs)

Teaching Points

- Warnings about ADHD drugs should NOT dissuade providers from using these drugs
- Psychostimulants remain the drugs of choice for ADHD
- It is important to “fine tune” medications by ascertaining effects over the day
- Psychostimulants can be mixed and matched

Warnings about ADHD drugs

- 12/04 Strattera: black box warning about possible hepatitis following 2 reports of hepatitis
- 2/05 Adderall:FDA Alert- should not be used in individuals with underlying cardiac abnormalities following 12 sudden unexpected deaths over time Adderall in USA; only XR available in Canada and pulled from market
- 6/05 Ped Adv Com of FDA-Will delay labeling change to all MPH products of side effects of psychiatric (visual hallucination, psychosis, aggression) and cardiovascular until amphetamines and atomoxetine also evaluated in early 2006
- 6/05 Lilly observed increase in aggression and hostility "not statistically significant", but will add information to Strattera label voluntarily
- 10/05 Canada re-allowed Adderall XR back on market
- 11/05 FDA requires Black Box warning on Strattera for increased risk of suicidality 4/1000
- 2-3/06 FDA advisory committee recommends black box warnings for CV risk on psychostimulants, but in March 2006, a pediatric advisory committee votes only a parent guide and NOT a black box warning
- 3/06 European review highlights increased risk of seizures and QTc prolongation with Strattera

Special Problems: pharmacotherapy of youth

- Clinician must have working alliance with parents
- Children may be reluctant consumers
- Children should be told that they may not recognize changes in themselves before first med trial
- Each school may have different requirements for medicating children (and some wont do it)
- Importance of school placement
- From MTA study, parents recognize side effects and teachers recognize efficacy

Medications commonly used to Rx ADHD

- Psychostimulants
- Noradrenergic alpha 2 agonists
- Bupropion
- Tricyclic antidepressants (TCAs)
- Atomoxetine

PSYCHOSTIMULANTS

- Best studied of all psychotropics (since 1937-benzadrine)
- 70% kids respond to either MPH or DAS and 90% will respond to one or the other
- If side effects intolerable or no efficacy, try another class
- May be slightly reduced efficacy in adults
- Array of drugs with different pharmacokinetics
- Drugs of choice

Contraindications to PS

- Previous sensitivity, glaucoma, CVD; hyperthyroidism, hypertension, active psychosis, MAOIs
- Great care with hx of child or family drug abuse
- Package insert warnings:not use in motor tics or family hx TS, marked anxiety or seizures, MPHs under 6 yrs ; AMPs under 3
- However, in last 10 years, RCT support for treating children with tics or TS with psychostimulants

Metabolism

- MPH is a racemic mixture where d-enantiomer is active form metabolized about 90% by carboxylesterase CES1A1 (Sun 2004) and small amount via CYP2D6
- Amphetamines are metabolized via CYP2D6

Many formulations of MPH

- ***immediate release: 3-4 hrs***

  MPH (Ritalin)

  SR-Ritalin 3-4 hrs (wax-matrix)

  Metadate ER (wax matrix)

  Methylin (wax matrix)

  Methylin chewable (grape)2.5, 5, 10 and liquid 5mg/tsp and 10mg/tsp

  Focalin-twice as potent (D-methylphenidate)

- ***long acting:***

  Focalin XR-(particles, can use out of capsule)

  Metadate CD (particles, can use out of capsule)

  LA-Ritalin (particles, can use out of capsule)

  Concerta 10-12 hrs (OROS)

Many formulations of AMPs

- Dextroamphetamine sulfate (4-5 hrs)
- Dexedrine spansules (5-9 hrs) (particles, a-2 hr delay in onset of action)
- Adderall (4 mixed salts), generic (4-5 hrs)
- Adderall XR (remove from capsule and sprinkle, 8 hrs)

Adderall XR
-delivers mixed
Salts using immediate
And released
Beads
50% immediate
50% delayed

Concerta
-delivers MPH
Using immediate
Release coating and
Delayed release
Osmotic mechanism
22% immediate
78% delayed

Metadate CD
-biphasic delivery of
MPH using immediate
And delay release beads
In capsule
30% immediate
70% delayed

Ritalin LA
-biphasic delivery of
MPH using immediate
And delay release beads
In capsule
50% immediate
50% delayed

Focalin XR
-biphasic delivery of
dexMPH using immediate
And delay release beads
In capsule
50% immediate
50% delayed

Short v long-acting formulations

- MPH-IR, Focalin, DAS, Adderall- use 2-4 times a day dosing-"bactrian camel effect"
- Long-acting forms *may* last a school day,
- Longer acting forms may cause side effects later in day--- especially sleeping and eating, but not shown to be true (Swanson 2003)
- Generics may differ slightly (MPH absorbed faster and peaks sooner)
- Behavioral effects may appear before cognitive

Different formulations/Different kids

- Different shapes to AUC: 2 issues

-Tmax: LA-Ritalin peaks first (2x higher than Concerta at 2.1 hrs, NCDEU 2003): then Metadate-CD, then Concerta at 7-9 hrs (Swanson 2004) 2 equal peaks with Focalin XR

- As increase dosage, what happens over time to see if another dose is necessary

- Remember whatever the "means", each child is unique, must make the drug fit the child, not the child fit the drug
- Since DAS additional effects on cellular DA and therefore different than MPH (Volkow 1995), like using a different drug

Match the formulation with needs of the youth

- Have to know when youth "needs" the psychostimulant (e.g., early in AM for school only, or including homework, peer activities, week-ends)
- Parents sometimes have definite preferences for one or another and so does HMOs
- Train parents to observe efficacy and side effects through the day and into the evening

How to initiate dosing

- Not by weight, including teens (Findling 2001) (pediatricians use 0.3-0.6 mg/kg)
- Titrate to efficacy or intolerable side effects: start at 5 mg MPHs or 2.5 mg for Focalin or 5 mg Focalin XR, AMP, DEX- can get weekly reports and adjust upward, checking for side effects and efficacy
- 13 % placebo response in MTA study

The Art of Fine-tuning

- Must have accurate info about kid's performance "over the day"; use scales and talk to teachers: titrate as needed
- Can mix and match PSs (e.g., if dysphoric at days end, add MPH to Concerta at the end of the day; DAS to DAS-spansules at the start of the day because of delayed effect of spansules, bunch or stretch dosing of immediate release)

The Art of Fine-tuning -II

- If only partial efficacy with PSs, can "mix and match"PSs and other anti-ADHD drugs (e.g., clonidine or bupropion or TCAs or atomoxetine)

Common errors in dosing psychostimulants

- Fail to increase dosing slowly to maximum if no side effects (MTA study showed lower dosing in community sample, CMAP study showed 15-30 mg MPH "instinctive dose", Pliska 2003)
- Not assessing the duration of action; (may need to "bunch up " dosing with IR formulations)
- Fail to use another psychostimulant if the first or second trial fails
- Fail to use input from school

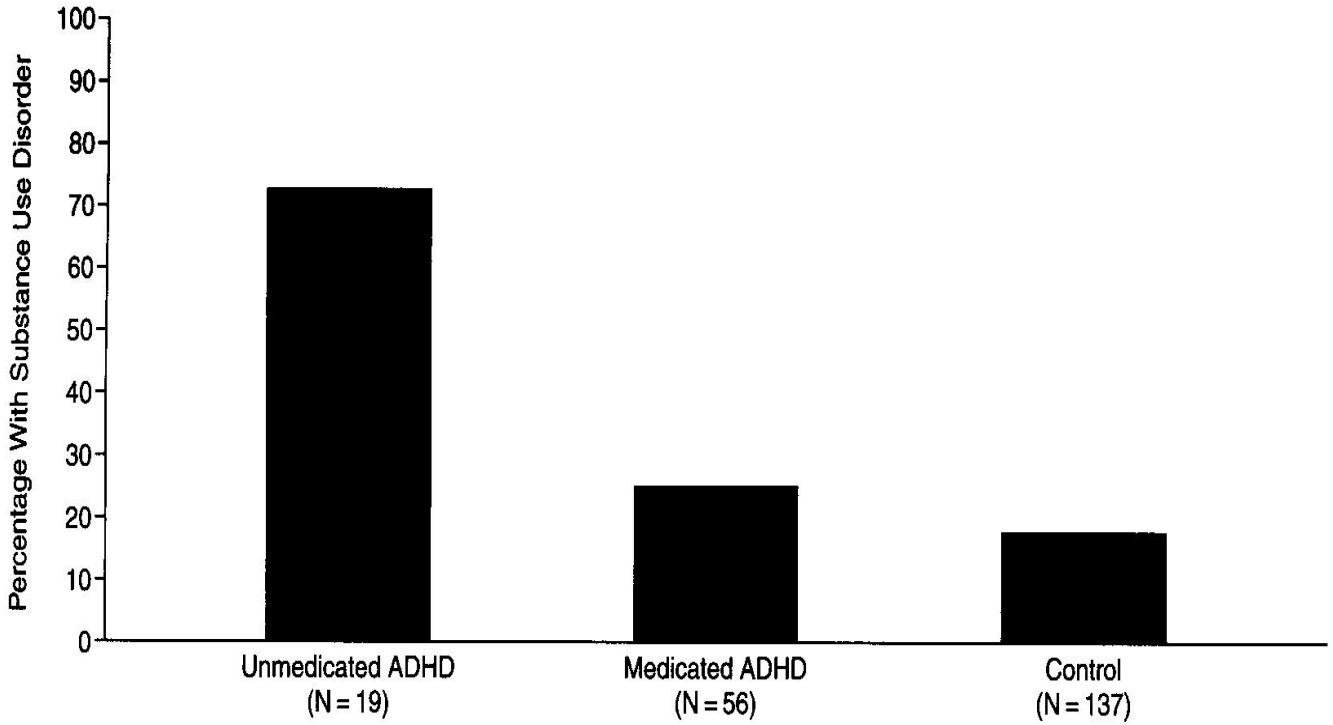
SIDE EFFECTS OF PS

What parents wants to know: addiction,

will the youth need it forever , tics.

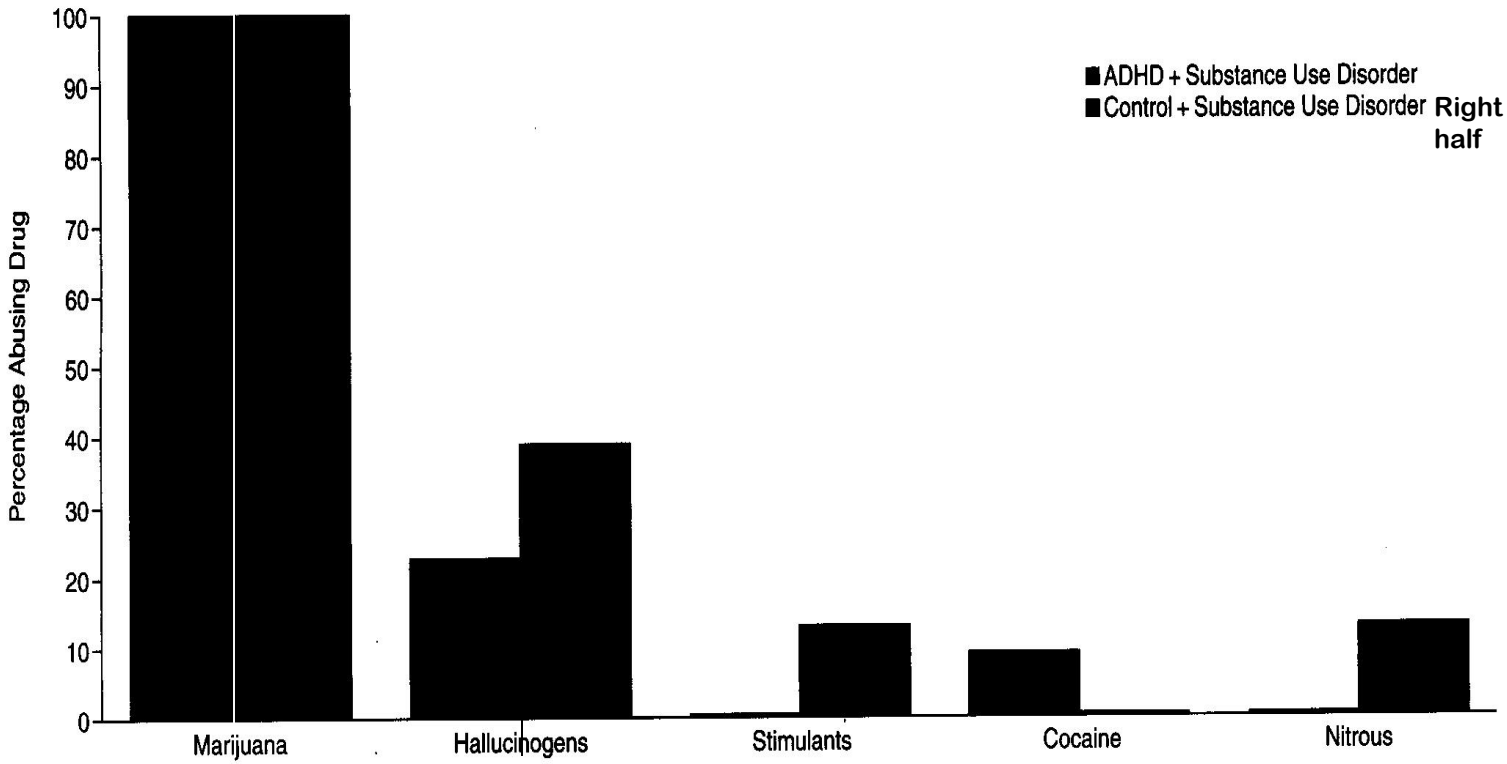
depression

Figure 5. Substance Use Disorder in Unmedicated and Medicated ADHD and Control Adolescents (≥ 15 years)[a]



Biederman 2004, 4 year follow-up

Figure 2. Preferred Drugs of Abuse by Attention-Deficit/Hyperactivity Disorder (ADHD) Probands Versus Controls[a]



[a]Data from Biederman et al.[17]
No pairwise comparisons were significant.

Side Effects

Common side effects

- **insomnia**
- **decreased appetite**
- **irritability**
- **abdominal pain**
- **headaches**
- **“zombie” effect- overfocusing or listlessness at CMax**

Use Barkley Side Effect Questionnaire (BSEQ)

Side effects-II

- Insomnia- probably dose related-tolerance may develop, change timing, Rx CND, melatonin, others
- Decreased appetite—dose related, dose after meals, add calorie supplements and monitor
- Irritability--check timing; reduce dosage: change to long acting formulation
- Abdominal pain—dose with meals, change to long acting formulations
- Headaches--not dose related, ? tolerance

Serious side effects of psychostimulants

- 30+ cases of psychosis or formic hallucinations: discontinue the medication
- ? Growth Suppression (MTA 2004) effects made up in late teens or by drug holidays; especially at risk, those with nausea and vomiting
- Tics: may be minor or substantial or they may improve while psychostimulants active; discontinue only if serious

Psychostimulant Usage/Adherence and Dosing Changes

- After 12 months, 74% of youth took 50% of more of pills (Corkum 1999)
- By year 3, 50% of children stop using PS; Moderators (specific to child) no ODD, more severe sxs, younger age of Rx initiation (Thiruchelvam 2001)
- In MTA study, better outcomes with monthly visits; community docs saw kids only 1-2 /year
- Since pre-teen boys hate PSs, start having conversation about time off years ahead
- May need changes in dosing over time

Psychostimulants over time

- 2 year study MTA 2003- PS advantage over behavior diminishes slightly over time
- 5 year study (Charach 2004), more severe sxs at baseline tended to still take meds
- Continued adverse effects over time especially reduction in appetite
- Adherents had greater improvement than nonadherents in teacher reported symptoms at 2 years and 5 years

Beware advertising!

- Prior to Concerta, Adderall had gained market shares by aggressive marketing
- Adderall received an admonishing letter from FDA for advertising superiority to MPH
- Straterra is after 25% of the market
- Drug companies are marketing directly to the consumer via women's magazines
- No demonstrated differences in efficacy between equivalently dosed formulations of MPHs or amphetamine

When to add parent training

MTA Study:

- **ADHD+ Anxiety = efficacy to PS**
- **ADHD or ADHD+ ODD/CD best outcome is with both PS and parent training**
- **Behavioral training less effective with older youth**

Strattera Hepatits/Suicidality/Seizures /QTc prolongation warnings

- 1/250 individuals may have increased suicidal thinking, dysphoria, agitation
- http://www.fda.gov/cder/drug/infopage/atomoxetine/default.htm
- Black box warning by FDA on hepatitis
- http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01335.html
- Recent European review shows risk of seizures and QTc prolongation

Psychostimulants in Children with MR

- Heterogeneous response within these youth (Aman 2003)
- Only 55% response at 0.6 mg/kg bid doses of IR MPH in youth with mild/moderate MR (Pearson 2004)
- Behavioral v cognitive effects vary within an individual (Pearson 2004)

PDD and ADHD/Psychostimulants

- Little research base
- Only 25% of children with PDD and ADHD had good response (except Asperger, Stigler 2004)
- DB placebo crossover study with differing doses of MPH-> 49% response in RUPP study, AEs led to discontinuation in 18% (RUPP 2004)

ADHD and Anxiety

- Until 1999,believed that youth with ADHD/ANX were both unresponsive to psychostimulants and had more AEs- increased somatic symptoms and anxiety
- Studies showed this is not true, same efficacy and AEs (MTA 2000, Abikoff 2005)
- MPD alone improves anxiety in youth with both disorders (Abikoff 2005)

Pemoline (Cylert) removed from US market 11/05

- Least abuse potential, but can cause insomnia, choreiform movements and tics: start low, go slow: may need bid dosing
- Onset of efficacy is rapid and dose related
- Pemoline is efficacious for ADHD but does not have an impact on CD or substance abuse in the absence of specific treatment for SUD
- Labeling change; 13 cases of acute hepatic failure since 1975 (4-17 times the expected rate). Pre-check LFTs, educate parents on signs and symptoms of hepatitis:FDA requires biweekly LFTs- impractical requirement
- Chewable form

Atomoxetine (Straterra)

- Introduced as treatment for ADHD in 2003
- Selective reuptake inhibitor of NA
- Can potentiate heart rate and BP effects of Albuterol
- CMAX 1-2 hrs, Half life less than 5 hrs
- Less abuse potential than PS, not classified as a controlled drug, not schedule IV
- Metabolized by CYP2D6, therefore increased concentration (up to 5-fold) in slow metabolizers and in combo with 2D6 inhibitors (e.g., paroxetine, fluoxetine)
- Very modest inhibitor of CYP2D6 and 3A4 (midazolam AUC 15%)

Atomoxetine

- Should not be taken with MAOIs, narrow angle glaucoma
- Side effects: may increase BP and pulse, in less than 2% orthostatic hypotension
- Other side effects: initial weight and height loss with more early effect most on younger children, but after 2 years, modest only height effect with growth resumption (Spencer 2005); others GI, fatigue, dizziness, mydriasis, mood swings
- Can be stopped " on a dime"

Atomoxetine- Mechanism of Action

- Increases NA in prefrontal cortex only
- MPH increases NA and DA in prefrontal cortex but also in striatum and nucleus acumbens
- Hypothesized therefore NOT involved in abuse or motoric effects (Bymaster 2002), but case reports of increased tics in vulnerable youth (Ledbetter 2005, Feldman 2005, Lee 2004)

Atomoxetine

- Dosed according to weight
- Less than 70 kg, start at 0.5 mg/kg and gradually increase up to 1.2mg/kg
- More than 70kg, start with 40 mg and gradually increase up to 100 mg/day
- Clinical effects may take up to 4 weeks
- Dosage available in 5, 10, 18, 25, 40 and 60 mg capsules.
- Dosage per day 100mg maximum
- Start with once-a-day dosing, but may need bid

Atomoxetine

- Early experience suggests a slow titration will reduce side effects; can start h.s. mitigate fatigue, then switch
- Can mix PSs and Atomoxetine -> “smoother” day and reduced PS dose
- Good choice in families with drug abuse and prior history in child of “bad” PS side effects
- Not effective in ODD with ADHD (Kaplan 2004), but another study showed that ODD effects only shown at 1.8mg/kg (Newcorn 2005)

Head-to-head

- Vary according to the drug company underwriting study
- Lilly claims ES 0.6-0.8 compared with IR MPH, but only used CPRS
- Study by Concerta folks-Open study of Concerta n=422 and atomoxetine n=229 once daily
- 18 mg Concerta and titrated upward
- 0.5mg Atomoxetine and titrated upward
- 71% responded to Concerta and 56.1% to Atomoxetine with 20+% had AEs in both

Bupropion (Wellbutrin), (Zyban)

- Phenylethylamine, withdrawn in 1986 and reintroduced
- In kids,half-life of regular form 14+/- hours
- Dosing range 3 mg-6 mg/kg/dy: tid: SR bid, XL once daily
- Single dose below 150 mg: (maximum for children 300 mg and 450 mg for teens)
- Efficacy for ADHD may start by day 3
- Some clinicians find only mild effects: ES smaller than PS +/- 0.4-0.5 (Connors 1996)
- IR, SR and XL formulations (Zyban), XL reduces N

Bupropion DBPC studies

Name,yr	description		outcome	
Wilens 2005	Bup XL up to 450 adults		30% reduction ADHD scale	53% v 31% ES=0.6
Kuperman 2001	BupSR, MPH, placebo adults		CGI	64%, 50% 27%
Wilens 2001	BupSR up to 400, adults		30% reduction ADHD scale	76% v 37%
Connors 1996	Bup, 3-6 mg/kg/d bid In 6-12 y		Only 5 pts on Connors for Bupropion	Derm 16% v 8% placebo
Barrickman 1995	Bup 1.4-3.7 mg/kg/d v 0.7 mg/kg/d MPH 7-17			Non-sig trend for

Side effects of Bupropion

Most common: rash, increased appetite, nausea, stomach discomfort, minimal weight loss, blood pressure changes, agitation, tics (Spencer 1993) 4/72 rash (Connors 1996)

Serious:

- seizures, 4/1000 (adults, Johnston 1991); lower incidence with SR :
- rash-> Stevens Johnson, serum sickness

Bupropion (BP): Drug interactions

- substrate of CYP2B6, and potent inhibitor of CYP2D6 substrates (e.g., atomoxetine, some TCAs, dextroamphetamine sulfate, nortriptyline)
- Principal metabolite is OHBP-substrate of CYP2D6
- CBZ induces CYP2B6 and decreases parent compound
- VPA and CYP2D6 inhibitors (e.g., paroxetine, fluoxetine) increase metabolite levels (Ketter 1995)
- Guanfacine addition can cause seizures (Tilton 1998 ?, Nemerow 1999)
- Bupropion may increase VPA levels (Popli 1995)

Clonidine (Catapres)

- Alpha 1, alpha 2A (pre and post synaptic), 2B, 2C, opiate, imidazoline agonist
- 0.1 mg tablets; TTS patches TTS1, TTS2 and TTS3 deliver daily doses of 0.1 mg, 0.2 mg and 0.3 mg: use overlap of 2 days since efficacy only 5 days
- ***Behavioral half-life*** 3-6 hours; dose tid, qid
- Dosing range 5-8 micrograms/kg/day
- Start hs, maximum effect over 2-3 months, sedation is immediate
- Metabolism unknown

Efficacy of CND in ADHD-new evidence

- Meta-analysis of CND- reduces sxs of ADHD but less ES than psychostims ES 0.58 (Connor 1999) also with MR (Agarwal 2001)
- In youth with tic and ADHD, CND + psychostim helped hyperactivity and impulsivity (TS Study Group 2002)
- CND shown to reduce ODD and CD sxs in youth with ADHD in DBPC trial not related to sedative effect with 58% responders minus 21% placebo responders= risk reduction of 37% (3 children needed to show effect); reduced psychostim side effects (Hazell and Stuart 2003)

Pre-treatment workup for Clonidine

- Check for history of arrhythmias, relatives early sudden death
- Check for Raynaud's Disease, Diabetes Mellitus
- ECG if indicated (Biederman 1999, Kofoed 1999, Oesterheld 1996)
- Orthostatic blood pressure
- Pulse

Clonidine:Side effects

Common

- Sedation, dry mouth, dizziness
- Nighttime awakenings, nightmares,night terrors

Serious

- Idiosyncratic aggravation of cardiac arrhythmias
- Danger rebound hypertension if stop suddenly
- Depression in about 5%
- Hyperglycemia

No contraindication to use with psychostimulants

Overdoses of CND

- American Association of Poison Control Center's database from 1993-99
- In 6042 symptomatic children (60%), the most common symptoms were lethargy (80%), bradycardia (17%), hypotension (15%), and respiratory depression (5%). Most exposures resulted in no effect (40%) or minor effects (39%). Moderate (effects occurred in 1907 children (19%), major effects in 230 children (2%); there was 1 fatality (Klein-Swartz 2002

Guanfacine (Tenex)

- 1 mg tablets, no patch
- Dosing range 1.5-4 mg/ day: tid
- Mainly alpha 2A agonist--> less sedation, less hypertensive rebound after sudden stop
- 2 DBPC trials: 1trial of ADHD + tics showed improvements in 9/17 of 37% (equals DMI and bupropion but PS have 50-60%)(Scahill 2001) and 1 trial showed no improvement of tic and neuropsychologic performance studies (Cummings 2002)
- May improve working memory (Jakala 1999)
- If shifting from clonidine; must do "cross-taper"
- Drug interactions: GUA+VPA-->> inc plasma levels VPA (Ambrosini 1998); GUA+bupropion-->> seizures (Tilton 1998 (correction),Nemerow 1999)

Overdoses of Guanfacine

- American Association of Poison Control Centers Toxic Exposure Surveillance System from 1993 to 1999
- No symptoms in 546 (62.8%) children. In 324 symptomatic children, the most common symptoms were drowsiness/lethargy (76.8%), bradycardia (30.0%), and hypotension (25.8%). 195 (22.4%) exposures coded as minor, 121 (13.9%) as moderate, and 8 (0.9%) as major effects (McGrath 2002)

Commonly used TCAs

Imipramine (IMI) not consistently more effective than placebo PMID: 10790990

Generic: 10,25, 50 mg tablets

Tofranil: 10, 25, and 50mg: IM preparation

Nortriptyline (NT) single DBPC trial- PMID: 11052409

Pamelor: 10,25, 50, 75 mg and oral solution 10mg/5ml

Clomipramine (CMI) used for OCD

Anafranil: 25, 50, 75 mg tablets

DMI at least 9 DBPC trials but 7 deaths

Dosing 3-5mg/kg/day for kids (NT 1-3 mg/kg/day)
bid with NT (Geller 1983), tid with IMI

TCA Metabolism in kids

- Less protein binding than adults,70-95% (Ryan 1990)
- Half life shorter in kids than teens than adults (2/3)
- CYP 1st metabolism: tertiary TCAs --> deCH3 to secondary TCA AMI-> NT IMI-> DMI CMI-->deCH3CMI
- Kids more extensive demethylators (Potter 1982)
- CYP 2nd metabolism --> hydroxymetabolites (OHMs) via CYP2D6 : Kids have lowest OHM levels (Wilens 1992)
- Many genetic variations in CYP2D6 activity exist including extensive (normal), slow metabolizers, “sort of slow”, ultrafast
- Each TCA unique neurotransmitter profile

Pre-treatment workup for TCAs

- Hx of family members early or sudden death or arrthymias or cardiac sxs in child
- CBC with differential, creatinine, LFTs
- ECG
- Orthostatic blood pressure, pulse

TCA side effects

- **Most common**

  Dysphoria, irritability, aggression,weight loss increased heart rate, increased diastolic BP, central anticholinergic symptoms (e.g., confusion,sedation)

- **Most serious**

  7 deaths with DMI in kids ,? only small increased risk of sudden death (Werry 1994)

  Toddler siblings may accidentally overdose

  Mania induction

  Changes in cardiac status: Get ECGs at baseline, at 3 mg/kg, highest dosing , when add another drug and 6 mo-year

Cardiovascular parameters for TCAs: consult cardiologist if:

	Resting heart beats/min	Resting BP	PR	QTc
	= or <	=or<	=or<	=or<
< 10 yrs	110	140/90 or 135/85 > 1/2 time 3 wks	0.18	0.44
>10 yrs	100	150/95 or 140/85 > 1/2 time 3 wks	0.20	0.44

Adapted from Rye and Ryan: Child and Adolesc Psychiatric Clinics NA 4:275, 1995

TCAs drug interactions

- Very complicated, must check
- TCAs demethylated by variety of CYPs and then hydroxylated via CYP2D6
- Paroxetine/ fluoxetine decrease clearance 400% of CYP2D6 substrates
- Sertraline/citalopram decrease clearance 25% of CYP2D6 substrates

CMAP-ADHD

- http://www.mhmr.state.tx.us/centraloffice/medicaldirector/adhdalgo.pdf
- 4 algorithms: ADHD, with tics, with MDD and with IED
- Tactic Tables: Dosing schedules for Stimulants,TCAs,Bupropion, Alpha Agonists and SSRIs

ADHD
Educational Placement

- Federal law PL 94-142 (1975 Education for All Handicapped Children Act) requires school systems to test any child within 30 days after a written, signed request has been presented to them
- Section 504 of the Rehabilitation Act requires that children who are underperforming relative to their expected level should receive classroom modifications to improve their academic progress

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- E-Atomoxetine has been shown to be effective in depression

Answers

- 1-D
- 2-C
- 3-E
- 4-D
- 5-A